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[1] Text with EEA relevance

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(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 288/2004

of 19 February 2004

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 20 February 2004.

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

Done at Brussels, 19 February 2004.

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

[1] OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 1947/2002 (OJ L 299, 1.11.2002, p. 17).

ANNEX

to the Commission Regulation of 19 February 2004 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	87,9
	204	33,4
	212	114,0
	624	109,5
	999	86,2
0707 00 05	052	112,7
	204	38,5
	999	75,6
0709 90 70	052	85,6
	204	73,4
	999	79,5
0805 10 10, 0805 10 30, 0805 10 50	052	71,9
	204	43,4
	212	49,1
	220	43,4
	600	41,5
	624	57,4
	999	51,1
0805 20 10	204	96,9
	999	96,9
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	052	64,9
	204	95,9
	220	74,5
	400	58,9
	464	78,4
	600	69,8
	624	78,2
	999	74,4
0805 50 10	600	65,3
	999	65,3
0808 10 20, 0808 10 50, 0808 10 90	052	65,0
	060	38,7
	400	105,1
	404	90,0
	512	85,7
	524	85,9
	528	121,9
	720	84,0
	999	84,5
0808 20 50	060	50,5
	388	81,6
	400	88,5
	512	66,2
	528	84,1
	720	48,3
	800	77,5
	999	71,0

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2081/2003 (OJ L 313, 28.11.2003, p. 11). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 289/2004
of 19 February 2004
fixing the representative prices and the additional import duties for molasses in the sugar sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Having regard to Commission Regulation (EC) No 1422/95 of 23 June 1995 laying down detailed rules of application for imports of molasses in the sugar sector and amending Regulation (EEC) No 785/68 [2], and in particular Article 1(2) and Article 3(1) thereof,

Whereas:

(1) Regulation (EC) No 1422/95 stipulates that the cif import price for molasses, hereinafter referred to as the 'representative price', should be set in accordance with Commission Regulation (EEC) No 785/68 [3]. That price should be fixed for the standard quality defined in Article 1 of the above Regulation.

(2) The representative price for molasses is calculated at the frontier crossing point into the Community, in this case Amsterdam; that price must be based on the most favourable purchasing opportunities on the world market established on the basis of the quotations or prices on that market adjusted for any deviations from the standard quality. The standard quality for molasses is defined in Regulation (EEC) No 785/68.

(3) When the most favourable purchasing opportunities on the world market are being established, account must be taken of all available information on offers on the world market, on the prices recorded on important third-country markets and on sales concluded in international trade of which the Commission is aware, either directly or through the Member States. Under Article 7 of Regulation (EEC) No 785/68, the Commission may for this purpose take an average of several prices as a basis, provided that this average is representative of actual market trends.

(4) The information must be disregarded if the goods concerned are not of sound and fair marketable quality or if the price quoted in the offer relates only to a small quantity that is not representative of the market. Offer prices which can be regarded as not representative of actual market trends must also be disregarded.

(5) If information on molasses of the standard quality is to be comparable, prices must, depending on the quality of the molasses offered, be increased or reduced in the light of the results achieved by applying Article 6 of Regulation (EEC) No 785/68.

(6) A representative price may be left unchanged by way of exception for a limited period if the offer price which served as a basis for the previous calculation of the representative price is not available to the Commission and if the offer prices which are available and which appear not to be sufficiently representative of actual market trends would entail sudden and considerable changes in the representative price.

(7) Where there is a difference between the trigger price for the product in question and the representative price, additional import duties should be fixed under the conditions set out in Article 3 of Regulation (EC) No 1422/95. Should the import duties be suspended pursuant to Article 5 of Regulation (EC) No 1422/95, specific amounts for these duties should be fixed.

(8) Application of these provisions will have the effect of fixing the representative prices and the additional import duties for the products in question as set out in the Annex to this Regulation.

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

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and the additional duties applying to imports of the products referred to in Article 1 of Regulation (EC) No 1422/95 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 20 February 2004.

[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 141, 24.6.1995 p. 12. Regulation as amended by Commission Regulation (EC) No 79/2003 (OJ L 13, 18.1.2003, p. 4).
[3] OJ L 145, 27.6.1968, p. 12.

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

Done at Brussels, 19 February 2004.

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

ANNEX

to the Commission Regulation of 19 February 2004 fixing the representative prices and additional import duties to imports of molasses in the sugar sector

(in EUR)

CN code	Amount of the representative price in 100 kg net of the product in question	Amount of the additional duty in 100 kg net of the product in question	Amount of the duty to be applied to imports in 100 kg net of the product in question because of suspension as referred to in Article 5 of Regulation (EC) No 1422/95 (2)
1703 10 00 (1)	5,85	0,38	—
1703 90 00 (1)	8,58	—	0

(1) For the standard quality as defined in Article 1 of amended Regulation (EEC) No 785/68.
(2) This amount replaces, in accordance with Article 5 of Regulation (EC) No 1422/95, the rate of the Common Customs Tariff duty fixed for these products.

COMMISSION REGULATION (EC) No 290/2004
of 19 February 2004
fixing the export refunds on white sugar and raw sugar exported in its unaltered state

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 second subparagraph of Article 27(5) thereof,

Whereas:

(1) Article 27 of Regulation (EC) No 1260/2001 provides that the difference between quotations or prices on the world market for the products listed in Article 1(1)(a) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) Regulation (EC) No 1260/2001 provides that when refunds on white and raw sugar, undenatured and exported in its unaltered state, are being fixed account must be taken of the situation on the Community and world markets in sugar and in particular of the price and cost factors set out in Article 28 of that Regulation. The same Article provides that the economic aspect of the proposed exports should also be taken into account.

(3) The refund on raw sugar must be fixed in respect of the standard quality. The latter is defined in Annex I, point II, to Regulation (EC) No 1260/2001. Furthermore, this refund should be fixed in accordance with Article 28(4) of that Regulation. Candy sugar is defined in Commission Regulation (EC) No 2135/95 of 7 September 1995 laying down detailed rules of application for the grant of export refunds in the sugar sector [2]. The refund thus calculated for sugar containing added flavouring or colouring matter must apply to their sucrose content and, accordingly, be fixed per 1 % of the said content.

(4) In special cases, the amount of the refund may be fixed by other legal instruments.

(5) The refund must be fixed every two weeks. It may be altered in the intervening period.

(6) The first subparagraph of Article 27(5) of Regulation (EC) No 1260/2001 provides that refunds on the products referred to in Article 1 of that Regulation may vary according to destination, where the world market situation or the specific requirements of certain markets make this necessary.

(7) The significant and rapid increase in preferential imports of sugar from the western Balkan countries since the start of 2001 and in exports of sugar to those countries from the Community seems to be highly artificial.

(8) To prevent any abuse through the re-import into the Community of sugar products in receipt of an export refund, no refund should be set for all the countries of the western Balkans for the products covered by this Regulation.

(9) Import duties and export refunds still apply to certain sugar products traded between the Community, of the one part, and the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, hereinafter referred to as 'new Member States', of the other part, and the level of export refunds is appreciably greater than the level of import duties. In view of the accession of these countries to the Community on 1 May 2004, the appreciable gap between the level of import duties and the level of export refunds granted for the products in question may result in speculative trade flows.

(10) To prevent any abuse through the re-import or re-introduction into the Community of sugar products in receipt of an export refund, no refund or levy should be set for all the new Member States for the products covered by this Regulation.

(11) In view of the above and of the present situation on the market in sugar, and in particular of the quotations or prices for sugar within the Community and on the world market, refunds should be set at the appropriate amounts.

(12) 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 export refunds on the products listed in Article 1(1)(a) of Regulation (EC) No 1260/2001, undenatured and exported in the natural state, are hereby fixed to the amounts shown in the Annex hereto.

Article 2

This Regulation shall enter into force on 20 February 2004.

[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 214, 8.9.1995, p. 16.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

REFUNDS ON WHITE SUGAR AND RAW SUGAR EXPORTED WITHOUT FURTHER PROCESSING APPLICABLE FROM 20 FEBRUARY 2004

Product code	Destination	Unit of measurement	Amount of refund
1701 11 90 9100	S00	EUR/100 kg	45,19 (1)
1701 11 90 9910	S00	EUR/100 kg	45,19 (1)
1701 12 90 9100	S00	EUR/100 kg	45,19 (1)
1701 12 90 9910	S00	EUR/100 kg	45,19 (1)
1701 91 00 9000	S00	EUR/1 % of sucrose × 100 kg product net	0,4913
1701 99 10 9100	S00	EUR/100 kg	49,13
1701 99 10 9910	S00	EUR/100 kg	49,13
1701 99 10 9950	S00	EUR/100 kg	49,13
1701 99 90 9100	S00	EUR/1 % of sucrose × 100 kg of net product	0,4913

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).

The numeric destination codes are set out in Commission Regulation (EC) No 1779/2002 (OJ L 269, 5.10.2002, p. 6).

The other destinations are:

S00: all destinations (third countries, other territories, victualling and destinations treated as exports from the Community) with the exception of Albania, Croatia, Bosnia and Herzegovina, Serbia and Montenegro (including Kosovo, as defined in UN Security Council Resolution 1244 of 10 June 1999), the former Yugoslav Republic of Macedonia, the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, save for sugar incorporated in the products referred to in Article 1(2)(b) of Council Regulation (EC) No 2201/96 (OJ L 297, 21.11.1996, p. 29).

(1) This amount is applicable to raw sugar with a yield of 92 %. Where the yield for exported raw sugar differs from 92 %, the refund amount applicable shall be calculated in accordance with Article 28(4) of Regulation (EC) No 1260/2001.

COMMISSION REGULATION (EC) No 291/2004

of 19 February 2004

fixing the maximum export refund for white sugar to certain third countries for the 21st partial invitation to tender issued within the framework of the standing invitation to tender provided for in Regulation (EC) No 1290/2003

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 Article 27(5) thereof,

Whereas:

(1) Commission Regulation (EC) No 1290/2003 of 18 July 2003 on a standing invitation to tender to determine levies and/or refunds on exports of white sugar [2], for the 2003/2004 marketing year, requires partial invitations to tender to be issued for the export of this sugar to certain third countries.

(2) Pursuant to Article 9(1) of Regulation (EC) No 1290/2003 a maximum export refund shall be fixed, as the case may be, account being taken in particular of the state and foreseeable development of the Community and world markets in sugar, for the partial invitation to tender in question.

(3) Following an examination of the tenders submitted in response to the 21st partial invitation to tender, the provisions set out in Article 1 should be adopted.

(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

For the 21st partial invitation to tender for white sugar issued pursuant to Regulation (EC) No 1290/2003 the maximum amount of the export refund to certain third countries is fixed at 52,427 EUR/100 kg.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
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 181, 19.7.2003, p. 7.

COMMISSION REGULATION (EC) No 292/2004

of 19 February 2004

fixing the export refunds on syrups and certain other sugar products exported in the natural state

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector [1], and in particular the second subparagraph of Article 27(5) thereof,

Whereas:

(1) Article 27 of Regulation (EC) No 1260/2001 provides that the difference between quotations or prices on the world market for the products listed in Article 1(1)(d) of that Regulation and prices for those products within the Community may be covered by an export refund.

(2) Article 3 of Commission Regulation (EC) No 2135/95 of 7 September 1995 laying down detailed rules of application for the grant of export refunds in the sugar sector [2], provides that the export refund on 100 kilograms of the products listed in Article 1(1)(d) of Regulation (EC) No 1260/2001 is equal to the basic amount multiplied by the sucrose content, including, where appropriate, other sugars expressed as sucrose; the sucrose content of the product in question is determined in accordance with Article 3 of Commission Regulation (EC) No 2135/95.

(3) Article 30(3) of Regulation (EC) No 1260/2001 provides that the basic amount of the refund on sorbose exported in the natural state must be equal to the basic amount of the refund less one hundredth of the production refund applicable, pursuant to 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 [3] to the products listed in the Annex to the last mentioned Regulation;

(4) According to the terms of Article 30(1) of Regulation (EC) No 1260/2001, the basic amount of the refund on the other products listed in Article 1(1)(d) of the said Regulation exported in the natural state must be equal to one-hundredth of an amount which takes account, on the one hand, of the difference between the intervention price for white sugar for the Community areas without deficit for the month for which the basic amount is fixed and quotations or prices for white sugar on the world market and, on the other, of the need to establish a balance between the use of Community basic products in the manufacture of processed goods for export to third countries and the use of third country products brought in under inward-processing arrangements.

(5) According to the terms of Article 30(4) of Regulation (EC) No 1260/2001, the application of the basic amount may be limited to some of the products listed in Article 1(1)(d) of the said Regulation.

(6) Article 27 of Regulation (EC) No 1260/2001 makes provision for setting refunds for export in the natural state of products referred to in Article 1(1)(f) and (g) and (h) of that Regulation; the refund must be fixed per 100 kilograms of dry matter, taking account of the export refund for products falling within CN code 1702 30 91 and for products referred to in Article 1(1)(d) of Regulation (EC) No 1260/2001 and of the economic aspects of the intended exports; in the case of the products referred to in the said Article (1)(f) and (g), the refund is to be granted only for products complying with the conditions in Article 5 of Regulation (EC) No 2135/95; for the products referred to in Article 1(1)(h), the refund shall be granted only for products complying with the conditions in Article 6 of Regulation (EC) No 2135/95.

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

(8) The first subparagraph of Article 27(5) of Regulation (EC) No 1260/2001 provides that refunds on the products referred to in Article 1 of that Regulation may vary according to destination, where the world market situation or the specific requirements of certain markets make this necessary.

(9) The significant and rapid increase in preferential imports of sugar from the western Balkan countries since the start of 2001 and in exports of sugar to those countries from the Community seems to be highly artificial in nature.

[1] OJ L 178, 30.6.2001, p. 1. Regulation as amended by Commission Regulation (EC) No 2196/2003 (OJ L 328, 17.12.2003, p. 17).
[2] OJ L 214, 8.9.1995, p. 16.
[3] OJ L 178, 30.6.2001, p. 63.

(10) In order to prevent any abuses associated with the reimportation into the Community of sugar sector products that have qualified for export refunds, refunds for the products covered by this Regulation should not be fixed for all the countries of the western Balkans.

(11) Import duties and export refunds still apply to certain sugar products traded between the Community, on the one hand, and the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, hereafter known as the 'new Member States', on the other, and the level of export refunds is appreciably greater than the level of import duties. In view of the accession of those countries to the Community on 1 May 2004, the appreciable gap between the level of import duties and the level of export refunds granted on the products in question may result in speculative trade movements.

(12) In order to prevent any abuse associated with the reimport or re-introduction into the Community of sugar sector products that have qualified for export refunds, levies and refunds for the products covered by this Regulation should not be set for all the new Member States.

(13) In view of the above, refunds for the products in question should be fixed at the appropriate amounts.

(14) 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 export refunds on the products listed in Article 1(1)(d), (f), (g) and (h) of Regulation (EC) No 1260/2001, exported in the natural state, shall be set out in the Annex hereto to this Regulation.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

EXPORT REFUNDS ON SYRUPS AND CERTAIN OTHER SUGAR PRODUCTS EXPORTED WITHOUT FURTHER PROCESSING APPLICABLE FROM 20 FEBRUARY 2004

Product code	Destination	Unit of measurement	Amount of refund
1702 40 10 9100	S00	EUR/100 kg dry matter	49,13 (1)
1702 60 10 9000	S00	EUR/100 kg dry matter	49,13 (1)
1702 60 80 9100	S00	EUR/100 kg dry matter	93,34 (2)
1702 60 95 9000	S00	EUR/1 % sucrose × net 100 kg of product	0,4913 (3)
1702 90 30 9000	S00	EUR/100 kg dry matter	49,13 (1)
1702 90 60 9000	S00	EUR/1 % sucrose × net 100 kg of product	0,4913 (3)
1702 90 71 9000	S00	EUR/1 % sucrose × net 100 kg of product	0,4913 (3)
1702 90 99 9900	S00	EUR/1 % sucrose × net 100 kg of product	0,4913 (3) (4)
2106 90 30 9000	S00	EUR/100 kg dry matter	49,13 (1)
2106 90 59 9000	S00	EUR/1 % sucrose × net 100 kg of product	0,4913 (3)

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).

The numeric destination codes are set out in Commission Regulation (EC) No 1779/2002 (OJ L 269, 5.10.2002, p. 6).

The other destinations are defined as follows:

S00: all destinations (third countries, other territories, victualling and destinations treated as exports from the Community) with the exception of Albania, Croatia, Bosnia and Herzegovina, Serbia and Montenegro (including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999), the former Yugoslav Republic of Macedonia, the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, except for sugar incorporated into the products referred to in Article 1(2)(b) of Council Regulation (EC) No 2201/96 (OJ L 297, 21.11.1996, p. 29).

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

(2) Applicable only to products referred to in Article 6 of Regulation (EC) No 2135/95.

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

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

COMMISSION REGULATION (EC) No 293/2004
of 19 February 2004
on the issue of import licences for olive oil under the Tunisian tariff quota

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 2000/822/EC of 22 December 2000 on the conclusion of an Agreement in the form of an Exchange of Letters between the European Community and the Republic of Tunisia concerning reciprocal liberalisation measures and amendment of the Agricultural Protocols to the EC/Tunisia Association Agreement [1],

Having regard to Council Regulation No 136/66/EEC of 22 September 1966 on the establishment of a common organisation of the market in oils and fats [2],

Having regard to Commission Regulation (EC) No 312/2001 of 15 February 2001 laying down detailed rules of application for the importation of olive oil originating in Tunisia and derogating from certain provisions of Regulations (EC) No 1476/95 and (EC) No 1291/2000 [3], and in particular Article 2(3) and (4) thereof,

Whereas:

(1) Article 3(1) and (2) of Protocol No 1 to the Euro-Mediterranean Agreement establishing an association between the European Communities and their Member States, of the one part, and the Republic of Tunisia, of the other part [4] opens a tariff quota, at a zero rate of duty, for imports of untreated olive oil falling within CN codes 1509 10 10 and 1509 10 90 wholly obtained in Tunisia and transported directly from Tunisia to the Community, up to the limit laid down for each year.

(2) Article 1(2) of Regulation (EC) No 312/2001 also lays down the maximum monthly quantities covered by the licences to be issued.

(3) Applications were submitted to the competent authorities in accordance with Article 2(2) of Regulation (EC) No 312/2001 for import licences covering a total quantity exceeding the limit of 1 000 tonnes laid down for February.

(4) Under these circumstances, the Commission must set a reduction coefficient to allow the issue of licences in proportion to the quantity available,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for import licences submitted on 16 and 17 February 2004 under Article 2(2) of Regulation (EC) No 312/2001 shall be accepted for 14,20 % of the quantity applied for. The limit of 1 000 tonnes laid down for February has been reached.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

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

[1] OJ L 336, 30.12.2000, p. 92.
[2] OJ 172, 30.9.1966, p. 3025/66. Regulation as last amended by Regulation (EC) No 1513/2001 (OJ L 201, 26.7.2001, p. 4).
[3] OJ L 46, 16.2.2001, p. 3.
[4] OJ L 97, 30.3.1998, p. 1.

COMMISSION REGULATION (EC) No 294/2004

of 19 February 2004

fixing certain indicative quantities and individual ceilings for the issuing of licences for importing bananas into the Community under the tariff quotas for the second quarter of 2004

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 404/93 of 13 February 1993 on the common organisation of the market in bananas [1], and in particular Article 20 thereof,

Whereas:

(1) Article 14(1) of Commission Regulation (EC) No 896/2001 of 7 May 2001 laying down detailed rules for applying Council Regulation (EEC) No 404/93 as regards the arrangements for importing bananas into the Community [2] provides for the possibility of fixing an indicative quantity, expressed as the same percentage of quantities available under each of the tariff quotas, for the purposes of issuing import licences for the first three quarters of the year.

(2) The data relating, on the one hand, to the quantities of bananas marketed in the Community in 2003, and in particular actual imports, especially during the second quarter, and, on the other hand, to the outlook for supply and consumption on the Community market in the same quarter of 2004, call for the fixing of indicative quantities for quotas A, B and C that ensure satisfactory supply to the Community as a whole and continuity of trade flows between the production and marketing sectors.

(3) On the basis of the same data, the ceiling on the quantities for which individual operators can submit licence applications in respect of the second quarter of 2004 should be fixed for the purposes of Article 14(2) of Regulation (EC) No 896/2001.

(4) Since this Regulation must apply before the beginning of the period for the submission of licence applications in respect of the second quarter of 2004, it should enter into force immediately.

(5) It is necessary to stipulate that this Regulation is to apply only to the Community as constituted on 30 April 2004 in view of the fact that the accession of the new Member States takes effect on 1 May 2004 and that appropriate provisions will be adopted in due course to guarantee supplies to the enlarged Community.

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

HAS ADOPTED THIS REGULATION:

Article 1

The indicative quantity provided for in Article 14(1) of Regulation (EC) No 896/2001 for banana imports under the tariff quotas provided for in Article 18 of Regulation (EEC) No 404/93 shall be 29 % of the quantities available for traditional and non-traditional operators under tariff quotas A/B and C for the second quarter of 2004.

Article 2

For the second quarter of 2004 the quantity referred to in Article 14(2) of Regulation (EC) No 896/2001 that may be authorised for banana imports under the tariff quotas provided for in Article 18 of Regulation (EEC) No 404/93 shall be:

(a) 29 % of the reference quantity established pursuant to Articles 4 and 5 of Regulation (EC) No 896/2001 for traditional operators under tariff quotas A/B and C;

(b) 29 % of the quantity determined and notified pursuant to Article 9(3) of Regulation (EC) No 896/2001 for non-traditional operators under tariff quotas A/B and C.

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 47, 25.2.1993, p. 1. Regulation as last amended by Regulation (EC) No 2587/2001 (OJ L 345, 29.12.2001, p. 13).
[2] OJ L 126, 8.5.2001, p. 6. Regulation as last amended by Regulation (EC) No 1439/2003 (OJ L 204, 13.8.2003, p. 30).

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

COMMISSION REGULATION (EC) No 295/2004

of 19 February 2004

amending Regulation (EC) No 2314/2003 as regards the quantity covered by the standing invitation to tender for the resale on the internal market of rye held by the German intervention agency

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals [1], and in particular Article 5 thereof,

Whereas:

(1) Commission Regulation (EC) No 2314/2003 [2] opened a standing invitation to tender for the resale on the internal market of 1 139 000 tonnes of rye held by the German intervention agency.

(2) In the present situation on the market the quantities of rye held by the German intervention agency put up for sale on the internal market of the Community should be increased to 1 639 000 tonnes.

(3) 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

Regulation (EC) No 2314/2003 is amended as follows:

1. in Article 1(1), '1 139 000 tonnes' is replaced by '1 639 000 tonnes';
2. in the title of Annex, '1 139 000 tonnes' is replaced by '1 639 000 tonnes'.

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, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

[1] 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).
[2] OJ L 345, 30.12.2003, p. 32.

COMMISSION REGULATION (EC) No 296/2004

of 19 February 2004

amending Regulation (EEC) No 1848/93 laying down detailed rules for the application of Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2082/92 of 14 July 1992 on certificates of specific character for agricultural products and foodstuffs ([1]), and in particular Article 20 thereof,

Whereas:

(1) The Community symbol and the indication referred to in Articles 12 and 15 of Regulation (EEC) No 2082/92 are composed of the models shown in parts A and B of Annex I to Regulation (EC) No 1848/93 ([2]).

(2) The Finnish and Swedish symbols and indications should be added to the abovementioned Annex and the symbols and indications used since the entry into force of the Treaty of Accession of Austria, Finland and Sweden should be declared valid in so far as they conform to the models shown in the Annex hereto.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Regulatory Committee on Certificates of Specific Character,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EEC) No 1848/93 is hereby replaced by the Annex to this Regulation.

The symbols and indications in Finnish and Swedish used since the entry into force of the Act of Accession of Austria, Sweden and Finland shall be valid in so far as they conform to the models shown in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) OJ L 208, 24.7.1992, p. 9. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
([2]) OJ L 168, 10.7.1993, p. 35. Regulation as last amended by Regulation (EC) No 2182/98 (OJ L 275, 10.10.1998, p. 18).

ANNEX

Part A

Dansk

Deutsch

Ελληνικά

English

Español

Français

Italiano

Nederlands

Português

Suomi

Svenska

Part B

Dansk	GARANTI FOR TRADITIONEL SPECIALITET
Deutsch	GARANTIERT TRADITIONELLE SPEZIALITÄT
Ελληνικά	ΕΙΔΙΚΟ ΠΑΡΑΔΟΣΙΑΚΟ ΠΡΟΪΟΝ ΕΓΓΥΗΜΕΝΟ
English	TRADITIONAL SPECIALITY GUARANTEED
Español	ESPECIALIDAD TRADICIONAL GARANTIZADA
Français	SPÉCIALITÉ TRADITIONNELLE GARANTIE
Italiano	SPECIALITÀ TRADIZIONALE GARANTITA
Nederlands	GEGARANDEERDE TRADITIONELE SPECIALITEIT
Português	ESPECIALIDADE TRADICIONAL GARANTIDA
Suomi	AITO PERINTEINEN TUOTE
Svenska	GARANTERAD TRADITIONELL SPECIALITET

COMMISSION REGULATION (EC) No 297/2004

of 19 February 2004

supplementing the Annex to Regulation (EC) No 2400/96 on the entry of certain names in the Register of protected designations of origin and protected geographical indications (Ensaimada de Mallorca or Ensaimada mallorquina)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2081/92 of 14 July 1992 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ([1]), and in particular Article 6(3) and (4) thereof,

Whereas:

(1) Under Article 5 of Regulation (EEC) No 2081/92, Spain has sent the Commission an application for the registration of the name 'Ensaimada de Mallorca' or 'Ensaimada mallorquina' as a geographical indication.

(2) In accordance with Article 6(1) of that Regulation, the application has been found to meet all the requirements laid down therein and in particular to contain all the information required in accordance with Article 4 thereof.

(3) No statement of objection, within the meaning of Article 7 of Regulation (EEC) No 2081/92 ([2]), has been sent to the Commission following the publication in the *Official Journal of the European Union* of the name listed in the Annex to this Regulation.

(4) The name consequently qualifies for inclusion in the 'Register of protected designations of origin and protected geographical indications' and protection at Community level as a protected geographical indication.

(5) The Annex to this Regulation supplements the Annex to Commission Regulation (EC) No 2400/96 ([3]),

HAS ADOPTED THIS REGULATION:

Article 1

The name listed in the Annex to this Regulation is hereby added to the Annex to Regulation (EC) No 2400/96 and entered as a protected geographical indication (PGI) in the 'Register of protected designations of origin and protected geographical indications' provided for in Article 6(3) of Regulation (EEC) No 2081/92.

Article 2

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

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

ANNEX

Bread, pastry, cakes, confectionery, biscuits and other baker's wares

SPAIN

Ensaimada de Mallorca or Ensaimada mallorquina.

([1]) OJ L 208, 24.7.1992, p. 1. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).
([2]) OJ C 131, 5.6.2003, p. 14 (Ensaimada de Mallorca or Ensaimada mallorquina).
([3]) OJ L 327, 18.12.1996, p. 11. Regulation as last amended by Regulation (EC) No 135/2004 (OJ L 21, 28.1.2004, p. 9).

COMMISSION REGULATION (EC) No 298/2004
of 19 February 2004
fixing production refunds on cereals and rice

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992, on the common organisation of the market in cereals ([1]), and in particular Article 7(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 8(e) thereof,

Whereas:

(1) Commission Regulation (EEC) No 1722/93 of 30 June 1993 laying down detailed rules for the application of Council Regulations (EEC) No 1766/92 and (EEC) No 1418/76 concerning production refunds in the cereals and rice sectors respectively ([3]) lays down the conditions for granting production refunds. The basis for calculating the refund is laid down in Article 3 of that Regulation. The refund thus calculated, differentiated where necessary for potato starch, must be fixed once a month and may be amended if the price of maize and/or wheat changes significantly.

(2) The production refunds fixed in this Regulation should be adjusted by the coefficients listed in the Annex II to Regulation (EEC) No 1722/93 to establish the exact amount to be paid.

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

HAS ADOPTED THIS REGULATION:

Article 1

The refund per tonne of starch referred to in Article 3(2) of Regulation (EEC) No 1722/93, is hereby fixed at:

(a) EUR 11,36/tonne for starch from maize, wheat, barley, oats, rice or broken rice;

(b) EUR 0,00/tonne for potato starch.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) 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).
([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 159, 1.7.1993, p. 112. Regulation as last amended by Regulation (EC) No 216/2004 (OJ L 36, 7.2.2004, p. 13).

COMMISSION REGULATION (EC) No 299/2004
of 19 February 2004
fixing the export refunds on olive oil

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation No 136/66/EEC of 22 September 1966 on the establishment of a common organisation of the market in oils and fats [1], and in particular Article 3(3) thereof,

Whereas:

(1) Article 3 of Regulation No 136/66/EEC provides that, where prices within the Community are higher than world market prices, the difference between these prices may be covered by a refund when olive oil is exported to third countries.

(2) The detailed rules for fixing and granting export refunds on olive oil are contained in Commission Regulation (EEC) No 616/72 [2].

(3) Article 3(3) of Regulation No 136/66/EEC provides that the refund must be the same for the whole Community.

(4) In accordance with Article 3(4) of Regulation No 136/66/EEC, the refund for olive oil must be fixed in the light of the existing situation and outlook in relation to olive oil prices and availability on the Community market and olive oil prices on the world market. However, where the world market situation is such that the most favourable olive oil prices cannot be determined, account may be taken of the price of the main competing vegetable oils on the world market and the difference recorded between that price and the price of olive oil during a representative period. The amount of the refund may not exceed the difference between the price of olive oil in the Community and that on the world market, adjusted, where appropriate, to take account of export costs for the products on the world market.

(5) In accordance with Article 3(3) third indent, point (b) of Regulation No 136/66/EEC, it may be decided that the refund shall be fixed by tender. The tendering procedure should cover the amount of the refund and may be limited to certain countries of destination, quantities, qualities and presentations.

(6) The second indent of Article 3(3) of Regulation No 136/66/EEC provides that the refund on olive oil may be varied according to destination where the world market situation or the specific requirements of certain markets make this necessary.

(7) The refund must be fixed at least once every month. It may, if necessary, be altered in the intervening period.

(8) It follows from applying these detailed rules to the present situation on the market in olive oil and in particular to olive oil prices within the Community and on the markets of third countries that the refund should be as set out in the Annex hereto.

(9) The Management Committee for Oils and Fats has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1(2)(c) of Regulation No 136/66/EEC shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

[1] OJ 172, 30.9.1966, p. 3025/66. Regulation as last amended by Regulation (EC) No 1513/2001 (OJ L 201, 26.7.2001, p. 4).
[2] OJ L 78, 31.3.1972, p. 1. Regulation as last amended by Regulation (EEC) No 2962/77 (OJ L 348, 30.12.1977, p. 53).

ANNEX

to the Commission Regulation of 19 February 2004 fixing the export refunds on olive oil

Product code	Destination	Unit of measurement	Amount of refund
1509 10 90 9100	A00	EUR/100 kg	0,00
1509 10 90 9900	A00	EUR/100 kg	0,00
1509 90 00 9100	A00	EUR/100 kg	0,00
1509 90 00 9900	A00	EUR/100 kg	0,00
1510 00 90 9100	A00	EUR/100 kg	0,00
1510 00 90 9900	A00	EUR/100 kg	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, 27.11.2003, p. 11).

COMMISSION REGULATION (EC) No 300/2004

of 19 February 2004

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the market in sugar [1], as amended by Commission Regulation (EC) No 2196/2003 [2], and in particular Article 27(5)(a) and (15),

Whereas:

(1) Article 27(1) and (2) of Regulation (EEC) No 1260/2001 provides that the differences between the prices in international trade for the products listed in Article 1(1)(a), (c), (d), (f), (g) and (h) of that Regulation and prices within the Community may be covered by an export refund where these products are exported in the form of goods listed in Annex V to that Regulation. Commission Regulation (EC) No 1520/2000 of 13 July 2000 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty and the criteria for fixing the amount of such refunds [3], as last amended by Regulation (EC) No 740/2003 [4], specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex I to Regulation (EC) No 1260/2001.

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

(3) Article 27(3) of Regulation (EC) No 1260/2001 and Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lay down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

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

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

(6) In accordance with Council Regulation (EC) No 1039/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Estonia and the exportation of certain agricultural products to Estonia [5], Council Regulation (EC) No 1086/2003 of 18 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Slovenia and the exportation of certain processed agricultural products to Slovenia [6], Council Regulation (EC) No 1087/2003 of 18 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Latvia and the exportation of certain processed agricultural products to Latvia [7], Council Regulation (EC) No 1088/2003 of 18 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Lithuania and the exportation of certain processed agricultural products to Lithuania [8], Council Regulation (EC) No 1089/2003 of 18 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in the Slovak Republic and the exportation of certain processed agricultural products to the Slovak Republic [9] and Council Regulation (EC) No 1090/2003 of 18 June 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in the Czech Republic and the exportation of certain processed agricultural products to the Czech Republic [10] with effect from 1 July 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Estonia, Slovenia, Latvia, Lithuania, Slovakia or the Czech Republic are not eligible for export refunds.

[1] OJ L 178, 30.6.2001, p. 1.
[2] OJ L 328, 17.12.2003, p. 17.
[3] OJ L 177, 15.7.2000, p. 1.
[4] OJ L 106, 29.4.2003, p. 12.
[5] OJ L 151, 19.6.2003, p. 1.
[6] OJ L 163, 1.7.2003, p. 1.
[7] OJ L 163, 1.7.2003, p. 19.
[8] OJ L 163, 1.7.2003, p. 38.
[9] OJ L 163, 1.7.2003, p. 56.
[10] OJ L 163, 1.7.2003, p. 73.

(7) In accordance with Council Regulation (EC) No 999/2003 of 2 June 2003 adopting autonomous and transitional measures concerning the import of certain processed agricultural products originating in Hungary and the export of certain processed agricultural products to Hungary [1], with effect from 1 July 2003, the goods referred to in its Article 1(2) which are exported to Hungary shall not be eligible for export refunds.

(8) In accordance with Council Regulation (EC) No 1890/2003 of 27 October 2003 adopting autonomous and transitional measures concerning the importation of certain processed agricultural products originating in Malta and the exportation of certain processed agricultural products to Malta [2] with effect from 1 November 2003, processed agricultural products not listed in Annex I to the Treaty which are exported to Malta, are not eligible for export refunds.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex A to Regulation (EC) No 1520/2000 and in Article 1(1) and (2) of Regulation (EC) No 1260/2001, exported in the form of goods listed in Annex V to Regulation (EC) No 1260/2001, are fixed as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Erkki LIIKANEN
Member of the Commission

[1] OJ L 146, 13.6.2003, p. 10.
[2] OJ L 278, 29.10.2003, p. 1.

ANNEX

Rates of refunds applicable from 20 February 2004 to certain products from the sugar sector exported in the form of goods not covered by Annex I to the Treaty

CN code	Description	Rate of refund in EUR/100 kg (1)	
		In case of advance fixing of refunds	Other
1701 99 10	White sugar	49,13	49,13

(1) With effect from 1 July 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Estonia, Slovenia, Latvia, Lithuania, the Czech Republic or Slovakia and to the goods referred to in Article 1(2) of Regulation (EC) No 999/2003 when exported to Hungary. With effect from 1 November 2003 these rates are not applicable to goods not covered by Annex I to the Treaty when exported to Malta.

COMMISSION REGULATION (EC) No 301/2004

of 19 February 2004

fixing the maximum export refund on oats in connection with the invitation to tender issued in Regulation (EC) No 1814/2003

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]),

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of 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]), and in particular Article 4 thereof,

Having regard to Commission Regulation (EC) No 1814/2003 of 15 October 2003 on a special intervention measure for cereals in Finland and Sweden for the marketing year 2003/04 ([3]), and in particular Article 9 thereof,

Whereas:

(1) An invitation to tender for the refund for the export of oats produced in Finland and Sweden for export from Finland or Sweden to all third countries except Bulgaria, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Czech Republic, Romania, Slovakia and Slovenia was opened pursuant to Regulation (EC) No 1814/2003.

(2) Article 9 of Regulation (EC) No 1814/2003 provides that the Commission may, on the basis of the tenders notified, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92, decide to fix a maximum export refund taking account of the criteria referred to in Article 1 of Regulation (EC) No 1501/95. In that case a contract is awarded to any tenderer whose bid is equal to or lower than the maximum refund.

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

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

HAS ADOPTED THIS REGULATION:

Article 1

For tenders notified from 13 to 19 February 2004, pursuant to the invitation to tender issued in Regulation (EC) No 1814/2003, the maximum refund on exportation of oats shall be EUR 21,95/t.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission

Franz FISCHLER

Member of the Commission

([1]) 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).

([2]) OJ L 147, 30.6.1995, p. 7. Regulation as last amended by Regulation (EC) No 1431/2003 (OJ L 203, 12.8.2003, p. 16).

([3]) OJ L 265, 16.10.2003, p. 25.

COMMISSION REGULATION (EC) No 302/2004

of 19 February 2004

concerning tenders notified in response to the invitation to tender for the import of sorghum issued in Regulation (EC) No 238/2004

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992, on the common organization of the market in cereals ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) An invitation to tender for the maximum reduction in the duty on sorghum imported into Spain was opened pursuant to Commission Regulation (EC) No 238/2004 ([2]).

(2) Article 5 of Commission Regulation (EC) No 1839/95 ([3]), allows the Commission to decide, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 and on the basis of the tenders notified to make no award.

(3) On the basis of the criteria laid down in Articles 6 and 7 of Regulation (EC) No 1839/95 a maximum reduction in the duty should not be fixed.

(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

No action shall be taken on the tenders notified from 13 to 19 February 2004 in response to the invitation to tender for the reduction in the duty on imported sorghum issued in Regulation (EC) No 238/2004.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) OJ L 181, 1.7.1992, p. 21. Regulation as last amended by Commission Regulation (EC) No 1104/2003 (OJ L 158, 27.6.2003, p. 1).
([2]) OJ L 40, 12.2.2004, p. 23.
([3]) OJ L 177, 28.7.1995, p. 4. Regulation as last amended by Regulation (EC) No 2235/2000 (OJ L 256, 10.10.2000, p. 13).

COMMISSION REGULATION (EC) No 303/2004

of 19 February 2004

concerning tenders notified in response to the invitation to tender for the import of maize issued in Regulation (EC) No 2315/2003

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals ([1]), and in particular Article 12(1) thereof,

Whereas:

(1) An invitation to tender for the maximum reduction in the duty on maize imported into Portugal from third countries was opened pursuant to Commission Regulation (EC) No 2315/2003 ([2]).

(2) Article 5 of Commission Regulation (EC) No 1839/95 ([3]), allows the Commission to decide, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92 and on the basis of the tenders notified, to make no award.

(3) On the basis of the criteria laid down in Articles 6 and 7 of Regulation (EC) No 1839/95 a maximum reduction in the duty should not be fixed.

(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

No action shall be taken on the tenders notified from 13 to 19 February 2004 in response to the invitation to tender for the reduction in the duty on imported maize issued in Regulation (EC) No 2315/2003.

Article 2

This Regulation shall enter into force on 20 February 2004.

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

Done at Brussels, 19 February 2004.

For the Commission
Franz FISCHLER
Member of the Commission

([1]) 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).
([2]) OJ L 342, 30.12.2003, p. 34.
([3]) OJ L 177, 28.7.1995, p. 4. Regulation as last amended by Regulation (EC) No 2235/2000 (OJ L 256, 10.10.2000, p. 13).

DIRECTIVE 2004/9/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2004

on the inspection and verification of good laboratory practice (GLP)

(Codified version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ([1]),

Acting in accordance with the procedure laid down in Article 251 of the Treaty ([2]),

Whereas:

(1) Council Directive 88/320/EEC of 7 June 1988 on the inspection and verification of Good Laboratory Practice (GLP) ([3]) has been significantly amended several times. In the interests of clarity and rationality the said Directive should be codified.

(2) The application of standardised organisational processes and conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing of chemicals for the protection of man, animals and the environment, hereinafter referred to as 'good laboratory practice' (GLP), contributes to the reassurance of Member States as to the quality of the test data generated.

(3) In Annex 2 to its Decision of 12 May 1981 on the mutual acceptance of data in the assessment of chemicals, the Council of the Organisation for Economic Cooperation and Development (OECD) adopted principles of good laboratory practice which are accepted within the Community and are specified in the European Parliament and Council Directive 2004/10/EC of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances ([4]).

(4) In the conduct of tests on chemicals, it is desirable that specialist manpower and testing laboratory resources should not be wasted owing to the need to duplicate tests because of differences in laboratory practices from one Member State to another. This applies especially for animal protection which requires that the number of experiments on animals be restricted in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulations and administrative provisions of the Member States regarding the protection of animals used for experimental and other scientific purposes ([5]). Mutual recognition of the results of tests obtained using standard and recognised methods is an essential condition for reducing the number of experiments in this area.

(5) However, in order to ensure that test data generated by laboratories in one Member State are also recognised by other Member States, it is necessary to provide for a harmonised system for study audit and inspection of laboratories to ensure that they are working under GLP conditions.

(6) Member States should designate the authorities responsible for carrying out monitoring on compliance with GLP.

(7) A committee, the members of which will be appointed by the Member States, would be of assistance to the Commission in the technical application of this Directive and would cooperate in its efforts to encourage the free movement of goods through the mutual recognition by Member States of procedures for monitoring compliance with GLP. The Committee set up by Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances ([6]) should be used for this purpose.

(8) That Committee may assist the Commission not only in the application of this Directive but also in contributing to the exchange of information and experience in this field.

([1]) OJ C 85, 8.4.2003, p. 137.
([2]) Opinion of the European Parliament of 1 July 2003 (not yet published in the Official Journal) and Decision of the Council of 20 January 2004.
([3]) OJ L 145, 11.6.1988, p.35. 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).
([4]) See page 44 of this Official Journal.
([5]) OJ L 358, 18.12.1986, p. 1.
([6]) OJ 196, 16.8.1967, p. 1. Directive as last amended by Council Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

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

(10) This Directive should be without prejudice to the obligations of the Member States concerning the time-limits for transposition of the Directives set out in Annex II, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. This Directive shall apply to the inspection and verification of the organisational processes and the conditions under which laboratory studies are planned, performed, recorded and reported for the non-clinical testing, carried out in accordance with the rules and regulations, of all chemicals (e.g. cosmetics, industrial chemicals, medicinal products, food additives, animal feed additives, pesticides) in order to assess the effect of such products on man, animals and the environment.

2. For the purposes of this Directive, 'good laboratory practice' (GLP), shall mean laboratory practice conducted in accordance with the principles set out in Directive 2004/10/EC.

3. This Directive does not concern the interpretation and evaluation of test results.

Article 2

1. Using the procedure laid down in Article 3, Member States shall verify the compliance with GLP of any testing laboratory within their territory claiming to use GLP in the conduct of tests on chemicals.

2. Where the provisions of paragraph 1 have been complied with, and the results of the inspection and verification are satisfactory, the Member State in question may provide endorsement of a claim by a laboratory that it and the tests that it carries out comply with GLP, using the formula 'Assessment of conformity with GLP according to Directive 2004/9/EC on … (date)'.

Article 3

1. Member States shall designate the authorities responsible for the inspection of laboratories within their territories and for the audit of studies carried out by laboratories to assess compliance with GLP.

2. The authorities referred to in paragraph 1 shall inspect the laboratory and audit the studies in accordance with the provisions laid down in Annex I.

Article 4

1. Each year, Member States shall draw up a report relating to the implementation of GLP within their territory.

This report shall contain a list of laboratories inspected, the date on which such inspection was carried out and a brief summary of the conclusions of the inspections.

2. The reports shall be forwarded to the Commission each year, not later than 31 March. The Commission shall communicate them to the Committee referred to in Article 7(1). The Committee may request information in addition to those elements mentioned in paragraph 1 of this Article.

3. Member States shall ensure that commercially sensitive and other confidential information to which they gain access as a result of GLP compliance monitoring activities is made available only to the Commission, to national regulatory and designated authorities and to a laboratory or study sponsor directly concerned with a particular inspection or study audit.

4. The names of laboratories subject to inspection by a designated authority, their GLP compliance status and the dates upon which laboratory inspections or study audits have been conducted shall not be considered to be confidential.

Article 5

1. Without prejudice to Article 6, the results of laboratory inspections and study audits on GLP compliance carried out by a Member State shall be binding on the other Member States.

2. Where a Member State considers that a laboratory within its territory claiming GLP compliance does not in fact comply with GLP to the extent that the integrity or authenticity of the studies it performs might be compromised, it shall forthwith inform the Commission. The Commission shall inform the other Member States.

Article 6

1. Where a Member State has sufficient reason to believe that a laboratory in another Member State claiming GLP compliance has not carried out a test in accordance with GLP, it may request further information from that Member State and in particular may request a study audit, possibly in conjunction with a new inspection.

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

Should it not be possible for the Member States concerned to reach agreement, the Member States in question shall immediately inform the other Member States and the Commission, giving reasons for their decision.

2. The Commission shall examine as soon as possible the reasons put forward by the Member States within the Committee referred to in Article 7(1); it shall then take the appropriate measures in accordance with procedure referred to in Article 7(2). It may in this connection ask for expert opinions from the designated authorities in the Member States.

3. If the Commission considers that amendments to this Directive are necessary in order to resolve the matters referred to in paragraph 1, it shall initiate the procedure referred to in Article 7(2) with a view to adopting those amendments.

Article 7

1. The Commission shall be assisted by the Committee set up in Article 29 of Directive 67/548/EEC, hereinafter 'the Committee'.

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

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

4. The Committee shall adopt its Rules of Procedure.

Article 8

1. The Committee may examine any question which is referred to it by its chairman either on his own initiative or at the request of a representative of a Member State, concerning the implementation of this Directive and in particular regarding:

— cooperation between the authorities designated by the Member States in technical and administrative matters arising from the implementation of GLP, and

— the exchange of information on the training of inspectors.

2. The amendments necessary for the adaptation of the formula referred to in Article 2(2) and of Annex I to take account of technical progress shall be adopted in accordance with the procedure referred to in Article 7(2).

Article 9

Directive 88/320/EEC is hereby repealed, without prejudice to the obligations of the Member States concerning the time limits for transposition of the said Directives as set out in Annex II, Part B.

References made to the repealed Directive shall be construed as being made to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 10

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

Article 11

This Directive is addressed to the Member States.

Done at Strasbourg, 11 February 2004.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	M. McDOWELL

ANNEX I

The provisions for the inspection and verification of GLP which are contained in Parts A and B are those contained in Annexes I (Guides for compliance monitoring procedures for good laboratory practice) and II (Guidance for the conduct of test facility inspections and study audits) respectively of the OECD Council Decision-Recommendation on compliance with principles of good laboratory practice (C(89)87(Final)) of 2 October 1989 as revised by the OECD Council Decision amending the Annexes to the Council Decision-Recommendation on compliance with principles of good laboratory practice of 9 March 1995 (C(95)8(Final)).

PART A

REVISED GUIDES FOR COMPLIANCE MONITORING PROCEDURES FOR GLP

To facilitate the mutual acceptance of test data generated for submission to Regulatory Authorities of the OECD member countries, harmonisation of the procedures adopted to monitor GLP compliance, as well as comparability of their quality and rigour, are essential. The aim of this part of this Annex is to provide detailed practical guidance to the Member States on the structure, mechanisms and procedures they should adopt when establishing national GLP compliance monitoring programmes so that these programmes may be internationally acceptable.

It is recognised that Member States will adopt GLP principles and establish compliance monitoring procedures according to national legal and administrative practices, and according to priorities they give to, for example the scope of initial and subsequent coverage concerning categories of chemicals and types of testing. Since Member States may establish more than one GLP Monitoring Authority due to their legal framework for chemicals control, more than one GLP compliance programme may be established. The guidance set forth in the following paragraphs concerns each of these Authorities and compliance programmes, as appropriate.

Definitions of terms

The definitions of terms in the OECD principles of good laboratory practice adopted in Article 1 of Directive 2004/10/EC of the European Parliament and of the Council are applicable to this part of this Annex. In addition, the following definitions apply:

— GLP principles: principles of good laboratory practice that are consistent with the OECD principles of good laboratory practice as adopted in Article 1 of Directive 2004/10/EC,

— GLP compliance monitoring: the periodic inspection of test facilities and/or auditing of studies for the purpose of verifying adherence to GLP principles,

— (national) GLP compliance programme: the particular scheme established by a Member State to monitor GLP compliance by test facilities within its territories, by means of inspections and study audits,

— (national) GLP Monitoring Authority: a body established within a Member State with responsibility for monitoring the GLP compliance of test facilities within its territories and for discharging other such functions related to GLP as may be nationally determined. It is understood that more than one such body may be established in a Member State,

— test facility inspection: an on-site examination of the test facility's procedures and practices to assess the degree of compliance with GLP principles. During inspections, the management structures and operational procedures of the test facility are examined, key technical personnel are interviewed, and the quality and integrity of data generated by the facility are assessed and reported,

— study audit: a comparison of raw data and associated records with the interim or final report in order to determine whether the raw data have been accurately reported, to determine whether testing was carried out in accordance with the study plan and standard operating procedures, to obtain additional information not provided in the report, and to establish whether practices were employed in the development of data that would impair their validity,

— inspector: a person who performs the test facility inspections and study audits on behalf of the (national) GLP Monitoring Authority,

— GLP compliance status: the level of adherence of a test facility to the GLP principles as assessed by the (national) GLP Monitoring Authority,

— Regulatory Authority: a national body with legal responsibility for aspects of the control of chemicals.

Components of good laboratory practice compliance monitoring procedures

Administration

A (national) GLP compliance programme should be the responsibility of a properly constituted, legally identifiable body adequately staffed and working within a defined administrative framework.

Member States should:

— ensure that the (national) GLP Monitoring Authority is directly responsible for an adequate 'team' of inspectors having the necessary technical/scientific expertise or is ultimately responsible for such a team,

— publish documents relating to the adoption of GLP principles within their territories,

— publish documents providing details of the (national) GLP compliance programme, including information on the legal or administrative framework within which the programme operates and references to published acts, normative documents (e.g., regulations, codes of practice), inspection manuals, guidance notes, periodicity of inspections and/or criteria for inspection schedules, etc.,

— maintain records of test facilities inspected (and their GLP compliance status) and of studies audited for both national and international purposes.

Confidentiality

(National) GLP Monitoring Authorities will have access to commercially valuable information and, on occasion, may even need to remove commercially sensitive documents from a test facility or refer to them in detail in their reports.

Member States should:

— make provision for the maintenance of confidentiality, not only by Inspectors but also by any other persons who gain access to confidential information as a result of GLP compliance monitoring activities,

— ensure that, unless all commercially sensitive and confidential information has been excised, reports of test facility inspections and study audits are made available only to Regulatory Authorities and, where appropriate, to the test facilities inspected or concerned with study audits and/or to study sponsors.

Personnel and training

(National) GLP Monitoring Authorities should:

— ensure that an adequate number of inspectors is available.

  The number of inspectors required will depend on:

  (a) the number of test facilities involved in the (national) GLP compliance programme;

  (b) the frequency with which the GLP compliance status of the test facilities is to be assessed;

  (c) the number and complexity of the studies undertaken by those test facilities;

  (d) the number of special inspections or audits requested by Regulatory Authorities,

— ensure that inspectors are adequately qualified and trained.

  Inspectors should have qualifications and practical experience in the range of scientific disciplines relevant to the testing of chemicals. (National) GLP Monitoring Authorities should:

  (a) ensure that arrangements are made for the appropriate training of GLP inspectors, having regard to their individual qualifications and experience;

  (b) encourage consultations, including joint training activities where necessary, with the staff of (national) GLP Monitoring Authorities in other OECD member countries in order to promote international harmonisation in the interpretation and application of GLP principles, and in the monitoring of compliance with such principles,

— ensure that inspectorate personnel, including experts under contract, have no financial or other interests in the test facilities inspected, the studies audited or the firms sponsoring such studies,

— provide inspectors with a suitable means of identification (e.g., an identity card).

Inspectors may be:

— on the permanent staff of the (national) GLP Monitoring Authority,

— on the permanent staff of a body separate from the (national) GLP Monitoring Authority, or

— employed on contract, or in another way, by the (national) GLP Monitoring Authority to perform test facility inspections or study audits.

In the latter two cases, the (national) GLP Monitoring Authority should have ultimate responsibility for determining the GLP compliance status of test facilities and the quality/acceptability of a study audit, and for taking any action based on the results of test facility inspections or study audits which may be necessary.

(National) GLP compliance programmes

GLP compliance monitoring is intended to ascertain whether test facilities have implemented GLP principles for the conduct of studies and are capable of assuring that the resulting data are of adequate quality. As indicated above, Member States should publish the details of their (national) GLP compliance programmes. Such information should, *inter alia*:

— define the scope and extent of the programme.

A (national) GLP compliance programme may cover only a limited range of chemicals, for example, industrial chemicals, pesticides, pharmaceuticals, etc., or may include all chemicals. The scope of the monitoring for compliance should be defined, both with respect to the categories of chemicals and to the types of tests subject to it, for example, physical, chemical, toxicological and/or ecotoxicological,

— provide an indication as to the mechanism whereby test facilities enter the programme.

The application of GLP principles to health and environmental safety data generated for regulatory purposes may be mandatory. A mechanism should be available whereby test facilities may have their compliance with GLP principles monitored by the appropriate (national) GLP Monitoring Authority,

— provide information on categories of test facility inspections/study audits.

A (national) GLP compliance programme should include:

(a) provision for test facility inspections. These inspections include both a general test facility inspection and a study audit of one or more on-going or completed studies;

(b) provisions for special test facility inspections/study audits at the request of a Regulatory Authority, for example, prompted by a query arising from the submission of data to a Regulatory Authority,

— define the powers of inspectors for entry into test facilities and their access to data held by test facilities (including specimens, SOPs (standard operating procedures) other documentation, etc.).

While inspectors will not normally wish to enter test facilities against the will of the facility's management, circumstances may arise where test facility entry and access to data are essential to protect public health or the environment. The powers available to the (national) GLP Monitoring Authority in such cases should be defined,

— describe the test facility inspection and study audit procedures for verification of GLP compliance.

The documentation should indicate the procedures which will be used to examine both the organisational processes and the conditions under which studies are planned, performed, monitored and recorded. Guidance for such procedures is available in part B of this Annex,

— describe actions that may be taken as follow-up test facility inspections and study audits.

Follow-up to test facility inspections and study audits

When a test facility inspection or study audit has been completed, the inspector should prepare a written report of the findings.

Member States should take action where deviations from GLP principles are found during or after a test facility inspection or study audit. The appropriate actions should be described in documents from the (national) GLP Monitoring Authority.

If a test facility inspection or study audit reveals only minor deviations from GLP principles, the facility should be required to correct such minor deviations. The inspector may need, at an appropriate time, to return to the facility to verify that corrections have been introduced.

Where no, or where only minor deviations have been found, the (national) GLP Monitoring Authority may:

— issue a statement that the test facility has been inspected and found to be operating in compliance with GLP principles. The date of the inspections and, if appropriate, the categories of test inspected in the test facility at that time should be included. Such statements may be used to provide information to (national) GLP Monitoring Authorities in other OECD member countries,

and/or

— provide the Regulatory Authority which requested a study audit with a detailed report of the findings.

Where serious deviations are found, the action taken by (national) GLP Monitoring Authorities will depend on the particular circumstances of each case and the legal or administrative provisions under which GLP compliance monitoring has been established within their countries. Actions which may be taken include, but are not limited to, the following:

— issuance of a statement, giving details of the inadequacies or faults found which might affect the validity of studies conducted in the test facility,

— issuance of a recommendation to a Regulatory Authority that a study be rejected,

— suspension of test facility inspections or study audits of a test facility and, for example and where administratively possible, removal of the test facility from the (national) GLP compliance programme or from any existing list or register of test facilities subject to GLP test facility inspections,

— requiring that a statement detailing the deviations be attached to specific study reports,

— action through the courts, where warranted by circumstances and where legal/administrative procedures so permit.

Appeals procedures

Problems, or differences of opinion, between inspectors and test facility management will normally be resolved during the course of a test facility inspection or study audit. However, it may not always be possible for agreement to be reached. A procedure should exist whereby a test facility may make representations relating to the outcome of a test facility inspection or study audit for GLP compliance monitoring and/or relating to the action the GLP Monitoring Authority proposes to take thereon.

PART B

REVISED GUIDANCE FOR THE CONDUCT OF TEST FACILITY INSPECTIONS AND STUDY AUDITS

Introduction

The purpose of this part of this Annex is to provide guidance for the conduct of test facility inspections and study audits which would be mutually acceptable to OECD member countries. It is principally concerned with test facility inspections, an activity which occupies much of the time of GLP inspectors. A test facility inspection will usually include a study audit or review as a part of the inspection, but study audits will also have to be conducted from time to time at the request, for example, of a Regulatory Authority. General guidance for the conduct of study audits will be found at the end of this Annex.

Test facility inspections are conducted to determine the degree of conformity of test facilities and studies with GLP principles and to determine the integrity of data to assure that resulting data are of adequate quality for assessment and decision-making by national Regulatory Authorities. They result in reports which describe the degree of adherence of a test facility to the GLP principles. Test facility inspections should be conducted on a regular, routine basis to establish and maintain records of the GLP compliance status of test facilities.

Further clarification of many of the points in this part of this Annex may be obtained by referring to the OECD consensus documents on GLP (on, e.g., the role and responsibilities of the study director).

Definitions of terms

The definitions of terms in the OECD principles of GLP adopted in Article 1 of Directive 2004/10/EC and in Part A of this Annex are applicable to this part of this Annex.

Test facility inspections

Inspections for compliance with GLP principles may take place in any test facility generating health or environmental safety data for regulatory purposes. Inspectors may be required to audit data relating to the physical, chemical, toxicological or ecotoxicological properties of a substance or preparation. In some cases, inspectors may need assistance from experts in particular disciplines.

The wide diversity of facilities (in terms both of physical layout and management structure), together with the variety of types of studies encountered by inspectors, means that the inspectors must use their own judgment to assess the degree and extent of compliance with GLP principles. Nevertheless, inspectors should strive for a consistent approach in evaluating whether, in the case of a particular test facility or study, an adequate level of compliance with each GLP principle has been achieved.

In the following sections, guidance is provided on the various aspects of the testing facility, including its personnel and procedures, which are likely to be examined by inspectors. In each section, there is a statement of purpose, as well as an illustrative list of specific items which could be considered during the course of a test facility inspection. These lists are not meant to be comprehensive and should not be taken as such.

Inspectors should not concern themselves with the scientific design of the study or the interpretation of the findings of studies with respect to risks for human health or the environment. These aspects are the responsibility of those Regulatory Authorities to which the data are submitted for regulatory purposes.

Test facility inspections and study audits inevitably disturb the normal work in a facility. Inspectors should therefore carry out their work in a carefully planned way and, so far as practicable, respect the wishes of the management of the test facility as to the timing of visits to certain sections of the facility.

Inspectors will, while conducting test facility inspections and study audits, have access to confidential, commercially valuable information. It is essential that they ensure that such information is seen by authorised personnel only. Their responsibilities in this respect will have been established within their (national) GLP compliance monitoring programme.

Inspection procedures

Pre-inspection

Purpose: to familiarise the inspector with the facility which is about to be inspected in respect of management structure, physical layout of buildings and range of studies.

Prior to conducting a test facility inspection or study audit, inspectors should familiarise themselves with the facility which is to be visited. Any existing information on the facility should be reviewed. This may include previous inspection reports, the layout of the facility, organisation charts, study reports, protocols and curricula vitae (CVs) of personnel. Such documents would provide information on:

— the type, size and layout of the facility,

— the range of studies likely to be encountered during the inspection,

— the management structure of the facility.

Inspectors should note, in particular, any deficiencies from previous test facility inspections. Where no previous test facility inspections have been conducted, a pre-inspection visit can be made to obtain relevant information.

Test facilities may be informed of the date and time of inspector's arrival, the objective of their visit and the length of time they expect to be on the premises. This could allow the test facility to ensure that the appropriate personnel and documentation are available. In cases where particular documents or records are to be examined, it may be useful to identify these to the test facility in advance of the visit so that they will be immediately available during the test facility inspection.

Starting conference

Purpose: to inform the management and staff of the facility of the reason for the test facility inspection or study audit that is about to take place, and to identify the facility areas, study(ies) selected for audit, documents and personnel likely to be involved.

The administrative and practical details of a test facility inspection or study audit should be discussed with the management of the facility at the start of the visit. At the starting conference, inspectors should:

— outline the purpose and scope of the visit,

— describe the documentation which will be required for the test facility inspection, such as lists of on-going and completed studies, study plans, standard operating procedures, study reports, etc. Access to and, if necessary, arrangements for the copying of relevant documents should be agreed on at this time,

— clarify or request information as to the management structure (organisation) and personnel of the facility,

— request information as to the conduct of studies not subject to GLP principles in the areas of the test facility where GLP studies are being conducted,

— make an initial determination as to the parts of the facility to be covered during the test facility inspection,

— describe the documents and specimens that will be needed for on-going or completed study(ies) selected for study audit,

— indicate that a closing conference will be held at the completion of the inspection.

Before proceeding further with a test facility inspection, it is advisable for the inspector(s) to establish contact with the facility's quality assurance (QA) unit.

As a general rule, when inspecting a facility, inspectors will find it helpful to be accompanied by a member of the QA unit.

Inspectors may wish to request that a room be set aside for examination of documents and other activities.

Organisation and personnel

Purpose: to determine whether the test facility has sufficient qualified personnel, staff resources and support services for the variety and number of studies undertaken; the organisational structure is appropriate, and management has established a policy regarding training and staff health surveillance appropriate to the studies undertaken in the facility.

The management should be asked to produce certain documents, such as:

— floor plans,

— facility management and scientific organisation charts,

— CVs of personnel involved in the type(s) of studies selected for the study audit,

— list(s) of on-going and completed studies with information on the type of study, initiation/completion dates, test system, method of application of test substance and name of study director,

— staff health surveillance policies,

— staff job descriptions and staff training programmes and records,

— an index to the facility's standard operating procedures (SOPs),

— specific SOPs as related to the studies or procedures being inspected or audited,

— list(s) of the study directors and sponsors associated with the study(ies) being audited.

The inspector should check, in particular:

— lists of on-going and completed studies to ascertain the level of work being undertaken by the test facility,

— the identity and qualifications of the study director(s), the head of the quality assurance unit and other personnel,

— existence of SOPs for all relevant areas of testing.

Quality assurance programme

Purpose: to determine whether the mechanisms used to assure management that studies are conducted in accordance with GLP principles are adequate.

The head of the QA unit should be asked to demonstrate the systems and methods for QA inspection and monitoring of studies, and the system for recording observations made during QA monitoring. Inspectors should check:

— the qualifications of the head of QA, and of all QA staff,

— that the QA unit functions independently from the staff involved in the studies,

— how the QA unit schedules and conducts inspections, how it monitors identified critical phases in a study, and what resources are available for QA inspections and monitoring activities,

— that where studies are of such short duration that monitoring of each study is impracticable, arrangements exist for monitoring on a sample basis,

— the extent and depth of QA monitoring during the practical phases of the study,

— the extent and depth of QA monitoring of routine test facility operation,

— the QA procedure for checking the final report to ensure its agreement with the raw data,

— that management receives reports from QA concerning problems likely to affect the quality or integrity of a study,

— the actions taken by QA when deviations are found,

— the QA role, if any, if studies or parts of studies are done in contract laboratories,

— the part played, if any, by QA in the review, revision and updating of SOPs.

Facilities

Purpose: to determine if the test facility, whether indoor or outdoor, is of suitable size, design and location to meet the demands of the studies being undertaken.

The inspector should check that:

— the design enables an adequate degree of separation so that, for example, test substances, animals, diets, pathological specimens, etc. of one study cannot be confused with those of another,

— environmental control and monitoring procedures exist and function adequately in critical areas, for example, animal and other biological test systems rooms, test substance storage areas, laboratory areas,

— the general housekeeping is adequate for the various facilities and that there are, if necessary, pest control procedures.

Care, housing and containment of biological test systems

Purpose: to determine whether the test facility, if engaged in studies using animals or other biological test systems, has support facilities and conditions for their care, housing and containment, adequate to prevent stress and other problems which could affect the test system and hence the quality of data.

A test facility may be carrying out studies which require a diversity of animal or plant species as well as microbial or other cellular or sub-cellular systems. The type of test systems being used will determine the aspects relating to care, housing or containment that the inspector will monitor. Using his judgment, the inspector will check, according to the test systems, that:

— there are facilities adequate for the test systems used and for testing needs,

— there are arrangements to quarantine animals and plants being introduced into the facility and that these arrangements are working satisfactorily,

— there are arrangements to isolate animals (or other elements of a test system, if necessary) known to be, or suspected of being, diseased or carriers of disease,

— there is adequate monitoring and record-keeping of health, behaviour or other aspects, as appropriate to the test system,

— the equipment for maintaining the environmental conditions required for each test system is adequate, well maintained, and effective,

— animal cages, racks, tanks and other containers, as well as accessory equipment, are kept sufficiently clean,

— analyses to check environmental conditions and support systems are carried out as required,

— facilities exist for removal and disposal of animal waste and refuse from the test systems and that these are operated so as to minimise vermin infestation, odours, disease hazards and environmental contamination,

— storage areas are provided for animal feed or equivalent materials for all test systems; that these areas are not used for the storage of other materials such as test substances, pest control chemicals or disinfectants, and that they are separate from areas in which animals are housed or other biological test systems are kept,

— stored feed and bedding are protected from deterioration by adverse environmental conditions, infestation or contamination.

Apparatus, materials, reagents and specimens

Purpose: to determine whether the test facility has suitably located, operational apparatus in sufficient quantity and of adequate capacity to meet the requirements of the tests being conducted in the facility and that the materials, reagents and specimens are properly labelled, used and stored.

The inspector should check that:

— apparatus is clean and in good working order,

— records have been kept of operation, maintenance, verification, calibration and validation of measuring equipment and apparatus (including computerised systems),

— materials and chemical reagents are properly labelled and stored at appropriate temperatures and that expiry dates are not being ignored. Labels for reagents should indicate their source, identity and concentration and/or other pertinent information,

— specimens are well identified by test system, study, nature and date of collection,

— apparatus and materials used do not alter to any appreciable extent the test systems.

Test systems

Purpose: to determine whether adequate procedures exist for the handling and control of the variety of test systems required by the studies undertaken in the facility, for example, chemical and physical systems, cellular and microbic systems, plants or animals.

Physical and chemical systems

The inspector should check that:

— where required by study plans, the stability of test and reference substances was determined and that the reference substances specified in test plans were used,

— in automated systems, data generated as graphs, recorder traces or computer print-outs are documented as raw data and archived.

Biological test systems

Taking account of the relevant aspects referred to above relating to care, housing or containment of biological test systems, the inspector should check that:

— test systems are as specified in study plans,

— test systems are adequately and, if necessary and appropriate, uniquely identified throughout the study, and that records exist regarding receipt of the test systems and document fully the number of test systems received, used, replaced or discarded,

— housing or containers of test systems are properly identified with all the necessary information,

— there is an adequate separation of studies being conducted on the same animal species (or the same biological test systems) but with different substances,

— there is an adequate separation of animal species (and other biological test systems) either in space or in time,

— the biological test system environment is as specified in the study plan or in SOPs for aspects such as temperature, or light/dark cycles,

— the recording of the receipt, handling, housing or containment, care and health evaluation is appropriate to the test systems,

— written records are kept of examination, quarantine, morbidity, mortality, behaviour, diagnosis and treatment of animal and plant test systems or other similar aspects as appropriate to each biological test system,

— there are provisions for the appropriate disposal of test systems at the end of tests.

Test and reference substances

Purpose: to determine whether the test facility has procedures designed (i) to ensure that the identity, potency, quantity and composition of test and reference substances are in accordance with their specifications, and (ii) to properly receive and store test and reference substances.

The inspector should check that:

— there are written records on the receipt (including identification of the person responsible), and for the handling, sampling, usage and storage of tests and reference substances,

— test and reference substances containers are properly labelled,

— storage conditions are appropriate to preserve the concentration, purity and stability of the test and reference substances,

— there are written records on the determination of identity, purity, composition, stability, and for the prevention of contamination of test and reference substances, where applicable,

— there are procedures for the determination of the homogeneity and stability of mixtures containing test and reference substances, where applicable,

— containers holding mixtures (or dilutions) of the test and reference substances are labelled and that records are kept of the homogeneity and stability of their contents, where applicable,

— when the test is of longer than four weeks duration, samples from each batch of test and reference substances have been taken for analytical purposes and that they have been retained for an appropriate time,

— procedures for mixing substances are designed to prevent errors in identification or cross-contamination.

Standard operating procedures

Purpose: to determine whether the test facility has written SOPs relating to all the important aspects of its operations, considering that one of the most important management techniques for controlling facility operations is the use of written SOPs. These relate directly to the routine elements of tests conducted by the test facility.

The inspector should check that:

— each test facility area has immediately available relevant, authorised copies of SOPs,

— procedures exist for revision and updating of SOPs,

— any amendments or changes to SOPs have been authorised and dated,

— historical files of SOPs are maintained,

— SOPs are available for, but not necessarily limited to, the following activities:

  (i) receipt; determination of identity, purity, composition and stability; labelling; handling; sampling; usage; and storage of test and reference substances;

  (ii) use, maintenance, cleaning, calibration and validation of measuring apparatus, computerised systems and environmental control equipment;

  (iii) preparation of reagents and dosing formulations;

  (iv) record-keeping, reporting, storage and retrieval of records and reports;

(v) preparation and environmental control of areas containing the test systems;

(vi) receipt, transfer, location, characterisation, identification and care of test systems;

(vii) handling of the test systems before, during and at the termination of the study;

(viii) disposal of test systems;

(ix) use of pest control and cleaning agents;

(x) quality assurance programme operations.

Performance of the study

Purpose: to verify that written study plans exist and that the plans and the conduct of the study are in accordance with GLP principles.

The inspector should check that:

— the study plan was signed by the study director,

— any amendments to the study plan were signed and dated by the study director,

— the date of the agreement to the study plan by the sponsor was recorded (where applicable),

— measurements, observations and examinations were in accordance with the study plan and relevant SOPs,

— the results of these measurements, observations and examinations were recorded directly, promptly, accurately and legibly and were signed (or initialled) and dated,

— any changes in the raw data, including data stored in computers, did not obscure previous entries, included the reason for the change and identified the person responsible for the change and the date it was made,

— computer-generated or stored data have been identified and that the procedures to protect them against unauthorised amendments or loss are adequate,

— the computerised systems used within the study are reliable, accurate and have been validated,

— any unforeseen events recorded in the raw data have been investigated and evaluated,

— the results presented in the reports of the study (interim or final) are consistent and complete and that they correctly reflect the raw data.

Reporting of study results

Purpose: to determine whether final reports are prepared in accordance with GLP principles.

When examining a final report, the inspector should check that:

— it is signed and dated by the study director to indicate acceptance of responsibility for the validity of the study and confirming that the study was conducted in accordance with GLP principles,

— it is signed and dated by other principal scientists, if reports from cooperating disciplines are included,

— a quality assurance statement is included in the report and that it is signed and dated,

— any amendments were made by the responsible personnel,

— it lists the archive location of all samples, specimens and raw data.

Storage and retention of records

Purpose: to determine whether the facility has generated adequate records and reports and whether adequate provision has been made for the safe storage and retention of records and materials.

The inspector should check:

— that a person has been identified as responsible for the archive,

— the archive facilities for the storage of study plans, raw data (including that from discontinued GLP studies), final reports, samples and specimens and records of education and training of personnel,

— the procedures for retrieval of archived materials,

— the procedures whereby access to the archives is limited to authorised personnel and records are kept of personnel given access to raw data, slides, etc.,

— that an inventory is maintained of materials removed from, and returned to, the archives,

— that records and materials are retained for the required or appropriate period of time and are protected from loss or damage by fire, adverse environmental conditions, etc.

Study audits

Test facility inspections will generally include, *inter alia*, study audits, which review on-going or completed studies. Specific study audits are also often requested by Regulatory Authorities, and can be conducted independently of test facility inspections. Because of the wide variation in the types of studies which might be audited, only general guidance is appropriate, and inspectors and others taking part in study audits will always need to exercise judgment as to the nature and extent of their examinations. The objective should be to reconstruct the study by comparing the final report with the study plan, relevant SOPs, raw data and other archived material.

In some cases, inspectors may need assistance from other experts in order to conduct an effective study audit, for example, where there is a need to examine tissue sections under the microscope.

When conducting a study audit, the inspector should:

— obtain names, job descriptions and summaries of training and experience for selected personnel engaged in the study(ies) such as the study director and principal scientists,

— check that there is sufficient staff trained in relevant areas for the study(ies) undertaken,

— identify individual items of apparatus or special equipment used in the study and examine the calibration, maintenance and service records for the equipment,

— review the records relating to the stability of the test substances, analyses of test substance and formulations, analyses of feed, etc.,

— attempt to determine, through the interview process if possible, the work assignments of selected individuals participating in the study to ascertain if these individuals had the time to accomplish the tasks specified in the study plan or report,

— obtain copies of all documentation concerning control procedures or forming integral parts of the study, including:

  (i) the study plan;

  (ii) SOPs in use at the time the study was done;

  (iii) logbooks, laboratory notebooks, files, worksheets, print-outs of computer-stored data, etc.; checking of calculations, where appropriate;

  (iv) the final report.

In studies in which animals (i.e., rodents and other mammals) are used, the inspectors should follow a certain percentage of individual animals from their arrival at the test facility to autopsy. They should pay particular attention to the records relating to:

— animal body weight, food/water intake, dose formulation and administration, etc.,

— clinical observations and autopsy findings,

— clinical chemistry,

— pathology.

Completion of inspection or study audit

When a test facility inspection or study audit has been completed, the inspector should be prepared to discuss his findings with representatives of the test facility at a closing conference and should prepare a written report, i.e., the inspection report.

A test facility inspection of any large facility is likely to reveal a number of minor deviations from GLP principles but, normally, these will not be sufficiently serious to affect the validity of studies emanating from that test facility. In such cases, it is reasonable for an inspector to report that the facility is operating in compliance with GLP principles according to the criteria established by the (national) GLP Monitoring Authority. Nevertheless, details of the inadequacies or faults detected should be provided to the test facility and assurances sought from its senior management that action will be taken to remedy them.

The inspector may need to revisit the facility after a period of time to verify that necessary action has been taken.

If a serious deviation from the GLP principles is identified during a test facility inspection or study audit which, in the opinion of the inspector, may have affected the validity of that study, or of other studies performed at the facility, the inspector should report back to the (national) GLP Monitoring Authority. The action taken by that Authority and/or the Regulatory Authority, as appropriate, will depend on the nature and extent of the non-compliance and the legal and/or administrative provisions within the GLP compliance programme.

Where a study audit has been conducted at the request of a Regulatory Authority, a full report of the findings should be prepared and sent via the relevant (national) GLP Monitoring Authority.

ANNEX II

PART A

REPEALED DIRECTIVE AND ITS AMENDMENTS

(Article 9)

Council Directive 88/320/EEC	(OJ L 145, 11.6.1988, p. 35)
Commission Directive 90/18/EEC	OJ L 11, 13.1.1990, p. 37)
Commission Directive 1999/12/EC	(OJ L 77, 23.3.1999, p. 22)
Regulation (EC) No 1882/2003 of the European Parliament and of the Council, Annex III, point 8 only	(OJ L 284, 31.10.2003, p. 1)

PART B

DEADLINES FOR TRANSPOSITION INTO NATIONAL LAW

(Article 9)

Directive	Deadline for transposition
88/320/EEC	1.1.1989
90/18/EEC	1.7.1990
1999/12/EC	30.9.1999

ANNEX III

CORRELATION TABLE

Directive 88/320/EEC	This Directive
Articles 1 to 6	Articles 1 to 6
Article 7	Article 8
Article 8	Article 7
Article 9	—
—	Article 9
—	Article 10
Article 10	Article 11
Annex	Annex I
—	Annex II
—	Annex III

DIRECTIVE 2004/10/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 11 February 2004

on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances (codified version)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee [1],

Acting in accordance with the procedure laid down in Article 251 of the Treaty [2],

Whereas:

(1) Council Directive 87/18/EEC of 18 December 1986 on the harmonisation of laws, regulations and administrative provisions relating to the application of principles of good laboratory practice and the verification of their applications for tests on chemical substances [3] has been significantly amended. In the interests of clarity and rationality the said Directive should be codified.

(2) Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances [4] requires tests to be carried out on chemical substances in order to enable their potential risk to man and the environment to be determined.

(3) When the active substances in pesticides undergo tests they should do so in accordance with Directive 67/548/EEC.

(4) Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [5] and 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 [6] lay down that non-clinical tests on pharmaceutical products are to be carried out in accordance with the principles of good laboratory practice (GLP) in force in the Community for chemical substances, compliance with which is also required by other Community legislation.

(5) The methods to be used for these tests are laid down in Annex V to Directive 67/548/EEC.

(6) It is necessary to comply with the principles of GLP in carrying out the tests laid down by Directive 67/548/EEC so as to ensure that the results are comparable and of high quality.

(7) The resources devoted to the tests should not be wasted by having to repeat tests owing to differences in laboratory practice from one Member State to another.

(8) The Council of the Organisation for Economic Cooperation and Development (OECD) took a Decision on 12 May 1981 on the mutual acceptance of data for the evaluation of chemical products. It issued a recommendation on 26 July 1983 concerning the mutual recognition of compliance with GLP. The principles of GLP have been modified by OECD Council Decision (C(97) 186 (final)).

(9) Animal protection requires that the number of experiments conducted on animals be restricted. Mutual recognition of the results of tests obtained using standard and recognised methods is an essential condition for reducing the number of experiments in this area.

(10) It is necessary to set up a procedure allowing rapid adaptation of the principles of GLP.

(11) This Directive should be without prejudice to the obligations of the Member States concerning the time limits for transposition of the directives set out in Annex II, part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice (GLP) as laid down in Annex I to this Directive.

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[1] OJ C 85, 8.4.2003, p. 138.
[2] Opinion of the European Parliament of 1 July 2003 (not yet published in the Official Journal) and Decision of the Council of 20 January 2004.
[3] OJ L 15, 17.1.1987, p. 29. Directive as amended by Commission Directive 1999/11/EC (OJ L 77, 23.3.1999, p. 8).
[4] OJ 196, 16.8.1967, p. 1. Directive as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).
[5] OJ L 311, 28.11.2001, p. 1.
[6] OJ L 311, 28. 11. 2001, p. 67. Directive as amended by Commission Directive 2003/63/EC (OJ L 159, 27.6.2003, p. 46).

2. Paragraph 1 shall apply also where other Community provisions provide for the application of the principles of GLP in respect of tests on chemical products to evaluate their safety for man and/or the environment.

Article 2

When submitting results, the laboratories referred to in Article 1 shall certify that the tests have been carried out in conformity with the principles of GLP referred to in that Article.

Article 3

1. Member States shall adopt the measures necessary for verification of compliance with the principles of GLP. These measures shall include, in particular, inspections and study checks in accordance with the recommendations of the OECD in this area.

2. Member States shall notify to the Commission the name or names of the authority or authorities responsible for verifying compliance with the principles of GLP, as referred to in paragraph 1. The Commission shall inform the other Member States thereof.

Article 4

Any adaptation to the principles of GLP mentioned in Article 1 shall be adopted in accordance with the procedure referred to in Article 29 of Directive 67/548/EEC.

Article 5

1. Where Community provisions require application of the principles of GLP following the entry into force of this Directive for tests on chemical products, Member States may not, on grounds relating to the principles of GLP, prohibit, restrict or impede the placing on the market of chemical products if the principles applied by the laboratories concerned are in conformity with those mentioned in Article 1.

2. Should a Member State establish on the basis of detailed evidence that the application of the principles of GLP and the verification of their application for tests on chemical substances show that, although a chemical substance has been examined in accordance with the requirements of this Directive, it presents a danger to man and the environment, the Member State may provisionally prohibit or make subject to special conditions the marketing of that substance on its territory. It shall immediately inform the Commission and the other Member States thereof and give the grounds for its decision.

The Commission shall, within six weeks, consult the Member States concerned and then give its opinion and take suitable measures without delay.

Should the Commission consider that technical adaptations to this Directive are necessary, those adaptations shall be adopted either by the Commission or by the Council in accordance with the procedure referred to in Article 4. In that case, the Member State which adopted the safeguard measures may maintain them until the entry into force of those adaptations.

Article 6

Directive 87/18/EEC is hereby repealed, without prejudice to the obligations of the Member States concerning the time limits for transposition of the Directives set out in Annex II, part B.

References made to the repealed Directive shall be construed as being made to this Directive and shall be read in accordance with the correlation table in Annex III.

Article 7

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

Article 8

This Directive is addressed to the Member States.

Done at Strasbourg, 11 February 2004.

For the European Parliament	*For the Council*
The President	*The President*
P. COX	M. McDOWELL

ANNEX I

THE OECD PRINCIPLES OF GOOD LABORATORY PRACTICE (GLP)

CONTENTS

SECTION I

INTRODUCTION

Preface

Government and industry are concerned about the quality of non-clinical health and environmental safety studies upon which hazard assessments are based. As a consequence, OECD Member States have established criteria for the performance of these studies.

To avoid different schemes of implementation that could impede international trade in chemicals, OECD Member States have pursued international harmonisation of test methods and good laboratory practice. In 1979 and 1980 an international group of experts, established under the special programme on the control of chemicals, developed the 'OECD principles of good laboratory practice' (GLP), utilising common managerial and scientific practices and experience from various national and international sources. These principles of GLP were adopted by the OECD Council in 1981, as an Annex to the Council Decision on the mutual acceptance of data in the assessment of chemicals (C(81) 30 (final)).

In 1995 and 1996, a new group of experts was formed to revise and update the principles. The current document is the result of the consensus reached by that group. It cancels and replaces the original principles adopted in 1981.

The purpose of these principles of good laboratory practice is to promote the development of quality test data. Comparable quality of test data forms the basis for the mutual acceptance of data among countries. If individual countries can confidently rely on test data developed in other countries, duplicative testing can be avoided, thereby saving time and resources. The application of these principles should help to avoid the creation of technical barriers to trade, and further improve the protection of human health and the environment.

1. Scope

These principles of good laboratory practice should be applied to the non-clinical safety testing of test items contained in pharmaceutical products, pesticide products, cosmetic products, veterinary drugs as well as food additives, feed additives, and industrial chemicals. These test items are frequently synthetic chemicals, but may be of natural or biological origin and, in some circumstances, may be living organisms. The purpose of testing these test items is to obtain data on their properties and/or their safety with respect to human health and/or the environment.

Non-clinical health and environmental safety studies covered by the principles of good laboratory practice include work conducted in the laboratory, in greenhouses, and in the field.

Unless specifically exempted by national legislation, these principles of good laboratory practice apply to all non-clinical health and environmental safety studies required by regulation for the purpose of registering or licensing pharmaceuticals, pesticides, food and feed additives, cosmetic products, veterinary drug products and similar products, and for the regulation of industrial chemicals.

2. Definition of terms

2.1. *Good laboratory practice*

Good laboratory practice (GLP) is a quality system concerned with the organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

2.2. *Terms concerning the organisation of a test facility*

1. Test facility means the persons, premises and operational unit(s) that are necessary for conducting the non-clinical health and environmental safety study. For multisite studies, those which are conducted at more than one site, the test facility comprises the site at which the study director is located and all individual test sites, which individually or collectively can be considered to be test facilities.

2. Test site means the location(s) at which a phase(s) of a study is conducted.

3. Test facility management means the person(s) who has the authority and formal responsibility for the organisation and functioning of the test facility according to these principles of good laboratory practice.

4. Test site management (if appointed) means the person(s) responsible for ensuring that the phase(s) of the study, for which he is responsible, are conducted according to these principles of good laboratory practice.

5. Sponsor means an entity which commissions, supports and/or submits a non-clinical health and environmental safety study.

6. Study director means the individual responsible for the overall conduct of the non-clinical health and environmental safety study.

7. Principal investigator means an individual who, for a multisite study, acts on behalf of the study director and has defined responsibility for delegated phases of the study. The study director's responsibility for the overall conduct of the study cannot be delegated to the principal investigator(s); this includes approval of the study plan and its amendments, approval of the final report, and ensuring that all applicable principles of good laboratory practice are followed.

8. Quality assurance programme: means a defined system, including personnel, which is independent of study conduct and is designed to assure test facility management of compliance with these principles of good laboratory practice.

9. Standard operating procedures (SOPs) means documented procedures which describe how to perform tests or activities normally not specified in detail in study plans or test guidelines.

10. Master schedule means a compilation of information to assist in the assessment of workload and for the tracking of studies at a test facility.

2.3. *Terms concerning the non-clinical health and environmental safety study*

1. Non-clinical health and environmental safety study, henceforth referred to simply as 'study', means an experiment or set of experiments in which a test item is examined under laboratory conditions or in the environment to obtain data on its properties and/or its safety, intended for submission to appropriate regulatory authorities.

2. Short-term study means a study of short duration with widely used, routine techniques.

3. Study plan means a document which defines the objectives and experimental design for the conduct of the study, and includes any amendments.

4. Study plan amendment means an intended change to the study plan after the study initiation date.

5. Study plan deviation means an unintended departure from the study plan after the study initiation date.

6. Test system means any biological, chemical or physical system, or a combination, thereof used in a study.

7. Raw data means all original test facility records and documentation, or verified copies thereof, which are the result of the original observations and activities in a study. Raw data also may include, for example, photographs, microfilm or microfiche copies, computer readable media, dictated observations, recorded data from automated instruments, or any other data storage medium that has been recognised as capable of providing secure storage of information for a time period as stated in section 10 below.

8. Specimen means any material derived from a test system for examination, analysis, or retention.

9. Experimental starting date means the date on which the first study-specific data are collected.

10. Experimental completion date means the last date on which data are collected from the study.

11. Study initiation date means the date the study director signs the study plan.

12. Study completion date means the date the study director signs the final report.

2.4. *Terms concerning the test item*

1. Test item means an article that is the subject of a study.

2. Reference item (control item) means any article used to provide a basis for comparison with the test item.

3. Batch means a specific quantity or lot of a test item or reference item produced during a defined cycle of manufacture in such a way that it could be expected to be of a uniform character and should be designated as such.

4. Vehicle means any agent which serves as a carrier used to mix, disperse, or solubilise the test item or reference item to facilitate the administration/application to the test system.

SECTION II

GOOD LABORATORY PRACTICE PRINCIPLES

1. Test facility organisation and personnel

1.1. *Test facility management's responsibilities*

1. Each test facility management should ensure that these principles of good laboratory practice are complied with, in its test facility.

2. At a minimum it should:

(a) ensure that a statement exists which identifies the individual(s) within a test facility who fulfil the responsibilities of management as defined by these principles of good laboratory practice;

(b) ensure that a sufficient number of qualified personnel, appropriate facilities, equipment, and materials are available for the timely and proper conduct of the study;

(c) ensure the maintenance of a record of the qualifications, training, experience and job description for each professional and technical individual;

(d) ensure that personnel clearly understand the functions they are to perform and, where necessary, provide training for these functions;

(e) ensure that appropriate and technically valid standard operating procedures are established and followed, and approve all original and revised standard operating procedures;

(f) ensure that there is a quality assurance programme with designated personnel and assure that the quality assurance responsibility is being performed in accordance with these principles of good laboratory practice;

(g) ensure that for each study an individual with the appropriate qualifications, training, and experience is designated by the management as the study director before the study is initiated. Replacement of a study director should be done according to established procedures, and should be documented;

(h) ensure, in the event of a multisite study, that, if needed, a principal investigator is designated, who is appropriately trained, qualified and experienced to supervise the delegated phase(s) of the study. Replacement of a principal investigator should be done according to established procedures, and should be documented;

(i) ensure documented approval of the study plan by the study director;

(j) ensure that the study director has made the approval study plan available to the quality assurance personnel;

(k) ensure the maintenance of a historical file of all standard operating procedures;

(l) ensure that an individual is identified as responsible for the management of the archive(s);

(m) ensure the maintenance of a master schedule;

(n) ensure that test facility supplies meet requirements appropriate to their use in a study;

(o) ensure for a multisite study that clear lines of communication exist between the study director, principal investigator(s), the quality assurance programme(s) and study personnel;

(p) ensure that test and reference items are appropriately characterised;

(q) establish procedures to ensure that computerised systems are suitable for their intended purpose, and are validated, operated and maintained in accordance with these principles of good laboratory practice.

3. When a phase(s) of a study is conducted at a test site, test site management (if appointed) will have the responsibilities as defined above with the following exceptions: 1.1.2(g), (i), (j) and (o).

1.2. *Study director's responsibilities*

1. The study director is the single point of study control and has the responsibility for the overall conduct of the study and for its final report.

2. These responsibilities should include, but not be limited to, the following functions. The study director should:

(a) approve the study plan and any amendments to the study plan by dated signature;

(b) ensure that the quality assurance personnel have a copy of the study plan and any amendments in a timely manner and communicate effectively with the quality assurance personnel as required during the conduct of the study;

(c) ensure that study plans and amendments and standard operating procedures are available to study personnel;

(d) ensure that the study plan and the final report for a multisite study identify and define the role of any principal investigator(s) and any test facilities and test sites involved in the conduct of the study;

(e) ensure that the procedures specified in the study plan are followed, and assess and document the impact of any deviations from the study plan on the quality and integrity of the study, and take appropriate corrective action if necessary; acknowledge deviations from standard operating procedures during the conduct of the study;

(f) ensure that all raw data generated are fully documented and recorded;

(g) ensure that computerised systems used in the study have been validated;

(h) sign and date the final report to indicate acceptance of responsibility for the validity of the data and to indicate the extent to which the study complies with these principles of good laboratory practice;

(i) ensure that after completion (including termination) of the study, the study plan, the final report, raw data and supporting material are archived.

1.3. *Principal investigator's responsibilities*

The principal investigator will ensure that the delegated phases of the study are conducted in accordance with the applicable principles of good laboratory practice.

1.4. *Study personnel's responsibilities*

1. All personnel involved in the conduct of the study must be knowledgeable in those parts of the principles of good laboratory practice which are applicable to their involvement in the study.

2. Study personnel will have access to the study plan and appropriate standard operating procedures applicable to their involvement in the study. It is their responsibility to comply with the instructions given in these documents. Any deviation from these instructions should be documented and communicated directly to the study director, and/or if appropriate, the principal investigator(s).

3. All study personnel are responsible for recording raw data promptly and accurately and in compliance with these principles of good laboratory practice, and are responsible for the quality of their data.

4. Study personnel should exercise health precautions to minimise risk to themselves and to ensure the integrity of the study. They should communicate to the appropriate person any relevant known health or medical condition in order that they can be excluded from operations that may affect the study.

2. **Quality assurance programme**

2.1. *General*

1. The test facility should have a documented quality assurance programme to assure that studies performed are in compliance with these principles of good laboratory practice.

2. The quality assurance programme should be carried out by an individual or by individuals designated by and directly responsible to management and who are familiar with the test procedures.

3. This individual(s) should not be involved in the conduct of the study being assured.

2.2. *Responsibilities of the quality assurance personnel*

The responsibilities of the quality assurance personnel include, but are not limited to, the following functions. They should:

(a) maintain copies of all approved study plans and standard operating procedures in use in the test facility and have access to an up-to-date copy of the master schedule;

(b) verify that the study plan contains the information required for compliance with these principles of good laboratory practice. This verification should be documented;

(c) conduct inspections to determine if all studies are conducted in accordance with these principles of good laboratory practice. Inspections should also determine that study plans and standard operating procedures have been made available to study personnel and are being followed.

Inspections can be of three types as specified by quality assurance programme standard operating procedures:

— study-based inspections,

— facility-based inspections,

— process-based inspections.

Records of such inspections should be retained;

(d) inspect the final reports to confirm that the methods, procedures, and observations are accurately and completely described, and that the reported results accurately and completely reflect the raw data of the studies;

(e) promptly report any inspection results in writing to management and to the study director, and to the principal investigator(s) and the respective management, when applicable;

(f) prepare and sign a statement, to be included with the final report, which specifies types of inspections and their dates, including the phase(s) of the study inspected, and the dates inspection results were reported to management and the study director and principal investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

3. **Facilities**

3.1. *General*

1. The test facility should be of suitable size, construction and location to meet the requirements of the study and to minimise disturbance that would interfere with the validity of the study.

2. The design of the test facility should provide an adequate degree of separation of the different activities to assure the proper conduct of each study.

3.2. *Test system facilities*

1. The test facility should have a sufficient number of rooms or areas to assure the isolation of test systems and the isolation of individual projects, involving substances or organisms known to be or suspected of being biohazardous.

2. Suitable rooms or areas should be available for the diagnosis, treatment and control of diseases, in order to ensure that there is no unacceptable degree of deterioration of test systems.

3. There should be storage rooms or areas as needed for supplies and equipment. Storage rooms or areas should be separated from rooms or areas housing the test systems and should provide adequate protection against infestation, contamination, and/or deterioration.

3.3. *Facilities for handling test and reference items*

1. To prevent contamination or mix-ups, there should be separate rooms or areas for receipt and storage of the test and reference items, and mixing of the test items with a vehicle.

2. Storage rooms or areas for the test items should be separate from rooms or areas containing the test systems. They should be adequate to preserve identity, concentration, purity, and stability, and ensure safe storage for hazardous substances.

3.4. *Archive facilities*

Archive facilities should be provided for the secure storage and retrieval of study plans, raw data, final reports, samples of test items and specimens. Archive design and archive conditions should protect contents from untimely deterioration.

3.5. *Waste disposal*

Handling and disposal of wastes should be carried out in such a way as not to jeopardise the integrity of studies. This includes provision for appropriate collection, storage and disposal facilities, and decontamination and transportation procedures.

4. **Apparatus, material, and reagents**

1. Apparatus, including validated computerised systems, used for the generation, storage and retrieval of data, and for controlling environmental factors relevant to the study should be suitably located and of appropriate design and adequate capacity.

2. Apparatus used in a study should be periodically inspected, cleaned, maintained, and calibrated according to standard operating procedures. Records of these activities should be maintained. Calibration should, where appropriate, be traceable to national or international standards of measurement.

3. Apparatus and materials used in a study should not interfere adversely with the test systems.

4. Chemicals, reagents, and solutions should be labelled to indicate identity (with concentration if appropriate), expiry date and specific storage instructions. Information concerning source, preparation date and stability should be available. The expiry date may be extended on the basis of documented evaluation or analysis.

5. **Test systems**

5.1. *Physical/chemical*

1. Apparatus used for the generation of physical/chemical data should be suitably located and of appropriate design and adequate capacity.

2. The integrity of the physical/chemical test systems should be ensured.

5.2. *Biological*

1. Proper conditions should be established and maintained for the storage, housing, handling and care of biological test systems, in order to ensure the quality of the data.

2. Newly received animal and plant test systems should be isolated until their health status has been evaluated. If any unusual mortality or morbidity occurs, this lot should not be used in studies and, when appropriate, should be humanely destroyed. At the experimental starting date of a study, test systems should be free of any disease or condition that might interfere with the purpose or conduct of the study. Test systems that become diseased or injured during the course of a study should be isolated and treated, if necessary to maintain the integrity of the study. Any diagnosis and treatment of any disease before or during a study should be recorded.

3. Records of source, date of arrival, and arrival condition of test systems should be maintained.

4. Biological test systems should be acclimatised to the test environment for an adequate period before the first administration/application of the test or reference item.

5. All information needed to properly identify the test systems should appear on their housing or containers. Individual test systems that are to be removed from their housing or containers during the conduct of the study should bear appropriate identification, wherever possible.

6. During use, housing or containers for test systems should be cleaned and sanitised at appropriate intervals. Any material that comes into contact with the test system should be free of contaminants at levels that would interfere with the study. Bedding for animals should be changed as required by sound husbandry practice. Use of pest control agents should be documented.

7. Test systems used in field studies should be located so as to avoid interference in the study from spray drift and from past usage of pesticides.

6. **Test and reference items**

6.1. *Receipt, handling, sampling and storage*

1. Records including test item and reference item characterisation, date of receipt, expiry date, quantities received and used in studies should be maintained.

2. Handling, sampling, and storage procedures should be identified in order that the homogeneity and stability are assured to the degree possible and contamination or mix-up are precluded.

3. Storage container(s) should carry identification information, expiry date, and specific storage instructions.

6.2. *Characterisation*

1. Each test and reference item should be appropriately identified (e.g. code, chemical abstracts service registry number (CAS number), name, biological parameters).

2. For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

3. In cases where the test item is supplied by the sponsor, there should be a mechanism, developed in cooperation between the sponsor and the test facility, to verify the identity of the test item subject to the study.

4. The stability of test and reference items under storage and test conditions should be known for all studies.

5. If the test item is administered or applied in a vehicle, the homogeneity, concentration and stability of the test item in that vehicle should be determined. For test items used in field studies (e.g. tank mixes), these may be determined through separate laboratory experiments.

6. A sample for analytical purposes from each batch of test item should be retained for all studies except short-term studies.

7. **Standard operating procedures**

1. A test facility should have written standard operating procedures approved by test facility management that are intended to ensure the quality and integrity of the data generated by that test facility. Revisions to standard operating procedures should be approved by test facility management.

2. Each separate test facility unit or area should have immediately available current standard operating procedures relevant to the activities being performed therein. Published text books, analytical methods, articles and manuals may be used as supplements to these standard operating procedures.

3. Deviations from standard operating procedures related to the study should be documented and should be acknowledged by the study director and the principal investigator(s), as applicable.

4. Standard operating procedures should be available for, but not be limited to, the following categories of test facility activities. The details given under each heading are to be considered as illustrative examples.

1. *Test and reference items*

Receipt, identification, labelling, handling, sampling and storage.

2. *Apparatus, materials and reagents*

(a) Apparatus:

use, maintenance, cleaning and calibration

(b) Computerised systems:

validation, operation, maintenance, security, change control and back-up

(c) Materials, reagents and solutions:

preparation and labelling.

3. *Record keeping, reporting, storage, and retrieval*

Coding of studies, data collection, preparation of reports, indexing systems, handling of data, including the use of computerised systems.

4. *Test system (where appropriate)*

(a) Room preparation and environmental room conditions for the test system.

(b) Procedures for receipt, transfer, proper placement, characterisation, identification and care of the test system.

(c) Test system preparation, observations and examinations, before, during and at the conclusion of the study.

(d) Handling of test system individuals found moribund or dead during the study.

(e) Collection, identification and handling of specimens including necropsy and histopathology.

(f) Siting and placement of test systems in test plots.

5. *Quality assurance procedures*

Operation of Quality Assurance personnel in planning, scheduling, performing, documenting and reporting inspections.

8. **Performance of the study**

8.1. *Study plan*

1. For each study, a written plan should exist prior to the initiation of the study. The study plan should be approved by dated signature of the study director and verified for GLP compliance by quality assurance personnel as specified in section II2(20)(b). The study plan should also be approved by the test facility management and the sponsor, if required by national regulation or legislation in the country where the study is being performed.

2. (a) Amendments to the study plan should be justified and approved by dated signature of the study director and maintained with the study plan.

(b) Deviations from the study plan should be described, explained, acknowledged and dated in a timely fashion by the study director and/or principal investigator(s) and maintained with the study raw data.

3. For short-term studies, a general study plan accompanied by a study specific supplement may be used.

8.2. *Content of the study plan*

The study plan should contain, but not be limited to the following information:

1. Identification of the study, the test item and reference item

(a) A descriptive title

(b) A statement which reveals the nature and purpose of the study

(c) Identification of the test item by code or name (IUPAC; CAS number, biological parameters, etc.)

(d) The reference item to be used.

2. Information concerning the sponsor and the test facility

(a) Name and address of the sponsor

(b) Name and address of any test facilities and test sites involved

(c) Name and address of the study director

(d) Name and address of the principal investigator(s), and the phase(s) of the study delegated by the study director and under the responsibility of the principal investigator(s).

3. Dates

(a) The date of approval of the study plan by signature of the study director. The date of approval of the study plan by signature of the test facility management and sponsor if required by national regulation or legislation in the country where the study is being performed.

(b) The proposed experimental starting and completion dates.

4. Test methods

Reference to the OECD test guideline or other test guideline or method to be used.

5. Issues (where applicable)

(a) The justification for selection of the test system

(b) Characterisation of the test system, such as the species, strain, substrain, source of supply, number, body weight range, sex, age and other pertinent information

(c) The method of administration and the reason for its choice

(d) The dose levels and/or concentration(s), frequency, and duration of administration/application;

(e) Detailed information on the experimental design, including a description of the chronological procedure of the study, all methods, materials and conditions, type and frequency of analysis, measurements, observations and examinations to be performed, and statistical methods to be used (if any).

6. Records

A list of records to be retained.

8.3. *Conduct of the study*

1. A unique identification should be given to each study. All items concerning this study should carry this identification. Specimens from the study should be identified to confirm their origin. Such identification should enable traceability, as appropriate for the specimen and study.

2. The study should be conducted in accordance with the study plan.

3. All data generated during the conduct of the study should be recorded directly, promptly, accurately, and legibly by the individual entering the data. These entries should be signed or initialled and dated.

4. Any change in the raw data should be made so as not to obscure the previous entry, should indicate the reason for change and should be dated and signed or initialled by the individual making the change.

5. Data generated as a direct computer input should be identified at the time of data input by the individual(s) responsible for direct data entries. Computerised system design should always provide for the retention of full audit trails to show all changes to the data without obscuring the original data. It should be possible to associate all changes to data with the persons having made those changes, for example, by use of timed and dated (electronic) signatures. Reason for changes should be given.

9. **Reporting of study results**

9.1. *General*

1. A final report should be prepared for each study. In the case of short-term studies, a standardised final report accompanied by a study specific extension may be prepared.

2. Reports of principal investigators or scientists involved in the study should be signed and dated by them.

3. The final report should be signed and dated by the study director to indicate acceptance of responsibility for the validity of the data. The extent of compliance with these principles of good laboratory practice should be indicated.

4. Corrections and additions to a final report should be in the form of amendments. Amendments should clearly specify the reason for the corrections or additions and should be signed and dated by the study director.

5. Reformatting of the final report to comply with the submission requirements of a national registration or regulatory authority does not constitute a correction, addition or amendment to the final report.

9.2. *Content of the final report*

The final report should include, but not be limited to, the following information:

1. Identification of the study, the test item and reference item

   (a) A descriptive title

   (b) Identification of the test item by code or name (IUPAC, CAS number, biological parameters, etc.)

   (c) Identification of the reference item by name

   (d) Characterisation of the test item including purity, stability and homogeneity.

2. Information concerning the sponsor and the test facility

   (a) Name and address of the sponsor

   (b) Name and address of any test facilities and test sites involved

   (c) Name and address of the study director

   (d) Name and address of the principal investigator(s) and the phase(s) of the study delegated, if applicable

   (e) Name and address of scientists having contributed reports to the final report.

3. Dates

   Experimental starting and completion dates.

4. Statement

   A quality assurance programme statement listing the types of inspections made and their dates, including the phase(s) inspected, and the dates any inspection results were reported to management and to the study director and principal investigator(s), if applicable. This statement would also serve to confirm that the final report reflects the raw data.

5. Description of materials and test methods

   (a) Description of methods and materials used

   (b) Reference to OECD test guideline or other test guideline or method.

6. Results

   (a) A summary of results

   (b) All information and data required by the study plan

   (c) A presentation of the results, including calculations and determinations of statistical significance

   (d) An evaluation and discussion of the results and, where appropriate, conclusions.

7. Storage

   The location(s) where the study plan, samples of test and reference items, specimens, raw data and the final report are to be stored.

10. **Storage and retention of records and materials**

10.1. The following should be retained in the archives for the period specified by the appropriate authorities:

(a) the study plan, raw data, samples of test and reference items, specimens, and the final report of each study;

(b) records of all inspections performed by the quality assurance programme, as well as master schedules;

(c) records of qualifications, training, experience and job descriptions of personnel;

(d) records and reports of the maintenance and calibration of apparatus;

(e) validation documentation for computerised systems;

(f) the historical file of all standard operating procedures;

(g) environmental monitoring records.

In the absence of a required retention period, the final disposition of any study materials should be documented. When samples of test and reference items and specimens are disposed of before the expiry of the required retention period for any reason, this should be justified and documented. Samples of test and reference items and specimens should be retained only as long as the quality of the preparation permits evaluation.

10.2. Material retained in the archives should be indexed so as to facilitate orderly storage and retrieval.

10.3. Only personnel authorised by management should have access to the archives. Movement of material in and out of the archives should be properly recorded.

10.4. If a test facility or an archive contracting facility goes out of business and has no legal successor, the archive should be transferred to the archives of the sponsor(s) of the study(s).

ANNEX II

PART A

Repealed Directive and its amendment

(Article 6)

Council Directive 87/18/EEC	(OJ L 15, 17.1.1987, p. 29)
Commission Directive 1999/11/EC	(OJ L 77, 23.3.1999, p. 8)

PART B

Deadlines for transposition into national law

(Article 6)

Directive	Deadline for transposition
87/18/EEC	30 June 1988
1999/11/EC	30 September 1999

ANNEX III

Correlation table

Directive 87/18/EEC	This Directive
Articles 1 to 5	Articles 1 to 5
Article 6	—
—	Article 6
—	Article 7
Article 7	Article 8
Annex	Annex I
—	Annex II
—	Annex III

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 19 February 2004

extending the period of application of the measures in Decision 2002/148/EC concluding consultations with Zimbabwe under Article 96 of the ACP-EC Partnership Agreement

(2004/157/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 300(2), second subparagraph thereof,

Having regard to the Internal Agreement on measures to be taken and procedures to be followed for the implementation of the ACP-EC Partnership Agreement signed in Cotonou on 23 June 2000 [1], as put into provisional application by Decision 2000/771/EC of the Representatives of the Governments of the Member States of 18 September 2000 [2], and in particular Article 3 thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) By Council Decision 2002/148/EC [3], the consultations with the Republic of Zimbabwe pursuant to Article 96(2)(c) of the ACP-EC Partnership Agreement were closed and appropriate measures, as specified in the Annex to that Decision, were taken.

(2) By Decision 2003/112/EC, the application of the measures referred to in Article 2 of Decision 2002/148/EC has been extended for a further period of 12 months. In accordance with Article 1 of Decision 2003/112/EC, the measures shall cease to apply on 20 February 2004.

(3) The essential elements cited in Article 9 of the ACP-EC Partnership Agreement continue to be violated by the Government of Zimbabwe and the current conditions in Zimbabwe do not ensure respect for human rights, democratic principles and the rule of law.

(4) The period of application of the measures should therefore be extended,

HAS DECIDED AS FOLLOWS:

Article 1

The application of the measures referred to in Article 2 of Decision 2002/148/EC, which were extended until 20 February 2004 by Article 1 of Decision 2003/112/EC, shall be extended for a further period of 12 months, until 20 February 2005. They shall be reviewed regularly and at least within six months.

The letter appearing in the Annex to this Decision shall be addressed to the President of Zimbabwe.

Article 2

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

Done at Brussels, 19 February 2004.

For the Council

The President

M. McDOWELL

[1] OJ L 317, 15.12.2000, p. 376.
[2] OJ L 317, 15.12.2000, p. 375.
[3] OJ L 50, 21.2.2002, p. 64. Decision amended by Decision 2003/112/EC (OJ L 46, 20.2.2003, p. 25).

ANNEX

Brussels, ... 19 -02- 2004

LETTER TO THE PRESIDENT OF ZIMBABWE

The European Union attaches the utmost importance to the provisions of Article 9 of the ACP-EC Partnership Agreement. As essential elements of the Partnership Agreement, respect for human rights, democratic institutions and the rule of law are the basis of our relations.

By letter of 19 February 2002, the European Union informed you of its decision to conclude the consultations held under Article 96 of the ACP-EC Partnership Agreement and to take certain 'appropriate measures' within the meaning of Article 96(2)(c) of that Agreement.

By letter of 19 February 2003, the European Union informed you of its decision not to revoke the application of the 'appropriate measures'.

Today, after a further 12-month period, the European Union considers that democratic principles are still not upheld in Zimbabwe and that no progress has been achieved by the Government of Zimbabwe in the five fields addressed by the 18 February 2002 Council Decision (end of politically motivated violence, free and fair elections, freedom of the media, independence of the judiciary, end of illegal farm occupations). Furthermore, the European Union notes that the Government of Zimbabwe has not taken any positive steps along the lines of the measures, considered as benchmarks to assess progress, which the European Union communicated to the SADC on the occasion of the last two SADC/EU Committee meetings.

In the light of the above, the European Union does not consider that the appropriate measures can be revoked.

The measures will only be revoked once conditions prevail which ensure respect for human rights, democratic principles and the rule of law. The European Union reserves the right to take additional restrictive measures.

The European Union will closely follow developments in Zimbabwe and would once again like to emphasise that these measures do not penalise the Zimbabwean people and will continue with its contribution to operations of a humanitarian nature and projects in direct support of the population, in particular those in social sectors, democratisation, respect for human rights and the rule of law, which are not affected by these measures. For the season 2003-2004 the European Community contribution to food and humanitarian aid operations in Zimbabwe has amounted to EUR 85 million in addition to bilateral assistance provided by the Member States of the European Union.

The European Union desires to pursue the dialogue with Zimbabwe, on the basis of the ACP-EC Partnership Agreement, and hopes that you will do everything you can to restore respect for the essential principles of the Partnership Agreement and to put the country on the path of social peace and economic recovery. This would permit the lifting of the suspension of the signing of the 9th EDF National Indicative Programme for Zimbabwe, thereby making possible the resumption of full cooperation instruments in the near future.

Yours faithfully,

For the Commission *For the Council*

COMMISSION

COMMISSION DECISION
of 16 February 2004
amending Decision 92/216/EEC as regards the publication of the list of coordinating authorities

(notified under document number C(2004) 390)

(Text with EEA relevance)

(2004/158/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/428/EEC of 26 June 1990 on trade in equidae intended for competitions and laying down the conditions for participation therein [1], and in particular Article 4(3) thereof,

Whereas:

(1) Under the rules adopted for implementing Article 4 of Directive 90/428/EEC each Member State should first designate a coordinating authority responsible for collecting the necessary data.

(2) Commission Decision 92/216/EEC of 26 March 1992 on the collection of data concerning competitions for equidae as referred to in Article 4(2) of Council Directive 90/428/EEC [2] provides for a publication of a list of such authorities in the Official Journal, C series.

(3) It appears more efficient for the information of interested public to publish this list on the website of the Commission.

(4) Decision 92/216/EEC should therefore be amended accordingly.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Zootechnics,

HAS ADOPTED THIS DECISION:

Article 1

The second paragraph of Article 1 of Decision 92/216/EEC is replaced by the following:

'2. Each Member State shall communicate to the Commission the name and address of the coordinating authority appointed in accordance with paragraph 1. On the basis of these communications, the Commission shall draw up a list of the coordinating authorities. This list will be published on the following website:

http://forum.europa.eu.int/Public/irc/sanco/vets/information'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 16 February 2004.

For the Commission
David BYRNE
Member of the Commission

[1] OJ L 224, 18.8.1990, p. 60.
[2] OJ L 104, 22.4.1992, p. 77.

COMMISSION DECISION

of 16 February 2004

amending for the second time Decision 2002/975/EC on introducing vaccinations to supplement the measures to control infections with low pathogenic avian influenza in Italy and on specific movement control measures

(notified under document number C(2004) 393)

(Text with EEA relevance)

(2004/159/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market ([1]), as last amended by Directive 2002/33/EC of the European Parliament and of the Council ([2]), and in particular Article 10(4) thereof,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market ([3]), as last amended by Regulation (EC) No 806/2003 ([4]), and in particular Article 9(4) thereof,

Having regard to Council Directive 92/40/EEC of 19 May 1992 introducing Community measures for the control of avian influenza ([5]), as last amended by Regulation (EC) No 806/2003 of 19 May 1992, and in particular Article 16 thereof,

Whereas:

(1) In October 2002, Italy reported to the Commission that infections of low pathogenic avian influenza of subtype H7N3 had occurred in the regions of Veneto and Lombardy and that the disease was spreading quickly.

(2) Subsequently, the Italian authorities took aggressive action including stamping out of infected flocks to control the propagation of the infection. As a supplementary measure the Italian authorities also requested approval for a vaccination programme against avian influenza for at least 18 months in order to avoid the further spread of infection.

(3) The vaccination programme was approved by Commission Decision 2002/975/EC ([6]), which laid down the rules concerning vaccination against avian influenza in an area described in the Annex. The Decision also includes specific control measures such as movement restrictions on live poultry, hatching and table eggs for intra-Community trade.

(4) Further experience suggests amending the approved vaccination programme in order to include possible vaccination of breeding poultry and to modify the vaccination schemes applied to different categories of poultry, in particular to layers. Restrictions on keeping certain categories of poultry above a defined age limit should be reviewed taking into account the favourable epidemiological evolution in the prevalence of avian influenza infections in those populations.

(5) Restrictions on intra-Community trade currently in place for products sourced from holdings located within a defined radius around a holding infected with low pathogenic avian influenza should be reviewed and lifted subject to certain precautionary measures being implemented.

(6) The 'discriminatory test' (iIFA test) approved by Commission Decision 2001/847/EC ([7]) for its use in turkeys has now been further developed and its application in other poultry species, in particular in chickens, should provide the necessary animal health guarantees for intra-Community trade in fresh meat derived from vaccinated chickens.

(7) The occurrence of avian influenza infections with virus of low pathogenicity has considerably decreased in the last few months; however it appears appropriate to prolong the vaccination programme for a further six months protecting the population against a re-introduction of the infection.

(8) Decision 2002/975/EC should be amended accordingly.

([1]) OJ L 224, 18.8.1990, p. 29.
([2]) OJ L 315, 19.11.2002, p. 14.
([3]) OJ L 395, 30.12.1989, p. 13.
([4]) OJ L 122, 16.5.2003, p. 1.
([5]) OJ L 167, 22.6.1992, p. 1.
([6]) OJ L 337, 13.12.2003, p. 87. Decision as amended by Decision 2003/436/EC (OJ L 149, 17.6.2003, p. 33).
([7]) OJ L 315, 1.12.2001, p. 61.

(9) Furthermore the opportunity should be taken to repeal Commission Decisions 2000/149/EC [1], 2003/153/EC [2], 2003/359/EC [3] and 2003/428/EC [4], taken in relation to outbreaks of highly pathogenic avian influenza that had occurred in Italy in 2000 and in the Netherlands and Belgium in 2003, and which are no longer applicable.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The amendments requested by Italy to the vaccination programme approved by Decision 2002/975/EC concerning in particular:

(a) the possibility of vaccinating breeding poultry;

(b) the modification of vaccination schemes for different categories of poultry according to their immune status, in particular in layers;

(c) the modification of the monitoring programme for poultry originating from the vaccination area;

(d) the use of an additional heterologous vaccine containing the strain A/ck/Italy/1067/1999/H7N1;

(e) the prolongation of the life span for certain categories of poultry; and

(f) the prolongation of the vaccination programme for six months (24 months in total),

are hereby approved.

Article 2

Decision 2002/975/EC is amended as follows:

1. Article 3(3) is deleted.

2. (a) In Article 5(1)(c) 'three kilometres' is replaced by 'one kilometre'.

   (b) In Article 5(2) and (3) 'and chickens' and 'and chicken' are inserted after the words 'turkeys' and 'turkey' respectively, and instead of 'turkey meat' it should read 'turkey and chicken meat'.

3. (a) In Annex II, first paragraph, 'and chickens' is inserted after the word 'turkeys'.

   (b) In Annex II, point 2 is replaced by the following:

   '2. **Use of the test for the purpose of dispatching fresh turkey and chicken meat from the vaccination area in Italy to other Member States**

   Meat originating from turkeys and chickens vaccinated against avian influenza may be dispatched to other Member States provided that, where all the birds are kept in one building, blood samples have been taken by the official veterinarian within seven days prior to slaughter from at least 10 vaccinated turkeys or chickens destined for slaughter. However, where the poultry are kept in more than one group or shed, at least 20 vaccinated birds selected randomly from all the groups or sheds on the farm shall be sampled.'

Article 3

Decisions 2000/149/EC, 2003/153/EC, 2003/359/EC and 2003/428/EC are repealed.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 16 February 2004.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 50, 23.2.2000, p. 22.
[2] OJ L 59, 4.3.2003, p. 32.
[3] OJ L 123, 17.5.2003, p. 59.
[4] OJ L 144, 12.6.2003, p. 15.

COMMISSION DECISION

of 16 February 2004

amending Decision 2003/71/EC as regards its period of validity

(notified under document number C(2004) 394)

(Text with EEA relevance)

(2004/160/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC ([1]), and in particular Article 18(7) thereof,

Having regard to Council Directive 97/78/EC of 18 December 1997 laying down the principles governing the organisation of veterinary checks on products entering the Community from third countries ([2]), and in particular Article 22(6) thereof,

Having regard to Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption ([3]), and in particular Article 8(4) thereof,

Whereas:

(1) The occurrence of infectious salmon anaemia (ISA) in the Faroe Islands led to the adoption of Commission Decision 2003/71/EC of 29 January 2003 on certain protective measures in respect of infectious salmon anaemia in the Faroe Islands ([4]).

(2) Despite the measures undertaken by the Faroe Islands, further outbreaks of ISA were notified by that State in 2003, and a rapid eradication of that disease cannot therefore be envisaged.

(3) In view of the disease situation in the Faroe Islands, the protective measures contained in Decision 2003/71/EC should remain applicable until February 2005.

(4) Decision 2003/71/EC should therefore be amended in order to extend its period of validity.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

In Article 6 of Decision 2003/71/EC, '1 February 2004' is replaced by '31 January 2005'.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 16 February 2004.

For the Commission

David BYRNE

Member of the Commission

([1]) OJ L 268, 24.9.1991, p. 56. Directive as amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).
([2]) OJ L 24, 30.1.1998, p. 9.
([3]) OJ L 18, 21.1.2003, p. 11.
([4]) OJ L 26, 31.1.2003, p. 80. Decision as amended by Decision 2003/392/EC (OJ L 135, 3.6.2003, p. 27).

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

COUNCIL COMMON POSITION 2004/161/CFSP
of 19 February 2004
renewing restrictive measures against Zimbabwe

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on European Union, and in particular Article 15 thereof,

Whereas:

(1) Pursuant to Common Position 2002/145/CFSP [1] the Council imposed a prohibition on the supply of arms and related materiel, on the provision of related technical training or assistance and on the supply of equipment that might be used for internal repression to Zimbabwe.

(2) Pursuant to Common Position 2002/145/CFSP the Council also imposed a travel ban and a freezing of funds on the Government of Zimbabwe and persons who bear a wide responsibility for serious violations of human rights and of the freedom of opinion, of association and of peaceful assembly.

(3) Common Position 2002/145/CFSP was amended by Common Position 2002/600/CFSP [2] by extending these restrictive measures to further persons who bear a wide responsibility for such violations.

(4) The list of persons subject to the restrictive measures annexed to Common Position 2002/145/CFSP was updated and replaced by Council Decision 2002/754/CFSP [3] following a government reshuffle in Zimbabwe.

(5) Common Position 2002/145/CFSP was further amended and extended by Common Position 2003/115/CFSP [4], which expires on 20 February 2004.

(6) In view of the continued deterioration in the human rights situation in Zimbabwe, the restrictive measures adopted by the European Union should be renewed for a further 12 months.

(7) The objective of these restrictive measures is to encourage the persons targeted to reject policies that lead to the suppression of human rights, of the freedom of expression and of good governance.

(8) The list of persons subject to restrictive measures annexed to Common Position 2002/145/CFSP, as amended and replaced, should be updated.

(9) Action by the Community is needed in order to implement certain measures,

HAS ADOPTED THIS COMMON POSITION:

Article 1

For the purposes of this Common Position, the term 'technical assistance' shall mean any technical support related to repairs, development, manufacture, assembly, testing, maintenance or any other technical service, and may take forms such as instruction, advice, training, transmission of working knowledge or skills or consulting services; technical assistance includes verbal forms of assistance.

Article 2

1. The sale, supply, transfer or export of arms and related materiel of all types, including weapons and ammunition, military vehicles and equipment, paramilitary equipment and spare parts for the aforementioned, as well as equipment which might be used for internal repression, to Zimbabwe by nationals of Member States or from the territories of Member States or using their flag vessels or aircraft shall be prohibited whether originating or not in their territories.

2. It shall be prohibited:

(a) to grant, sell, supply or transfer technical assistance, brokering services and other services related to military activities and to the provision, manufacture, maintenance and use of arms and related materiel of all types, including weapons and ammunition, military vehicles and equipment, paramilitary equipment and spare parts for the aforementioned, as well as equipment which might be used for internal repression, directly or indirectly to any person, entity or body in or for use in Zimbabwe;

[1] OJ L 50, 21.2.2002, p. 1.
[2] OJ L 195, 24.7.2002, p. 1.
[3] OJ L 247, 14.9.2002, p. 56.
[4] OJ L 46, 20.2.2003, p. 30.

(b) to provide financing or financial assistance related to military activities, including, in particular, grants, loans and export credit insurance, for any sale, supply, transfer or export of arms and related materiel, as well as equipment which might be used for internal repression, directly or indirectly to any person, entity or body in or for use in Zimbabwe.

Article 3

1. Article 2 shall not apply to:

(a) the sale, supply, transfer or export of non-lethal military equipment or of equipment which might be used for internal repression, intended solely for humanitarian or protective use, or for institution-building programmes of the UN, the EU and the Community, or of materiel intended for EU and UN crisis-management operations;

(b) the provision of financing and financial assistance related to such equipment;

(c) the provision of technical assistance related to such equipment,

on condition that such exports have been approved in advance by the relevant competent authority.

2. Article 2 shall not apply to protective clothing, including flak jackets and military helmets, temporarily exported to Zimbabwe by United Nations personnel, personnel of the EU, the Community or its Member States, representatives of the media and humanitarian and development workers and associated personnel for their personal use only.

Article 4

1. Member States shall take the necessary measures to prevent the entry into, or transit through, their territories of the natural persons listed in the Annex, who are engaged in activities that seriously undermine democracy, respect for human rights and the rule of law in Zimbabwe.

2. Paragraph 1 will not oblige a Member State to refuse its own nationals entry into its territory.

3. Paragraph 1 shall be without prejudice to the cases where a Member State is bound by an obligation of international law, namely:

(a) as a host country of an international intergovernmental organisation;

(b) as a host country to an international conference convened by, or under the auspices of, the United Nations; or

(c) under a multilateral agreement conferring privileges and immunities.

The Council shall be duly informed in each of these cases.

4. Paragraph 3 shall be considered as applying also in cases where a Member State is host country of the Organisation for Security and Cooperation in Europe (OSCE).

5. Member States may grant exemptions from the measures imposed in paragraph 1 where travel is justified on the grounds of urgent humanitarian need, or on grounds of attending intergovernmental meetings, including those promoted by the European Union, where a political dialogue is conducted that directly promotes democracy, human rights and the rule of law in Zimbabwe.

6. A Member State wishing to grant exemptions referred to in paragraph 5 shall notify the Council in writing. The exemption will be deemed to be granted unless one or more of the Council Members raises an objection in writing within 48 hours of receiving notification of the proposed exemption. In the event that one or more of the Council members raises an objection, the Council, acting by a qualified majority, may decide to grant the proposed exemption.

7. In cases where, pursuant to paragraphs 3, 4, 5 and 6, a Member State authorises the entry into, or transit through, its territory of persons listed in the Annex, the authorisation shall be limited to the purpose for which it is given and to the persons concerned thereby.

Article 5

1. All funds and economic resources belonging to individual members of the Government of Zimbabwe and to any natural or legal persons, entities or bodies associated with them as listed in the Annex shall be frozen.

2. No funds or economic resources shall be made available directly or indirectly to or for the benefit of natural or legal persons, entities or bodies listed in the Annex.

3. Exemptions may be made for funds or economic resources which are:

(a) necessary for basic expenses, including payments for foodstuffs, rent or mortgage, medicines and medical treatment, taxes, insurance premiums and public utility charges;

(b) intended exclusively for payment of reasonable professional fees and reimbursement of incurred expenses associated with the provision of legal services;

(c) intended exclusively for payment of fees or service charges for routine holding or maintenance of frozen funds or economic resources;

(d) necessary for extraordinary expenses.

4. Paragraph 2 shall not apply to the addition to frozen accounts of:

(a) interest or other earnings on those accounts; or

(b) payments due under contracts, agreements or obligations that were concluded or arose prior to the date on which those accounts became subject to restrictive measures,

provided that any such interest, other earnings and payments continue to be subject to paragraph 1.

Article 6

The Council, acting upon a proposal by a Member State or the Commission, shall adopt modifications of the list contained in the Annex as required by political developments in Zimbabwe.

Article 7

In order to maximise the impact of the abovementioned measures, the European Union shall encourage third States to adopt restrictive measures similar to those contained in this Common Position.

Article 8

This Common Position shall take effect on the date of its adoption.

It shall apply as from 21 February 2004.

Article 9

This Common Position shall apply for a 12-month period. It shall be kept under constant review. It shall be renewed, or amended as appropriate, if the Council deems that its objectives have not been met.

Article 10

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

Done at Brussels, 19 February 2004.

For the Council

The President

M. McDOWELL

ANNEX

List of persons referred to in Articles 4 and 5

1. Mugabe, Robert Gabriel	President, born 21.2.1924
2. Buka (a.k.a. Bhuka), Flora	Minister of State in Vice-President's Office (former Minister of State for the Land Reform Programme in the President's Office), born 25.2.1968
3. Bonyongwe, Happyton	Director-General Central Intelligence Organisation, born 6.11.1960
4. Chapfika, David	Deputy Minister of Finance and Economic Development
5. Charamba, George	Permanent Secretary Department for Information and Publicity, born 4.4.1963
6. Charumbira, Fortune Zefanaya	Deputy Minister for Local Government, Public Works and National Housing, born 10.6.1962
7. Chigwedere, Aeneas Soko	Minister of Education, Sports and Culture, born 25.11.1939
8. Chihuri, Augustine	Police Commissioner, born 10.3.1953
9. Chikowore, Enos C.	ZANU (PF) Politburo Secretary for Land and Resettlement, born 1936
10. Chinamasa, Patrick Anthony	Minister of Justice, Legal and Parliamentary Affairs, born 25.1.1947
11. Chindori-Chininga, Edward Takaruza	former Minister of Mines and Mining Development, born 14.3.1955
12. Chipanga, Tongesai Shadreck	Deputy Minister of Home Affairs
13. Chiwenga, Constantine	Commander Zimbabwe Defence Forces, General (former Army Commander, Lieutenant General), born 25.8.1956
14. Chiwewe, Willard	Senior Secretary responsible for Special Affairs in the President's Office (former Senior Secretary, Ministry of Foreign Affairs), born 19.3.1949
15. Chombo, Ignatius Morgan Chiminya	Minister of Local Government, Public Works and National Housing, born 1.8.1952
16. Dabengwa, Dumiso	ZANU (PF) Politburo Senior Committee Member, born 1939
17. Goche, Nicholas Tasunungurwa	Minister of State for National Security in the President's Office (former Security Minister), born 1.8.1946
18. Gula-Ndebele, Sobuza	Chairman of Electoral Supervisory Commission
19. Gumbo, Rugare Eleck Ngidi	Minister of State for State Enterprises and Parastatals in the President's Office (former Deputy Minister of Home Affairs, born 8.3.1940
20. Hove, Richard	ZANU (PF) Politburo Secretary for Economic Affairs, born 1935
21. Hungwe, Josaya (a.k.a. Josiah) Dunira	Provincial Governor: Masvingo, born 7.11.1935
22. Kangai, Kumbirai	ZANU (PF) Politburo Committee Member, born 17.2.1938
23. Karimanzira, David Ishemunyoro Godi	ZANU (PF) Politburo Secretary for Finance, born 25.5.1947
24. Kasukuwere, Saviour	ZANU (PF) Politburo Deputy-Secretary for Youth Affairs, born 23.10.1970

25. Kuruneri, Christopher Tichaona	Minister of Finance and Economic Development (former Deputy Minister of Finance and Economic Development), born 4.4.1949
26. Langa, Andrew	Deputy Minister of Transport and Communications
27. Lesabe, Thenjiwe V.	ZANU (PF) Politburo Secretary for Women's Affairs, born 1933
28. Machaya, Jason (a.k.a. Jaison) Max Kokerai	Deputy Minister of Mines and Mining Development, born 13.6.1952
29. Made, Joseph Mtakwese	Minister of Agriculture and Rural Development (former Minister of Lands, Agricultural and Rural Resettlement), born 21.11.1954
30. Madzongwe, Edna (a.k.a. Edina)	ZANU (PF) Politburo Deputy Secretary for Production and Labour, born 11.7.1943
31. Mahofa, Shuvai Ben	Deputy Minister for Youth Development, Gender and Employment Creation, born 4.4.1941
32. Mahoso, Tafataona	Chair, Media Information Commission
33. Makoni, Simbarashe	ZANU (PF) Politburo Deputy Secretary General for Economic Affairs (former Minister of Finance), born 22.3.1950
34. Malinga, Joshua	ZANU (PF) Politburo Deputy Secretary for Disabled and Disadvantaged, born 28.4.1944
35. Mangwana, Paul Munyaradzi	Minister of Public Service, Labour and Social Welfare (former Minister of State for State Enterprises and Parastatals in the President's Office), born 10.8.1961
36. Mangwende, Witness Pasichigare Madunda	Provincial Governor: Harare (former Minister for Transport and Communications), born 15.10.1946
37. Manyika, Elliot Tapfumanei	Minister without Portfolio (former Minister of Youth Development, Gender and Employment Creation), born 30.7.1955
38. Manyonda, Kenneth Vhundukai	Deputy Minister of Industry and International Trade, born 10.8.1934
39. Marumahoko, Rueben	Deputy Minister of Energy and Power Development, born 4.4.1948
40. Masawi, Ephrahim Sango	Provincial Governor: Mashonaland Central
41. Masuku, Angeline	Provincial Governor: Matabeleland South (ZANU (PF) Politburo Secretary for Disabled and Disadvantaged), born 14.10.1936
42. Mathema, Cain	Provincial Governor: Bulawayo
43. Mathuthu, T.	ZANU (PF) Politburo Deputy Secretary for Transport and Social Welfare
44. Midzi, Amos Bernard (Mugenva)	Minister of Mines and Mining Development (former Minister of Energy and Power Development), born 4.7.1952
45. Mnangagwa, Emmerson Dambudzo	Speaker of Parliament, born 15.9.1946
46. Mohadi, Kembo Campbell Dugishi	Minister of Home Affairs (former Deputy Minister of Local Government, Public Works and National Housing), born 15.11.1949
47. Moyo, Jonathan	Minister of State for Information and Publicity in the President's Office, born 12.1.1957
48. Moyo, July Gabarari	Minister of Energy and Power Development (former Minister of Public Service, Labour and Social Welfare), born 7.5.1950
49. Moyo, Simon Khaya	ZANU (PF) Politburo Deputy Secretary for Legal Affairs, born 1945

50. Mpofu, Obert Moses	Provincial Governor: Matabeleland North (ZANU (PF) Politburo Deputy Secretary for National Security), born 12.10.1951
51. Msika, Joseph W.	Vice-President, born 6.12.1923
52. Msipa, Cephas George	Provincial Governor: Midlands, born 7.7.1931
53. Muchena, Olivia Nyembesi (a.k.a. Nyembezi)	Minister of State for Science and Technology in the President's Office (former Minister of State in Vice-President Msika's Office), born 18.8.1946
54. Muchinguri, Oppah Chamu Zvipange	ZANU (PF) Politburo Secretary for Gender and Culture, born 14.12.1958
55. Mudede, Tobaiwa (Tonneth)	Registrar General, born 22.12.1942
56. Mudenge, Isack Stanilaus Gorerazvo	Minister of Foreign Affairs, born 17.12.1941
57. Mugabe, Grace	Spouse of Robert Gabriel Mugabe, born 23.7.1965
58. Mugabe, Sabina	ZANU (PF) Politburo Senior Committee Member, born 14.10.1934
59. Mujuru, Joyce Teurai Ropa	Minister of Water Resources and Infrastructural Development (former Minister of Rural Resources and Water Development), born 15.4.1955
60. Mujuru, Solomon T.R.	ZANU (PF) Politburo Senior Committee Member, born 1.5.1949
61. Mumbengegwi, Samuel Creighton	Minister of Industry and International Trade (former Minister of Higher Education and Technology), born 23.10.1942
62. Murerwa, Herbert Muchemwa	Minister of Higher and Tertiary Education (former Minister of Finance and Economic Development), born 31.7.1941
63. Mushohwe, Christopher Chindoti	Minister of Transport and Communications (former Deputy Minister of Transport and Communications, born 6.2.1954
64. Mutasa, Didymus Noel Edwin	Minister of Special Affiars in the President's Office in charge of the Anti-Corruption and Anti-Monopolies Programme (former ZANU (PF) Politburo Secretary for External Relations), born 27.7.1935
65. Mutinhiri, Ambros (a.k.a. Ambrose)	Minister of Youth Development, Gender and Employment Creation, Retired Brigadier
66. Mutiwekuziva, Kenneth Kaparadza	Deputy Minister of Small and Medium Enterprises Development, born 27.5.1948
67. Muzenda, Tsitsi V.	ZANU (PF) Politburo Senior Committee Member, born 28.10.1922
68. Muzonzini, Elisha	Brigadier (former Director-General Central Intelligence Organisation), born 24.6.1957
69. Ncube, Abedinico	Deputy Minister of Foreign Affairs, born 13.10.1954
70. Ndlovu, Naison K.	ZANU (PF) Politburo Secretary for Production and Labour, born 22.10.1930
71. Ndlovu, Sikhanyiso	ZANU (PF) Politburo Deputy Secretary for Commissariat, born 20.9.1949
72. Nhema, Francis	Minister of Environment and Tourism, born 17.4.1959
73. Nkomo, John Landa	Minister of Special Affairs in the President's Office
74. Nyambuya, Michael Reuben	Lieutenant General, Provincial Governor: Manicaland
75. Nyoni, Sithembiso Gile Glad	Minister of Small and Medium Enterprises Development (former Minister of State for the Informal Sector), born 20.9.1949

76. Parirenyatwa, David Pagwese	Minister of Health and Child Welfare (former Deputy Minister), born 2.8.1950
77. Pote, Selina M.	ZANU (PF) Politburo Deputy Secretary for Gender and Culture
78. Rusere, Tinos	Deputy Minister for Water Resources and Infrastructural Development (former Deputy Minister of Rural Resources and Water Development), born 10.5.1945
79. Sakupwanya, Stanley	ZANU (PF) Politburo Deputy Secretary for Health and Child Welfare
80. Samkange, Nelson Tapera Crispen	Provincial Governor: Mashonaland West
81. Sekeramayi, Sydney (a.k.a. Sidney) Tigere	Minister of Defence, born 30.3.1944
82. Shamu,Webster	Minister of State for Policy Implementation in the President's Office, born 6.6.1945
83. Shamuyarira, Nathan Marwirakuwa	ZANU (PF) Politburo Secretary for Information and Publicity, born 29.9.1928
84. Shiri, Perence	Air Marshal (Air Force), born 1.11.1955
85. Shumba, Isaiah Masvayamwando	Deputy Minister of Education, Sports and Culture, born 3.1.1949
86. Sibanda, Jabulani	Chair, National War Veterans Association, born 31.12.1970
87. Sibanda, Misheck Julius Mpande	Cabinet Secretary (successor to No. 93 Charles Utete), born 3.5.1949
88. Sibanda, Phillip Valerio (a.k.a. Valentine)	Commander Zimbabwe National Army, Lieutenant General, born 25.8.1956
89. Sikosana, Absolom	ZANU (PF) Politburo Secretary for Youth Affairs
90. Stamps, Timothy	Health Advisor in the Office of the President, born 15.10.1936
91. Tawengwa, Solomon Chirume	ZANU (PF) Politburo Deputy Secretary for Finance, born 15.6.1940
92. Tungamirai, Josiah T.	Minister of State for Indigenisation and Empowerment, Retired Air Marshall (former ZANU (PF) Politburo Secretary for Empowerment and Indigenisation), born 8.10.1948
93. Utete, Charles	Chairman of the Presidential Land Review Committee (former Cabinet Secretary), born 30.10.1938
94. Zimonte, Paradzai	Prisons Director, born 4.3.1947
95. Zvinavashe, Vitalis	Retired General (former Chief of Defense Staff), born 27.9.1943

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 276/2004 of 17 February 2004 on periodical sales by tender of beef held by certain intervention agencies

(Official Journal of the European Union L 47 of 18 February 2004)

On page 18, Annex I is replaced by the following:

'ANEXO I — BILAG I — ANHANG I — ΠΑΡΑΡΤΗΜΑ I — ANNEX I — ANNEXE I — ALLEGATO I — BIJLAGE I — ANEXO I — LIITE I — BILAGA I

Estado miembro	Productos (1)	Cantidad aproximada (toneladas)
Medlemsstat	Produkter (1)	Tilnærmet mængde (tons)
Mitgliedstaat	Erzeugnisse (1)	Ungefähre Mengen (Tonnen)
Κράτος μέλος	Προϊόντα (1)	Κατά προσέγγιση ποσότητα (τόνοι)
Member State	Products (1)	Approximate quantity (tonnes)
État membre	Produits (1)	Quantité approximative (tonnes)
Stato membro	Prodotti (1)	Quantità approssimativa (tonnellate)
Lidstaat	Producten (1)	Hoeveelheid bij benadering (ton)
Estado-Membro	Produtos (1)	Quantidade aproximada (toneladas)
Jäsenvaltio	Tuotteet (1)	Arvioitu määrä (tonneina)
Medlemsstat	Produkter (1)	Ungefärlig kvantitet (ton)

a) **Carne con hueso — Kød, ikke udbenet — Fleisch mit Knochen — Εμπρόσθια τέταρτα με κόκαλα — Bone-in Beef — Viande avec os — Carni non disossate — Vlees met been — Carne com osso — Luullinen naudanliha — Kött med ben**

FRANCE	— Quartiers arrière	1,579 (2)
	— Quartiers avant	5,000 (2)
ITALIA	— Quarti posteriori	4,5 (3)
	— Quarti anteriori	8,2 (3)

b) **Carne deshuesada — Udbenet kød — Fleisch ohne Knochen — Κρέατα χωρίς κόκαλα — Boneless beef — Viande désossée — Carni senza osso — Vlees zonder been — Carne desossada — Luuton naudanliha — Benfritt kött**

FRANCE	— Jarret arrière d'intervention (INT 11)	0,527 (4)
	— Tranche grasse d'intervention (INT 12)	0,759 (4)
	— Tranche d'intervention (INT 13)	0,225 (4)
	— Semelle d'intervention (INT 14)	1,023 (4)
	— Rumsteck d'intervention (INT 16)	12,664 (4)
	— Faux-filet d'intervention (INT 17)	1,547 (4)
	— Flanchet d'intervention (INT 18)	0,575 (4)
	— Jarret avant d'intervention (INT 21)	0,476 (4)
	— Épaule d'intervention (INT 22)	0,016 (4)
	— Poitrine d'intervention (INT 23)	0,035 (4)

(1) Véanse los anexos III y V del Reglamento (CE) nº 562/2000.
(1) Se bilag III og V til forordning (EF) nr. 562/2000.
(1) Vgl. Anhänge III und V der Verordnung (EG) Nr. 562/2000.
(1) Βλέπε παραρτήματα III και V του κανονισμού (ΕΚ) αριθ. 562/2000.
(1) See Annexes III and V to Regulation (EC) No 562/2000.
(1) Voir annexes III et V du règlement (CE) nº 562/2000.
(1) Cfr. allegati III e V del regolamento (CE) n. 562/2000.
(1) Zie de bijlagen III en V van Verordening (EG) nr. 562/2000.
(1) Ver anexos III e V do Regulamento (CE) n.º 562/2000.
(1) Katso asetuksen (EY) N:o 562/2000 liitteet III ja V.
(1) Se bilagorna III och V i förordning (EG) nr 562/2000.
(2) Para ser vendido en un lote — Sælges samlet som én mængde — Zu verkaufen in einer Menge — Προς πώληση σαν μία παρτίδα — To be sold as one lot — À vendre dans un lot — Da vendersi in un unico lotto — Te verkopen als één partij — Para ser vendido em um lote — Myytävä yhtenä eränä — Säljs tillsammans som en enhet.
(3) Para ser vendido en un lote — Sælges samlet som én mængde — Zu verkaufen in einer Menge — Προς πώληση σαν μία παρτίδα — To be sold as one lot — À vendre dans un lot — Da vendersi in un unico lotto — Te verkopen als één partij — Para ser vendido em um lote — Myytävä yhtenä eränä — Säljs tillsammans som en enhet.
(4) Para ser vendido en un lote — Sælges samlet som én mængde — Zu verkaufen in einer Menge — Προς πώληση σαν μία παρτίδα — To be sold as one lot — À vendre dans un lot — Da vendersi in un unico lotto — Te verkopen als één partij — Para ser vendido em um lote — Myytävä yhtenä eränä — Säljs tillsammans som en enhet."