

Official Journal

of the European Communities

ISSN 0378-6978

L 131

Volume 45

16 May 2002

English edition

Legislation

Contents

I Acts whose publication is obligatory

Commission Regulation (EC) No 799/2002 of 15 May 2002 establishing the standard import values for determining the entry price of certain fruit and vegetables	1
★ Commission Regulation (EC) No 800/2002 of 14 May 2002 amending Regulation (EEC) No 1686/72 on certain detailed rules for aid for seed as regards the stabiliser mechanism	3
Commission Regulation (EC) No 801/2002 of 15 May 2002 concerning applications for export licences for rice and broken rice with advance fixing of the refund	6
Commission Regulation (EC) No 802/2002 of 15 May 2002 fixing the import duties in the cereals sector	7
Commission Regulation (EC) No 803/2002 of 15 May 2002 fixing the export refunds on olive oil	10

II Acts whose publication is not obligatory

Council

2002/361/EC:

- ★ **Council Decision of 3 May 2002 on the granting of a national aid by the authorities of the Kingdom of the Netherlands in favour of road transport undertakings ...** 12

2002/362/EC:

- ★ **Council Decision of 3 May 2002 on the granting of a national aid by the authorities of the Italian Republic in favour of road transport undertakings** 14

- ★ **Council Decision of 3 May 2002 on the granting of aid by the French Government for road transport undertakings** 15

Commission

- ★ **Commission Decision of 7 May 2002 on common technical specifications for *in vitro*-diagnostic medical devices** ⁽¹⁾ (*notified under document number C(2002) 1344*) 17

Corrigenda

- ★ **Corrigendum to Regulation (EC) No 690/2002 of the European Central Bank of 18 April 2002 amending Regulation (EC) No 2818/98 (ECB/1998/15) on the application of minimum reserves (ECB/2002/3) (OJ L 106 of 23.4.2002)** 31
- ★ **Corrigendum to Commission Decision 2002/325/EC of 31 May 2001 approving the single programming document for Community structural assistance under Objective 2 in the Kustgebied-Westhoek in the province of West Flanders in Belgium (OJ L 122 of 8.5.2002)** 31

I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 799/2002
of 15 May 2002
establishing the standard import values for determining the entry price of certain fruit and
vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables ⁽¹⁾, as last amended by Regulation (EC) No 1498/98 ⁽²⁾, and in particular Article 4(1) thereof,

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 16 May 2002.

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

Done at Brussels, 15 May 2002.

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

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 15 May 2002 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	69,0
	204	26,6
	212	101,5
	999	65,7
0707 00 05	052	101,8
	220	149,6
	628	155,5
	999	135,6
0709 90 70	052	88,3
	999	88,3
0805 10 10, 0805 10 30, 0805 10 50	052	71,0
	204	46,3
	212	64,5
	220	62,4
	388	91,2
	600	63,8
	624	79,7
	999	68,4
0805 50 10	388	67,1
	999	67,1
0808 10 20, 0808 10 50, 0808 10 90	060	29,0
	388	93,9
	400	113,7
	404	108,1
	508	71,3
	512	91,9
	524	74,5
	528	82,6
	720	95,1
	804	98,4
	999	85,9

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

COMMISSION REGULATION (EC) No 800/2002**of 14 May 2002****amending Regulation (EEC) No 1686/72 on certain detailed rules for aid for seed as regards the stabiliser mechanism**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2358/71 of 26 October 1971 on the common organisation of the market in seeds ⁽¹⁾, as last amended by Regulation (EC) No 154/2002 ⁽²⁾, and in particular Article 3(4a) thereof,

Whereas:

- (1) Regulation (EEC) No 2358/71 establishes a stabiliser mechanism for seed other than rice seed which lays down a maximum quantity eligible for aid, the principle of allocating this maximum quantity among the Member States and the consequences to be applied, in terms of reducing the aid, in the event of an overrun on the maximum quantity.
- (2) The maximum quantity of seed other than rice seed eligible for aid in the Community, and the quantities for each Member State, should be laid down. The maximum quantity for each Member State is equal to the average of the quantities harvested during the reference period laid down in Regulation (EEC) No 2358/71. The quantities taken into account are those communicated to the Commission on the basis of point 6 of the Annex to Commission Regulation (EEC) No 3083/73 of 14 November 1973 on the communication of the information necessary for implementing Council Regulation (EEC) No 2358/71 on the common organisation of the market in seeds ⁽³⁾, as last amended by Regulation (EEC) No 1679/92 ⁽⁴⁾.
- (3) The different species of seed benefit from different amounts of aid. In order to make them equivalent in budget terms, a coefficient of equivalence must be fixed for each species, based on the relation between the amount of aid for each species and the average amount of aid. The average amount of aid is determined on the basis of the expenditure theoretically engendered by the quantities of seed constituting the maximum guaranteed quantity. The maximum quantity for the Community and the national quantities are expressed in equivalent quantities.
- (4) For the operation of the stabiliser mechanism, a deadline must be set for notification by the Member States to the Commission of the quantities of seed covered by aid

applications to allow the calculation of any reduction coefficients applicable in each Member State.

- (5) In Member States which have overrun their allocated national quantity, the payment of aid may be carried out only once the Commission has fixed any reduction coefficients which may be applicable for each of the Member States concerned. A deadline must therefore be laid down for fixing these coefficients.
- (6) To ensure that the stabiliser mechanism is applied only to the extent of the overrun on the maximum quantity for the Community, and to avoid any incitement to over-production, any quantities unused by certain Member States should be reallocated among Member States who have overrun their national quantity, in proportion to their national quantity, and the reduction coefficients for the aid should subsequently be calculated for each Member State concerned, in proportion to the overrun on the national quantity fixed.
- (7) The Commission fixes the reduction coefficients applicable to each Member State concerned. The method by which the Member States must calculate the aid applicable to each species should therefore be laid down.
- (8) To allow the Member States to take account of the specific nature of the structure of national production, and in particular of small production sectors, provision should be made for Member States to have the option of breaking down their national quantity among families or species of seeds.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Seeds,

HAS ADOPTED THIS REGULATION:

Article 1

Commission Regulation (EEC) No 1686/72 ⁽⁵⁾ is amended as follows:

1. Article 3 is replaced by the following:

'Article 3

1. From 1 July 2002, for seed other than rice seed, a maximum quantity of 305 754 tonnes per year is set on which aid may be granted in the Community, allocated to producer Member States as follows:

⁽¹⁾ OJ L 246, 5.11.1971, p. 1.

⁽²⁾ OJ L 25, 29.1.2002, p. 18.

⁽³⁾ OJ L 314, 15.11.1973, p. 20.

⁽⁴⁾ OJ L 176, 30.6.1992, p. 17.

⁽⁵⁾ OJ L 177, 4.8.1972, p. 26.

Belgium:	10 077 tonnes
Denmark:	93 697 tonnes
Germany:	31 654 tonnes
Greece:	3 846 tonnes
Spain:	23 976 tonnes
France:	52 981 tonnes
Ireland:	1 016 tonnes
Italy:	18 822 tonnes
Luxembourg:	865 tonnes
Netherlands:	35 856 tonnes
Austria:	769 tonnes
Portugal:	769 tonnes
Sweden:	8 132 tonnes
Finland:	5 853 tonnes
United Kingdom:	17 910 tonnes.

These quantities shall be expressed in equivalent quantities in accordance with paragraph 2.

2. The conversion into equivalent quantities of the quantities for which an aid application has been submitted shall be made by multiplying the quantity relating to each species by its coefficient of equivalence, laid down in the Annex to this Regulation.

3. Aid shall be granted to the seed grower in response to an application to be submitted after the harvest and before a date fixed by the Member State in question for each species or group of varieties.

4. Without prejudice to paragraph 5, the Member State shall pay the aid to the seed grower within two months of the application being lodged and at the latest by 31 July of the year following that of harvest.

By 15 August of the year following the harvest producer Member States shall notify to the Commission the quantities for which aid applications have been made.

5. Where, under the fourth subparagraph of Article 3(4a) of Regulation (EEC) No 2358/71, an overrun of the maximum quantity is found for a specific harvest, if the

information provided for in the second subparagraph of paragraph 4 has been received, the Commission shall fix the reduction coefficients for the aid applicable for each Member State concerned by 30 September for the marketing year following the overrun.

The reduction coefficients for the aid shall be established in proportion to the overrun on the national quantity laid down in paragraph 1.

Should the Commission find that the national quantity laid down in paragraph 1 has not been fully used by a particular Member State, the unused quantity shall be reallocated, for the same marketing year, among the Member States that have overrun their own national quantity. The Commission shall reallocate this amount on a pro rata basis in relation to the national quantities for these Member States.

6. The amount of reduced aid applicable for each species shall be calculated by the Member State by multiplying the amount of aid by the reduction coefficient obtained pursuant to paragraph 5.

7. The Member States may establish, before the start of the marketing year, at national level, a production profile, by allocating their national quantity among the various seed species and/or families of species.

Member States who intend to avail themselves of the option provided for in the above subparagraph shall inform the Commission thereof and shall notify it in good time of the measures planned at national level. These measures must be consistent with Article 3(4a) of Regulation (EEC) No 2358/71 and with paragraphs 5 and 6, in particular as regards the budget impact of the payment of the aid.'

2. The Annex to this Regulation is inserted as Annex I.

Article 2

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

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

Done at Brussels, 14 May 2002.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

ANNEX I

Product	Coefficient of equivalence
1. CEREALS (other than rice)	
<i>Triticum spelta</i> L.	0,45
2. OILSEEDS	
<i>Linum usitatiss.</i> (fibre flax)	0,89
<i>Linum usitatiss.</i> (linseed)	0,70
<i>Cannabis sativa</i> L.	0,64
3. GRAMINAE	
<i>Agrostis canina</i> L.	2,38
<i>Agrostis capillaris</i> L.	2,38
<i>Agrostis gigantea</i> Roth.	2,38
<i>Agrostis stolonifera</i> L.	2,38
<i>Arrhenatherum elatius</i> L.	2,10
<i>Dactylis glomerata</i> L.	1,65
<i>Festuca arundinaceae</i> Schreb.	1,84
<i>Festuca ovina</i> L.	1,36
<i>Festuca pratensis</i> Huds.	1,36
<i>Festuca rubra</i> L.	1,15
<i>Festulolium</i>	1,01
<i>Lolium multiflorum</i> Lam.	0,66
<i>Lolium perenne</i> L.	0,97
<i>Lolium x boucheanum</i>	0,66
<i>Phleum bertolonii</i> (DC)	1,60
<i>Phleum pratense</i> L.	2,62
<i>Poa nemoralis</i> L.	1,22
<i>Poa pratensis</i> L.	1,21
<i>Poa trivialis</i> L.	1,22
4. LEGUMINOUS PLANTS	
<i>Hedysarium coronarium</i> L.	1,14
<i>Medicago lupulina</i> L.	1,00
<i>Medicago sativa</i> L. (ecotypes)	0,69
<i>Medicago sativa</i> L. (varieties)	1,15
<i>Onobrichis viciifolia</i> SC	0,63
<i>Pisum sativum</i> L. partim.	—
<i>Trifolium alexandrinum</i> L.	1,43
<i>Trifolium hybridum</i> L.	1,44
<i>Trifolium incarnatum</i> L.	1,43
<i>Trifolium pratense</i> L.	1,67
<i>Trifolium repens</i> L.	2,35
<i>Trifolium repens</i> L. gigante	2,22
<i>Trifolium resupinatum</i> L.	1,43
<i>Vicia faba</i> L. partim.	—
<i>Vicia sativa</i> L.	0,96
<i>Vicia villosa</i> Roth.	0,75'

COMMISSION REGULATION (EC) No 801/2002**of 15 May 2002****concerning applications for export licences for rice and broken rice with advance fixing of the refund**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Having regard to Commission Regulation (EC) No 1162/95 of 23 May 1995, laying down special detailed rules for the application of the system of import and export licences for cereals and rice ⁽³⁾, as last amended by Regulation (EC) No 2298/2001 ⁽⁴⁾, and in particular the second subparagraph of Article 7(4) thereof,

Whereas:

- (1) Article 7(4) of Regulation (EC) No 1162/95 provides, where this paragraph is specifically referred to when an export refund is fixed, for an interval of three working days between the day of submission of applications and the granting of export licences with advance fixing of the refund and provides that the Commission is to fix a uniform percentage reduction in the quantities if applications for export licences exceed the quantities which may be exported. Commission Regulation (EC) No 718/2002 ⁽⁵⁾ fixes refunds under the procedure provided for in the abovementioned paragraph for 5 000 tonnes.

- (2) The quantities applied for on 14 May 2002 are in excess of the available quantity, a percentage reduction should therefore be fixed for export licence applications submitted on 14 May 2002.

- (3) In view of its purpose, this Regulation should take effect from the day of its publication in the *Official Journal of the European Communities*,

HAS ADOPTED THIS REGULATION:

Article 1

Applications for export licences for rice and broken rice with advance fixing of the refund submitted under Regulation (EC) No 718/2002 on 14 May 2002 shall give rise to the issue of licences for the quantities applied for to which a percentage reduction of 30,99 % has been applied.

Article 2

Applications for export licences for rice and broken rice submitted from 15 May 2002 shall not give rise to the issue of export licences under Regulation (EC) No 718/2002.

Article 3

This Regulation shall enter into force on 16 May 2002.

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

Done at Brussels, 15 May 2002.

For the Commission

J. M. SILVA RODRÍGUEZ

Member of the Commission

⁽¹⁾ OJ L 329, 30.12.1995, p. 18.

⁽²⁾ OJ L 62, 5.3.2002, p. 27.

⁽³⁾ OJ L 117, 24.5.1995, p. 2.

⁽⁴⁾ OJ L 308, 27.11.2001, p. 16.

⁽⁵⁾ OJ L 111, 26.4.2002, p. 47.

COMMISSION REGULATION (EC) No 802/2002
of 15 May 2002
fixing the import duties in the cereals sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Having regard to Commission Regulation (EC) No 1249/96 of 28 June 1996 laying down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards import duties in the cereals sector ⁽³⁾, as last amended by Regulation (EC) No 597/2002 ⁽⁴⁾, and in particular Article 2(1) thereof,

Whereas:

- (1) Article 10 of Regulation (EEC) No 1766/92 provides that the rates of duty in the Common Customs Tariff are to be charged on import of the products referred to in Article 1 of that Regulation. However, in the case of the products referred to in paragraph 2 of that Article, the import duty is to be equal to the intervention price valid for such products on importation and increased by 55 %, minus the cif import price applicable to the consignment in question. However, that duty may not exceed the rate of duty in the Common Customs Tariff.
- (2) Pursuant to Article 10(3) of Regulation (EEC) No 1766/92, the cif import prices are calculated on the basis of the representative prices for the product in question on the world market.

- (3) Regulation (EC) No 1249/96 lays down detailed rules for the application of Council Regulation (EEC) No 1766/92 as regards import duties in the cereals sector.
- (4) The import duties are applicable until new duties are fixed and enter into force. They also remain in force in cases where no quotation is available for the reference exchange referred to in Annex II to Regulation (EC) No 1249/96 during the two weeks preceding the next periodical fixing.
- (5) In order to allow the import duty system to function normally, the representative market rates recorded during a reference period should be used for calculating the duties.
- (6) Application of Regulation (EC) No 1249/96 results in import duties being fixed as set out in the Annex to this Regulation,

HAS ADOPTED THIS REGULATION:

Article 1

The import duties in the cereals sector referred to in Article 10(2) of Regulation (EEC) No 1766/92 shall be those fixed in Annex I to this Regulation on the basis of the information given in Annex II.

Article 2

This Regulation shall enter into force on 16 May 2002.

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

Done at Brussels, 15 May 2002.

For the Commission

J. M. SILVA RODRÍGUEZ

Agriculture Director-General

⁽¹⁾ OJ L 181, 1.7.1992, p. 21.

⁽²⁾ OJ L 193, 29.7.2000, p. 1.

⁽³⁾ OJ L 161, 29.6.1996, p. 125.

⁽⁴⁾ OJ L 91, 6.4.2002, p. 9.

ANNEX I

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

CN code	Description	Import duty ⁽²⁾ (EUR/tonne)
1001 10 00	Durum wheat high quality	0,00
	medium quality ⁽¹⁾	0,00
1001 90 91	Common wheat seed	0,00
1001 90 99	Common high quality wheat other than for sowing ⁽³⁾	0,00
	medium quality	14,67
	low quality	24,08
1002 00 00	Rye	31,45
1003 00 10	Barley, seed	31,45
1003 00 90	Barley, other ⁽⁴⁾	31,45
1005 10 90	Maize seed other than hybrid	49,71
1005 90 00	Maize other than seed ⁽⁵⁾	49,71
1007 00 90	Grain sorghum other than hybrids for sowing	31,45

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

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

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

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

⁽³⁾ The importer may benefit from a flat-rate reduction of EUR 14 per tonne, where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

⁽⁴⁾ The importer may benefit from a flat-rate reduction of EUR 8 per tonne, where the conditions laid down in Article 2(5) of Regulation (EC) No 1249/96 are met.

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

ANNEX II

Factors for calculating duties

(period from 1 to 14 May 2002)

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

Exchange quotations	Minneapolis	Kansas City	Chicago	Chicago	Minneapolis	Minneapolis	Minneapolis
Product (% proteins at 12 % humidity)	HRS2. 14 %	HRW2. 11,5 %	SRW2	YC3	HAD2	Medium quality (*)	US barley 2
Quotation (EUR/t)	119,47	113,68	108,99	88,00	193,18 (**)	183,18 (**)	109,53 (**)
Gulf premium (EUR/t)	—	21,44	16,73	12,08	—	—	—
Great Lakes premium (EUR/t)	25,72	—	—	—	—	—	—

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

(**) Fob Duluth.

2. Freight/cost: Gulf of Mexico–Rotterdam: 17,33 EUR/t; Great Lakes–Rotterdam: 26,14 EUR/t.

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

COMMISSION REGULATION (EC) No 803/2002
of 15 May 2002
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⁾, as last amended by Regulation (EC) No 1513/2001 ⁽²⁾, 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 ⁽³⁾, as last amended by Regulation (EEC) No 2962/77 ⁽⁴⁾.
- (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 16 May 2002.

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

Done at Brussels, 15 May 2002.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ 172, 30.9.1966, p. 3025/66.

⁽²⁾ OJ L 201, 26.7.2001, p. 4.

⁽³⁾ OJ L 78, 31.3.1972, p. 1.

⁽⁴⁾ OJ L 348, 30.12.1977, p. 53.

ANNEX

to the Commission Regulation of 15 May 2002 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 2020/2001 (OJ L 273, 16.10.2001, p. 6).

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 3 May 2002

on the granting of a national aid by the authorities of the Kingdom of the Netherlands in favour of road transport undertakings

(2002/361/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 88(2), third subparagraph, thereof,

Having regard to the request made by the Government of the Kingdom of the Netherlands on 4 February 2002,

Whereas:

- (1) Article 8(4) of Council Directive 92/81/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on mineral oils ⁽¹⁾ allows the Council to authorise Member States to introduce exemptions or reductions in the excise duty charged on mineral oils for specific policy purposes.
- (2) Under Article 3(5), first indent of Council Decision 1999/880/EC ⁽²⁾ and Article 2 of Council Decision 2001/224/EC of 12 March 2001 concerning reduced rates of excise duty and exemptions from such duty on certain mineral oils when used for specific purposes ⁽³⁾, until 31 December 2002, by way of derogation from the provisions of Council Directive 92/82/EEC ⁽⁴⁾, the Netherlands is authorised to continue to apply reduced rates of excise duty on diesel fuel used in commercial vehicles, provided that the rates respect the obligations laid down in Directive 92/82/EEC and in particular the minimum rates laid down in Article 5 thereof.
- (3) The Netherlands has included a provision in its national legislation on excise duty which provides for a refund of

part of the excise duty on diesel fuel used in heavy goods vehicles.

- (4) By means of a letter dated 18 April 2001 (published in OJ C 160, 2.6.2001), the Commission notified the Netherlands its decision to initiate the procedure laid down in Article 88(2) of the Treaty concerning the abovementioned measures.
- (5) Environmental and energy conservation purposes prompted the Netherlands authorities to raise the rate of excise duty on diesel oil. The increased taxation as well as the high rise of costs due to the rise of the international price of crude oil had severe negative repercussions on the activities in the road transport sector. The introduction of compensatory measures to avert serious economic and social difficulties for the road sector was necessary. No other remedy was adequate.
- (6) The measure is not discriminatory. The fact that some firms or sectors benefit from certain tax measures does not in itself mean that they are in form or substance contrary to the common interest.
- (7) The measure is temporary and will expire on 1 October 2002. With effect from 1 January 2002, the refundable amount has been substantially reduced.
- (8) Exceptional circumstances therefore exist, making it possible to consider such aid, by way of derogation and to the extent strictly necessary to remedy the economic and social difficulties of the road transport sector concerned which has arisen, to be compatible with the common market,

⁽¹⁾ OJ L 316, 31.10.1992, p. 12. Directive as last amended by Directive 94/74/EC (OJ L 365, 31.12.1994, p. 46).

⁽²⁾ OJ L 331, 23.12.1999, p. 73.

⁽³⁾ OJ L 84, 23.3.2001, p. 23.

⁽⁴⁾ OJ L 316, 31.10.1992, p. 19. Directive as last amended by Directive 94/74/EC.

HAS ADOPTED THIS DECISION:

Article 1

The measures adopted by the Netherlands in accordance with Article 3(5), first indent of Decision 1999/880/EC and Article 2 of Decision 2001/224/EC shall be considered to be compatible with the common market.

Article 2

This Decision is addressed to the Kingdom of the Netherlands.

Done at Brussels, 3 May 2002.

For the Council

The President

J. PIQUÉ I CAMPS

COUNCIL DECISION
of 3 May 2002
on the granting of a national aid by the authorities of the Italian Republic in favour of road
transport undertakings

(2002/362/EC)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 88(2), third subparagraph, thereof,

Having regard to the request made by the Government of the Italian Republic on 4 February 2002,

Whereas:

- (1) Article 8(4) of Council Directive 92/81/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on mineral oils ⁽¹⁾ allows the Council to authorise Member States to introduce exemptions or reductions in the excise duty charged on mineral oils for specific policy purposes.
- (2) Under Article 1 of Council Decision 2000/446/EC ⁽²⁾ and Article 2 of Council Decision 2001/224/EC of 12 March 2001 concerning reduced rates of excise duty and exemptions from such duty on certain mineral oils when used for specific purposes ⁽³⁾, until 31 December 2002, by way of derogation from the provisions of Council Directive 92/82/EEC ⁽⁴⁾, Italy is authorised to continue to apply reduced rates of excise duty on diesel used as fuel by road transport operators, provided that the rates respect the obligations laid down in Directive 92/82/EEC and in particular the minimum rates laid down in Article 5 thereof.
- (3) Italy has provided in its national legislation, since 16 January 1999, for a reduction in the rate of excise duty on diesel used as fuel by road transport operators.
- (4) By means of a letter dated 18 April 2001 (published in OJ C 160, 2.6.2001), the Commission notified Italy its decision to initiate the procedure laid down in Article 88(2) of the Treaty concerning the abovementioned measures.
- (5) Environmental and energy conservation purposes prompted the Italian authorities to raise the rate of excise duty on the most polluting fuels to discourage their use. The increased taxation as well as the high rise of costs due to the rise of the international price of

crude oil had severe negative repercussions on the activities in the road transport sector. The introduction of compensatory measures to avert serious economic and social difficulties for the road sector, which suffers from market fragmentation and from Italy's morphology, was necessary awaiting measures at infrastructural level. No other remedy was adequate.

- (6) The measure is not discriminatory. The fact that some firms or sectors benefit from certain tax measures does not in itself mean that they are in form or substance contrary to the common interest.
- (7) The measure is temporary and will expire on 31 December 2002. With effect from 1 July 2001, the refundable amount has been substantially reduced.
- (8) Exceptional circumstances therefore exist, making it possible to consider such aid, by way of derogation and to the extent strictly necessary to remedy the economic and social difficulties of the road transport sector concerned which has arisen, to be compatible with the common market,

HAS ADOPTED THIS DECISION:

Article 1

The measures adopted by Italy in accordance with Article 1 of Decision 2000/446/EC and Article 2 of Decision 2001/224/EC shall be considered to be compatible with the common market.

Article 2

This Decision is addressed to the Republic of Italy.

Done at Brussels, 3 May 2002.

For the Council

The President

J. PIQUÉ I CAMPS

⁽¹⁾ OJ L 316, 31.10.1992, p. 12. Directive as last amended by Directive 94/74/EC (OJ L 365, 31.12.1994, p. 46).

⁽²⁾ OJ L 180, 19.7.2000, p. 39.

⁽³⁾ OJ L 84, 23.3.2001, p. 23.

⁽⁴⁾ OJ L 316, 31.10.1992, p. 19. Directive as last amended by Directive 94/74/EC.

COUNCIL DECISION
of 3 May 2002
on the granting of aid by the French Government for road transport undertakings

(2002/363/EC)

THE COUNCIL OF THE EUROPEAN UNION,

measure has been extended to cover occasional passenger transport.

Having regard to the Treaty establishing the European Community, and in particular the third subparagraph of Article 88(2) thereof,

Having regard to the application made by the Government of the French Republic on 4 February 2002,

Whereas:

(1) Article 8(4) of Council Directive 92/81/EEC of 19 October 1992 on the harmonisation of the structures of excise duties on mineral oils⁽¹⁾ allows the Council to authorise Member States to introduce exemptions or reductions in the excise duty charged on mineral oils for specific policy purposes.

(2) Under the second indent of Article 3(3) of Council Decision 1999/880/EC⁽²⁾ and Article 2 of Council Decision 2001/224/EC of 12 March 2001 concerning reduced rates of excise duty and exemptions from such duty on certain mineral oils when used for specific purposes⁽³⁾, France is authorised, by way of derogation from the provisions of Council Directive 92/82/EEC⁽⁴⁾, to continue to apply, until 31 December 2002, differentiated rates of excise duty to diesel fuel used in commercial vehicles, provided that those differentiated rates comply with the obligations laid down in Directive 92/82/EEC and in particular the minimum rates of excise duty laid down in Article 5 thereof.

(3) In Article 26 of its 1999 Finance Act (No 98-1266 of 30 December 1998) France introduced an arrangement for the partial reimbursement of the excise duty applicable to diesel fuel for certain types of goods transport by road, with effect from 11 January 1999, consolidated in Article 265f of the Customs Code. At national level that

(4) By letter dated 18 April 2001 (published in OJ C 160, 2.6.2001), the Commission notified France of its decision to initiate the procedure laid down in Article 88(2) of the Treaty in connection with the abovementioned measures.

(5) For environmental and energy-conservation reasons, France adopted taxes on diesel oil that were much higher than the Community minimum. The increase in the tax burden, not to mention the very high increase in the price of crude oil, has had extremely negative repercussions on the activities of the road transport sector. In these circumstances, France has been compelled to introduce compensatory measures to meet the considerable economic and social difficulties to which the sector is prey, no other remedy being sufficient.

(6) The measure is not discriminatory as it is open to all firms established within the Community that obtain diesel fuel in France. Even when account is taken of this reimbursement arrangement, the TIPP rate in France is still much higher than the Community minimum rate for diesel fuel. The fact that some firms or sectors benefit from certain tax measures does not in itself mean that they are in form or substance contrary to the common interest.

(7) The arrangement is temporary. It will cease to apply on 31 December 2002. In 2002 the annual reimbursement will be substantially reduced compared with the figure for 2001.

(8) There are therefore exceptional circumstances that make it possible to consider such aid, by way of derogation and to the extent strictly necessary to remedy the economic and social difficulties of the transporters concerned, compatible with the common market,

⁽¹⁾ OJ L 316, 31.10.1992, p. 12. Directive as last amended by Directive 94/74/EC (OJ L 365, 31.12.1994, p. 46).

⁽²⁾ OJ L 331, 23.12.1999, p. 73.

⁽³⁾ OJ L 84, 23.3.2001, p. 23.

⁽⁴⁾ OJ L 316, 31.10.1992, p. 19. Directive as last amended by Directive 94/74/EC.

HAS ADOPTED THIS DECISION:

Article 1

The measures adopted by France in accordance with the second indent of Article 3(3) of Decision 1999/880/EC and with Article 2 of Decision 2001/224/EC shall be considered compatible with the common market.

Article 2

This Decision is addressed to the French Republic.

Done at Brussels, 3 May 2002.

For the Council

The President

J. PIQUÉ I CAMPS

COMMISSION

COMMISSION DECISION

of 7 May 2002

on common technical specifications for *in vitro*-diagnostic medical devices

(notified under document number C(2002) 1344)

(Text with EEA relevance)

(2002/364/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices ⁽¹⁾, and in particular the second subparagraph of Article 5(3) thereof,

Whereas:

- (1) Directive 98/79/EC sets out the essential requirements that *in vitro* diagnostic medical devices must meet when they are placed on the market and conformity with harmonised standards provides a presumption of conformity with the relevant essential requirements.
- (2) By way of exception to these general principles, the drawing up of common technical specifications takes account of a current practice in some Member States whereby for selected devices mainly used for the evaluation of the safety of blood supply and of organ donation, such specifications are adopted by the public authorities. These common technical specifications can be used for performance evaluation and re-evaluation.
- (3) Scientific experts from various interested parties have been involved in the drafting of the common technical specifications.
- (4) Directive 98/79/EC provides that Member States are to presume compliance with the essential requirements in respect of devices designed and manufactured in conformity with common technical specifications drawn up for certain devices in the highest risk category. These specifications are to establish appropriate performance

evaluation and re-evaluation criteria, batch release criteria, reference methods and reference materials.

- (5) Manufacturers are, as a general rule, to be required to comply with the common technical specifications. If, for duly justified reasons, manufacturers do not comply with those specifications they must adopt solutions of a level at least equivalent thereto.
- (6) The measures provided for in this Decision are in accordance with the opinion of the committee set up by Article 6(2) of Council Directive 90/385/EEC ⁽²⁾,

HAS ADOPTED THIS DECISION:

Article 1

The technical specifications set out in the Annex to this Decision are adopted as common technical specifications for *in vitro* diagnostic medical devices in list A of Annex II to Directive 98/79/EC.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 May 2002.

For the Commission

Erkki LIIKANEN

Member of the Commission

⁽¹⁾ OJ L 331, 7.12.1998, p. 1.

⁽²⁾ OJ L 189, 20.7.1990, p. 17.

ANNEX

CTS — COMMON TECHNICAL SPECIFICATIONS FOR IN VITRO-DIAGNOSTIC MEDICAL DEVICES**1. SCOPE**

These Common Technical Specifications are for the list of devices referred to in Annex II, list A:

- reagents and reagent products, including related calibrators and control materials, for determining the following blood groups: ABO system, Rhesus (C, c, D, E, e) anti-Kell,
- reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C and D.

2. DEFINITIONS**(Diagnostic) sensitivity**

The probability that the device gives a positive result in the presence of the target marker.

True positive

A specimen known to be positive for the target marker and correctly classified by the device.

False negative

A specimen known to be positive for the target marker and misclassified by the device.

(Diagnostic) specificity

The probability that the device gives a negative result in the absence of the target marker.

False positive

A specimen known to be negative for the target marker and misclassified by the device.

True negative

A specimen known to be negative for the target marker and correctly classified by the device.

Analytical sensitivity

In the context of the CTS it may be expressed as the limit of detection: i.e. the smallest amount of the target marker that can be precisely detected.

Analytical specificity

The ability of the method to determine solely the target marker.

Nucleic acid amplification techniques (NAT)

In the context of this document the term 'NAT' is used for tests for the detection and/or quantification of nucleic acids by either amplification of a target sequence, by amplification of a signal or by hybridisation.

Rapid test

In this context the term 'rapid test' is understood to mean those tests which can only be used singly or in a small series and which have been designed to give a rapid result for near patient testing.

Robustness

The robustness of an analytical procedure is a measure of its capacity to remain unaffected by small but deliberate variations in method parameters and provides an indication of its reliability during normal usage.

Whole system failure rate

The whole system failure rate is the frequency of failures when the entire process is performed as prescribed by the manufacturer.

3. COMMON TECHNICAL SPECIFICATIONS (CTS) FOR PRODUCTS DEFINED IN ANNEX II, LIST A OF DIRECTIVE 98/79/EC.

3.1. CTS for performance evaluation of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D:

GENERAL PRINCIPLES

- 3.1.1. Devices which detect virus infections placed on the market for use as either screening and/or diagnostic tests, shall meet the same requirements for sensitivity and specificity (see Table 1).
- 3.1.2. Devices intended by the manufacturer for testing body fluids other than serum or plasma, e.g. urine, saliva, etc. shall meet the same CTS requirements for sensitivity and specificity as serum or plasma tests. The performance evaluation shall test samples from the same individuals in both the tests to be approved and in a respective serum or plasma assay.
- 3.1.3. Devices intended by the manufacturer for self-test, i.e. home use, shall meet the same CTS requirements for sensitivity and specificity as respective devices for professional use. Relevant parts of the performance evaluation shall be carried out (or repeated) by appropriate lay users to validate the operation of the device and the instructions for use.
- 3.1.4. All performance evaluations shall be carried out in direct comparison with an established device with acceptable performance. Once the CE marking of IVDs is established, the device used for comparison shall be CE marked, if on the market at the time of the performance evaluation.
- 3.1.5. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:
 - by evaluation of the discrepant sample in further test systems,
 - by use of an alternative method or marker,
 - by a review of the clinical status and diagnosis of the patient, and
 - by the testing of follow-up-samples.
- 3.1.6. Performance evaluations shall be performed on a population equivalent to the European population.
- 3.1.7. Positive specimens used in the performance evaluation shall be selected to reflect different stages of the respective disease(s), different antibody patterns, different genotypes, different subtypes etc.
- 3.1.8. For blood screening devices (with the exception of HBsAg tests), all true positive samples shall be identified as positive by the device to be CE marked (Table 1). For HbsAg tests the new device shall have an overall performance at least equivalent to that of the established device (see principle 3.1.4). Diagnostic test sensitivity during the early infection phase (sero-conversion) has to represent the state of the art. Whether further testing of the same or additional sero-conversion panels is conducted by the notified body or by the manufacturer the results shall confirm the initial performance evaluation data (see Table 1).
- 3.1.9. Negative specimens used in a performance evaluation shall be defined so as to reflect the target population for which the test is intended, for example blood donors, hospitalised patients, pregnant women etc.
- 3.1.10. For performance evaluations for screening assays (Table 1), blood donor populations shall be investigated from at least two blood donation centres and consist of consecutive blood donations, which have not been selected to exclude first time donors.
- 3.1.11. Devices shall have a specificity of at least 99,5 % on blood donations, unless otherwise indicated in the accompanying tables. Specificity shall be calculated using the frequency of repeatedly reactive (i.e. false positive) results in blood donors negative for the target marker.
- 3.1.12. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device but may include, for example:
 - specimens representing 'related' infections;

- specimens from multipara, i.e. women who have had more than one pregnancy, or rheumatoid factor positive patients,
- for recombinant antigens, human antibodies to components of the expression system, for example anti-E. coli, or anti-yeast.

- 3.1.13. For devices intended by the manufacturer to be used with serum and plasma the performance evaluation must demonstrate serum to plasma equivalency. This shall be demonstrated for at least 50 donations.
- 3.1.14. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations.
- 3.1.15. As part of the required risk analysis the whole system failure rate leading to false-negative results shall be determined in repeat assays on low-positive specimens.

3.2. **Additional requirements for nucleic acid amplification techniques (NAT)**

The performance evaluation criteria for NAT assays can be found in Table 2.

- 3.2.1. For target sequence amplification assays, a functionality control for each test sample (internal control) shall reflect the state of the art. This control shall as far as possible be used throughout the whole process, i.e. extraction, amplification/hybridisation, detection.
- 3.2.2. The analytical sensitivity or detection limit for NAT assays shall be expressed by the 95 % positive cut-off value. This is the analyte concentration where 95 % of test runs give positive results following serial dilutions of an international reference material for example a WHO standard or calibrated reference materials.
- 3.2.3. Genotype detection shall be demonstrated by appropriate primer or probe design validation and shall also be validated by testing characterised genotyped samples.
- 3.2.4. Results of quantitative NAT assays shall be traceable to international standards or calibrated reference materials, if available, and be expressed in international units utilised in the specific field of application.
- 3.2.5. NAT assays may be used to detect virus in antibody negative samples, i.e. pre-sero-conversion samples. Viruses within immune –complexes may behave differently in comparison to free viruses, for example during a centrifugation step. It is therefore important that during robustness studies, antibody-negative (pre-sero-conversion) samples are included.
- 3.2.6. For investigation of potential carry-over, at least five runs with alternating high-positive and negative specimens shall be performed during robustness studies. The high positive samples shall comprise of samples with naturally occurring high virus titres.
- 3.2.7. The whole system failure rate leading to false-negative results shall be determined by testing low-positive specimens. Low positive specimens shall contain a virus concentration equivalent to 3 x the 95 % positive cut-off virus concentration.

3.3. **CTS for the manufacturer's release testing of reagents and reagent products for the detection, confirmation and quantification in human specimens of markers of HIV infection (HIV 1 and 2), HTLV I and II, and hepatitis B, C, D (immunological assays only)**

- 3.3.1. The manufacturer's release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.
- 3.3.2. The manufacturer's batch release testing shall include at least 100 specimens negative for the relevant analyte.

3.4. **CTS for performance evaluation of reagents and reagent products for determining the blood group antigens: ABO system (A, B), Rhesus (C, c, D, E, e) and Kell (K)**

Criteria for performance evaluation of reagents and reagent products for determining the blood groups: ABO system (A,B), Rhesus (C, c, D, E, e) and Kell (K) can be found in Table 9.

- 3.4.1. All performance evaluations shall be carried out in direct comparison with an established device with acceptable performance. Once the CE marking of IVDs is established, the device used for comparison shall be CE marked, if on the market at the time of the performance evaluation.
- 3.4.2. If discrepant test results are identified as part of an evaluation, these results shall be resolved as far as possible, for example:
- by evaluation of the discrepant sample in further test systems,
 - by use of an alternative method.
- 3.4.3. Performance evaluations shall be performed on a population equivalent to the European population.

- 3.4.4. Positive specimens used in the performance evaluation shall be selected to reflect variant and weak antigen expression.
- 3.4.5. Devices shall be evaluated to establish the effect of potential interfering substances, as part of the performance evaluation. The potential interfering substances to be evaluated will depend to some extent on the composition of the reagent and configuration of the assay. Potential interfering substances shall be identified as part of the risk analysis required by the essential requirements for each new device.
- 3.4.6. For devices intended for use with plasma the performance evaluation shall verify the performance of the device using all anticoagulants which the manufacturer indicates for use with the device. This shall be demonstrated for at least 50 donations.
- 3.5. **CTS for the manufacturer's release testing of reagents and reagent products for determining the blood group antigens: ABO system (A, B), Rhesus (C, c, D, E, e), and Kell (K)**
 - 3.5.1. The manufacturer's release testing criteria shall ensure that every batch consistently identifies the relevant antigens, epitopes, and antibodies.
 - 3.5.2. Requirements for manufacturer's batch release testing are outlined in Table 10.

Table 1: 'Screening' assays: anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg, anti-HBc

		Anti-HIV 1/2	Anti-HTLV I/II	Anti-HCV	HBsAg	Anti-HBc
Diagnostic sensitivity	Positive specimens	400 HIV 1 100 HIV 2 including 40 non-B-subtypes, all available HIV 1 subtypes should be represented by at least three samples per subtype	300 HTLV I 100 HTLV II	400 including genotypes 1a-4a: at least 20 samples/geno- type genotypes 4 non-a and 5: at least 10 samples/geno- type	400 including subtype-consid- eration	400 including evaluation of other HBV-markers
	Sero-conversion panels	20 panels 10 further panels (at Noti- fied Body or manufacturer)	To be defined when avail- able	20 panels 10 further panels (at Noti- fied Body or manufacturer)	20 panels 10 further panels (at Noti- fied Body or manufacturer)	To be defined when available
Analytical sensitivity	Standards				0,5 ng/ml (French/UK standard until WHO avail- able)	
Specificity	Unselected donors (including 1 st time donors)	5 000	5 000	5 000	5 000	5 000
	Hospitalised patients	200	200	200	200	200
	Potentially cross-reacting blood-specimens (RF+, related viruses, pregnant women etc.)	100	100	100	100	100

Table 2: NAT assays for HIV1, HCV, HBV, HTLV I/II (qualitative and quantitative; not molecular typing)

HIV 1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	
				As for HIV quantitative		As for HIV quantitative		As for HIV quantitative	
Sensitivity Detection limit Detection of analytical sensitivity (IU/ml; defined on WHO standards or calibrated reference materials)	According to EP validation guideline (1): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value	Detection limit: as for qualitative tests; Quantification limit: dilutions (half-log 10 or less) of calibrated reference preparations, definition of lower, upper quantification limit, precision, accuracy, 'linear', 'measuring range' 'dynamic range' Reproducibility at different concentration levels to be shown	According to EP validation guideline (1): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline (1): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		According to EP validation guideline (1): several dilution series into borderline concentration; statistical analysis (e.g. Probit analysis) on the basis of at least 24 replicates; calculation of 95 % cut-off value		
Genotype/subtype detection/quantification efficiency	At least 10 samples per subtype (as far as available) Cell culture supernatants (could substitute for rare HIV 1 subtypes) According to EP validation guideline (1) As far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option	Dilution series of all relevant genotypes/subtypes, preferably of reference materials, as far as available Transcripts or plasmids quantified by appropriate methods may be used	At least 10 samples per genotype (as far as available) According to EP validation guideline (1) as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		As far as calibrated genotype reference materials are available According to EP validation guideline (1) as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		As far as calibrated genotype reference materials are available According to EP validation guideline (1) as far as calibrated subtype reference materials are available; <i>in vitro</i> transcripts could be an option		

HIV 1			HCV		HBV		HTLV I/II		Acceptance criteria
NAT	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	qualitative	quantitative	
				As for HIV quantitative		As for HIV quantitative		As for HIV quantitative	
Diagnostic specificity negative samples	500 blood donors	100 blood donors	500 blood donors		500 blood donors		500 individual blood donations		
Potential cross reactive markers	By suitable assay design evidence (e.g. sequence comparison) and/or testing of at least 10 human retrovirus (e.g. HTLV) positive samples	As for qualitative tests	By assays design and/or testing of at least 10 human flavivirus (e.g. HGV, YFV) positive samples		By assays design and/or testing of at least 10 other DNA-virus positive samples		By assays design and/or testing of at least 10 human retrovirus (e.g. HIV) positive samples		
Robustness		As for qualitative tests							
Cross-contamination	At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		At least 5 runs using alternating high positive (known to occur naturally) and negative samples		
Inhibition	Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		Internal control preferably to go through the whole NAT procedure		
Whole system failure rate leading to false-neg results	At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		At least 100 samples virus-spiked with 3 × the 95 % pos cut-off concentration		99/100 assays positive

(¹) European Pharmacopoeia guideline.

Nota: Acceptance criteria for 'whole system failure rate leading to false-neg results' is 99/100 assays positive.

Table 3: **Rapid tests: anti HIV 1 and 2, anti HCV, HBsAg, anti HBc, anti HTLV I and II**

		Anti-HIV 1/2	Anti-HCV	HBsAg	Anti-HBc	Anti-HTLV I/III	Acceptance criteria
Diagnostic sensitivity	Positive specimens	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays	Same criteria as for screening assays
Diagnostic specificity	Negative specimens	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 100 potentially interfering samples	1 000 blood donations 200 clinical specimens 200 samples from pregnant women 100 potentially interfering samples	$\geq 99 \%$ (anti-HBc: $\geq 96 \%$)

Table 4: **Confirmatory/supplementary assays for anti-HIV 1 and 2, anti-HTLV I and II, anti-HCV, HBsAg**

		Anti-HIV confirmatory assay	Anti-HTLV confirmatory assay	HCV supplementary assay	HbsAg confirmatory assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 HIV 1 and 100 HIV 2 Including samples from different stages of infection and reflecting different anti-body patterns	200 HTLV I and 100 HTLV II	300 HCV Including samples from different stages of infection and reflecting different anti-body patterns genotypes 1 - 4a: 15 samples; genotypes 4 (non a), 5: five samples; six: if available	300 HBsAg Including samples from different stages of infection 20 'high pos' samples (> 50 ng HBsAg/ml); 20 samples in the cut-off range	Correct identification as positive (or indeterminate), not negative
	Sero-conversion panels	15 seroconversion panels/ low titre panels		15 seroconversion panels/ low titre panels	15 seroconversion panels/ low titre panels	
Analytical sensitivity	Standards				HBsAg standards (AdM, NIBSC, WHO)	
Diagnostic specificity	Negative specimens	200 blood donations	200 blood donations	200 blood donations	20 false-positives in the corresponding screening assay ⁽¹⁾	No false-positive results/ ⁽¹⁾ no neutralisation
		200 clinical samples including pregnant women 50 potentially interfering samples, including samples with indeterminate results in other confirmatory assays	200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other confirmatory assays	200 clinical samples including pregnant women 50 potentially interfering samples including samples with indeterminate results in other supplementary assays	50 potentially interfering samples	

⁽¹⁾ Acceptance criteria no neutralisation for HBsAg confirmatory assay.

Table 5: HIV 1 Antigen

		HIV 1 antigen assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	50 HIV 1 Ag-positive 50 cell culture supernatants including different HIV 1 subtypes and HIV 2	Correct identification (after neutralisation)
	Sero-conversion panels	20 sero-conversion panels/low titre panels	
Diagnostic specificity	Standards	ADM or 1 st international reference	< 50 pg/ml
Diagnostic specificity		200 blood donations 200 clinical samples 50 potentially interfering samples	≥ 99,5 % after neutralisation

Table 6: Serotyping Assay: HCV

		HCV 1 serotyping assay	Acceptance criteria
Diagnostic sensitivity	Positive specimens	200 incl. genotypes 1-4a: > 20 samples. 4 (non a); 5: > 10 samples, 6: if available	≥ 95 % agreement between serotyping and genotyping
Diagnostic specificity	Negative specimens	100	

Table 7: **HBV markers: anti-HBs, anti-HBc IgM, anti-HBe, HBeAg**

		Anti-HBs	Anti-HBc IgM	Anti-HBe	HBeAg	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 vaccinees 100 naturally infected persons	200 including samples from different stages of infection (acute/chronic etc.)	200 including samples from different stages of infection (acute/chronic etc.)	200 including samples from different stages of infection (acute/chronic etc.)	≥ 98 %
	Sero-con-version panels	10 follow-ups or anti/HBs sero-conversions	When available			
Analytical sensitivity	Standards	WHO standard			PEI standard	Anti-HBs: < 10 mIU/ml
Diagnostic specificity	Negative specimens	500 including clinical samples	200 blood donations	200 blood donations	200 blood donations	≥ 98 %
		50 potentially interfering samples	200 clinical samples 50 potentially interfering samples	200 clinical samples 50 potentially interfering samples	200 clinical samples 50 potentially interfering samples	

Table 8: **HDV markers: anti-HDV, anti-HDV IgM, Delta Antigen**

		Anti-HDV	Anti-HDV IgM	Delta Antigen	Acceptance criteria
Diagnostic sensitivity	Positive specimens	100 specifying HBV-markers	50 specifying HBV-markers	10 specifying HBV-markers	≥ 98 %
Diagnostic specificity	Negative specimens	200 including clinical samples 50 potentially interfering samples	200 including clinical samples 50 potentially interfering samples	200 including clinical samples 50 potentially interfering samples	≥ 98 %

Table 9: Blood Groups ABO, Rhesus (C, c, D, E, e) and Kell

	1	2	3
Specificity	Number of tests per recommended method	Total number of samples to be tested for a launch product	Total number of samples to be tested for a new formulation, or use of well-characterised reagents
Anti-A, B and AB	500	3 000	1 000
Anti-D	500	3 000	1 000
Anti-C, c, E	100	1 000	200
Anti-e	100	500	200
Anti-K	100	500	200

Acceptance criteria:

all of the above reagents shall show comparable test results with established reagents with acceptable performance with regard to claimed reactivity of the device. For established reagents, where the application or use has been changed or extended, further testing should be carried out in accordance with the requirements outlined in column 1 (above).

Performance evaluation of anti-D-reagents shall include tests against a range of weak RhD and partial Rh samples, depending on the intended use of the product.

Qualifications:

clinical samples: 10 % of the test population
 Neonatal specimens: > 2 % of the test population
 ABO samples: > 40 % A, B positives
 'weak D': > 2 % of Rhesus positives

Table 10: Batch release criteria for Blood Groups ABO, Rhesus (C, c, D, E, e), and Kell

Specificity Testing Requirements on each reagent

1. Test reagents

Blood Group Reagents				Minimum number of control cells to be tested			
	Positive reactions				Negative reactions		
	A1	A2B	Ax		B	0	
Anti-A	2	2	2 (*)		2	2	
	B	A1B			A1	0	
Anti-B	2	2			2	2	
	A1	A2	Ax	B	0		
Anti-AB	2	2	2	2	4		
	R1r	R2r	WeakD		R'r	r''r	rr
Anti-D	2	2	2 (*)		1	1	1
	R1R2	R1r	r'r		R2R2	r''r	rr
Anti-C	2	1	1		1	1	1
	R1R2	R1r	r'r		R1R1		
Anti-c	1	2	1		3		
	R1R2	R2r	r''r		R1R1	r'r	rr
Anti-E	2	1	1		1	1	1
	R1R2	R2r	r''r		R2R2		
Anti-e	2	1	1		3		
	Kk				kk		
Anti-K	4				3		

(*) Only by recommended techniques where reactivity against these antigens is claimed.

Note: Polyclonal reagents must be tested against a wider panel of cells to confirm specificity and exclude presence of unwanted contaminating antibodies.

Acceptance Criteria:

Each batch of reagent must exhibit unequivocal positive or negative results by all recommended techniques in accordance with the results obtained from the performance evaluation data.

2. Control Materials (red Cells)

The phenotype of red cells used in the control of blood typing reagents listed above should be confirmed using established device.

CORRIGENDA**Corrigendum to Regulation (EC) No 690/2002 of the European Central Bank of 18 April 2002 amending Regulation (EC) No 2818/98 (ECB/1998/15) on the application of minimum reserves (ECB/2002/3)**

(Official Journal of the European Communities L 106 of 23 April 2002)

On page 10, Article 1(4):

for:

$$R_t = \frac{H_t \cdot n_t \cdot r_t}{100 \cdot 360_t},$$

read:

$$R_t = \frac{H_t \cdot n_t \cdot r_t}{100 \cdot 360}$$

Corrigendum to Commission Decision 2002/325/EC of 31 May 2001 approving the single programming document for Community structural assistance under Objective 2 in the Kustgebied-Westhoek in the province of West Flanders in Belgium

(Official Journal of the European Communities L 122 of 8 May 2002)

On page 14, in the title:

for: '(notified under document number C(2001) 868)',

read: '(notified under document number C(2001) 1269)'.
