

Official Journal

of the European Communities

ISSN 0378-6978

L 313

Volume 43

13 December 2000

English edition

Legislation

Contents

I Acts whose publication is obligatory

Commission Regulation (EC) No 2710/2000 of 12 December 2000 establishing the standard import values for determining the entry price of certain fruit and vegetables	1
★ Commission Regulation (EC) No 2711/2000 of 11 December 2000 prohibiting fishing for common sole by vessels flying the flag of Sweden	3
★ Commission Regulation (EC) No 2712/2000 of 12 December 2000 amending Regulation (EEC) No 2123/89 establishing the list of representative markets for pigmeat in the Community	4
★ Commission Regulation (EC) No 2713/2000 of 12 December 2000 amending Regulation (EC) No 1555/96 on rules of application for additional import duties on fruit and vegetables	5
★ Commission Regulation (EC) No 2714/2000 of 12 December 2000 determining the revised estimate of production of unginned cotton for the 2000/01 marketing year and the relevant percentage increase	7
★ Commission Regulation (EC) No 2715/2000 of 12 December 2000 on the authorisation of transfers between the quantitative limits of textiles and clothing products originating in the People's Republic of China	8
★ Commission Regulation (EC) No 2716/2000 of 12 December 2000 prohibiting fishing for cod by vessels flying the flag of a Member State	11
★ Directive 2000/69/EC of the European Parliament and of the Council of 16 November 2000 relating to limit values for benzene and carbon monoxide in ambient air	12

★ Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of human blood or human plasma	22
--	----

II Acts whose publication is not obligatory

Council

2000/786/EC:

★ Council Decision of 27 November 2000 on the grant of funds to the Hellenic Republic in order to compensate partially for the interest paid on European Investment Bank loans for the reconstruction of the region which was devastated by the earthquake of September 1999	25
--	----

I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 2710/2000
of 12 December 2000
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 13 December 2000.

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

Done at Brussels, 12 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 198, 15.7.1998, p. 4.

ANNEX

to the Commission Regulation of 12 December 2000 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	111,6
	204	64,8
	999	88,2
0707 00 05	624	195,9
	628	152,5
	999	174,2
0709 90 70	052	89,7
	204	39,7
	628	109,0
0805 10 10, 0805 10 30, 0805 10 50	999	79,5
	052	40,5
	204	44,9
	388	40,5
0805 20 10	999	42,0
	052	93,5
	204	76,6
0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90	999	85,0
	052	72,3
	999	72,3
	052	71,3
0805 30 10	600	73,8
	999	72,5
0808 10 20, 0808 10 50, 0808 10 90	060	37,5
	400	80,9
	404	83,2
	720	120,5
	999	80,5
0808 20 50	052	73,7
	064	57,4
	400	90,4
	999	73,8

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2543/1999 (OJ L 307, 2.12.1999, p. 46). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 2711/2000
of 11 December 2000
prohibiting fishing for common sole by vessels flying the flag of Sweden

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy ⁽¹⁾, as last amended by Regulation (EC) No 2846/98 ⁽²⁾, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 2742/1999 of 17 December 1999 fixing for 2000 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where limitations in catch are required and amending Regulation (EC) No 66/98 ⁽³⁾, as last amended by Regulation (EC) No 2579/2000 ⁽⁴⁾, lays down quotas for common sole for 2000.
- (2) In order to ensure compliance with the provisions relating to the quantity limits on catches of stocks subject to quotas, the Commission must fix the date by which catches made by vessels flying the flag of a Member State are deemed to have exhausted the quota allocated.
- (3) According to the information received by the Commission, catches of common sole in the waters of Skagerrak and Kattegat, ICES Zone IIIbcd (EC waters) by vessels

flying the flag of Sweden or registered in Sweden have exhausted the quota allocated for 2000. Sweden has prohibited fishing for this stock from 27 November 2000. This date should be adopted in this Regulation also,

HAS ADOPTED THIS REGULATION:

Article 1

Catches of common sole in the waters of Skagerrak and Kattegat, ICES Zone IIIbcd (EC waters) by vessels flying the flag of Sweden or registered in Sweden are hereby deemed to have exhausted the quota allocated to Sweden for 2000.

Fishing for common sole in the waters of Skagerrak and Kattegat, ICES Zone IIIbcd (EC waters) by vessels flying the flag of Sweden or registered in Sweden is hereby prohibited, as are the retention on board, transshipment and landing of this stock caught by the above vessels after the date of application of this Regulation.

Article 2

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

It shall apply from 27 November 2000.

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

Done at Brussels, 11 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 261, 20.10.1993, p. 1.

⁽²⁾ OJ L 358, 31.12.1998, p. 5.

⁽³⁾ OJ L 341, 31.12.1999, p. 1.

⁽⁴⁾ OJ L 298, 25.11.2000, p. 3.

COMMISSION REGULATION (EC) No 2712/2000
of 12 December 2000
amending Regulation (EEC) No 2123/89 establishing the list of representative markets for pigmeat
in the Community

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2759/75 of 29 October 1975 on the common organisation of the market in pigmeat ⁽¹⁾, as last amended by Regulation (EC) No 1365/2000 ⁽²⁾, and in particular Article 4(6) thereof,

Whereas:

- (1) Commission Regulation (EEC) No 2123/89 ⁽³⁾, as last amended by Regulation (EC) No 1285/98 ⁽⁴⁾, established the list of representative markets for pigmeat in the Community.
- (2) In Ireland a change to the representative markets has taken place. The list of representative markets for pigmeat in the Community listed in the Annex to Regu-

lation (EEC) No 2123/89 should consequently be amended.

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

HAS ADOPTED THIS REGULATION:

Article 1

Point 7 of the Annex to Regulation (EEC) No 2123/89 is replaced by the following:

‘7. The following group of markets: Rooskey, Waterford and Mitchelstown.’

Article 2

This Regulation shall enter into force on 1 January 2001.

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

Done at Brussels, 12 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 282, 1.11.1975, p. 1.

⁽²⁾ OJ L 156, 29.6.2000, p. 5.

⁽³⁾ OJ L 203, 15.7.1989, p. 23.

⁽⁴⁾ OJ L 178, 23.6.1998, p. 5.

COMMISSION REGULATION (EC) No 2713/2000
of 12 December 2000
amending Regulation (EC) No 1555/96 on rules of application for additional import duties on fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables ⁽¹⁾, as last amended by Regulation (EC) No 1257/1999 ⁽²⁾, and in particular Article 33(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1555/96 ⁽³⁾, as last amended by Regulation (EC) No 2410/2000 ⁽⁴⁾, provides for surveillance of imports of the products listed in the Annex thereto. That surveillance is to be carried out in accordance with the rules on the surveillance of preferential imports laid down in Article 308d of Commission Regulation (EEC) No 2454/93 ⁽⁵⁾, as last amended by Regulation (EC) No 1602/2000 ⁽⁶⁾.
- (2) For the purposes of Article 5(4) of the Agreement on Agriculture ⁽⁷⁾ concluded during the Uruguay Round of multilateral trade negotiations and in the light of the

latest data available for 1997, 1998 and 1999, the trigger levels for additional duties on oranges should be amended.

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

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EC) No 1555/96 is replaced by the Annex hereto.

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, 12 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 297, 21.11.1996, p. 1.

⁽²⁾ OJ L 160, 26.6.1999, p. 80.

⁽³⁾ OJ L 193, 3.8.1996, p. 1.

⁽⁴⁾ OJ L 278, 31.10.2000, p. 5.

⁽⁵⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁶⁾ OJ L 188, 26.7.2000, p. 1.

⁽⁷⁾ OJ L 336, 23.12.1994, p. 22.

ANNEX

‘ANNEX

Without prejudice to the rules for the interpretation of the Combined Nomenclature, the description of the products is deemed to be indicative only. The scope of the additional duties for the purposes of this Annex is determined by the scope of the CN codes as they exist at the time of the adoption of this Regulation. Where “ex” appears before the CN code, the scope of the additional duties is determined both by the scope of the CN code and the corresponding trigger period.

Serial No	CN code	Description	Trigger period	Trigger level (tonnes)
78.0015 78.0020	ex 0702 00 00	Tomatoes	— 1 October to 31 March — 1 April to 30 September	501 111 639 884
78.0065 78.0075	ex 0707 00 05	Cucumbers	— 1 May to 31 October — 1 November to 30 April	22 411 11 658
78.0085	ex 0709 10 00	Artichokes	— 1 November to 30 June	661
78.0100	0709 90 70	Courgettes	— 1 January to 31 December	9 879
78.0110	ex 0805 10 10 ex 0805 10 30 ex 0805 10 50	Oranges	— 1 December to 31 May	372 855
78.0120	ex 0805 20 10	Clementines	— 1 November to end of February	100 949
78.0130	ex 0805 20 30 ex 0805 20 50 ex 0805 20 70 ex 0805 20 90	Mandarins (including tangerines and satsumas); wilkings and similar citrus hybrids	— 1 November to end of February	93 803
78.0155 78.0160	ex 0805 30 10	Lemons	— 1 June to 31 December — 1 January to 31 May	186 300 69 813
78.0170	ex 0806 10 10	Table grapes	— 21 July to 20 November	256 320
78.0175 78.0180	ex 0808 10 20 ex 0808 10 50 ex 0808 10 90	Apples	— 1 January to 31 August — 1 September to 31 December	625 202 88 229
78.0220 78.0235	ex 0808 20 50	Pears	— 1 January to 30 April — 1 July to 31 December	269 259 106 018
78.0250	ex 0809 10 00	Apricots	— 1 June to 31 July	2 236
78.0265	ex 0809 20 95	Cherries, other than sour cherries	— 21 May to 10 August	20 048
78.0270	ex 0809 30	Peaches, including nectarines	— 11 June to 30 September	349 940
78.0280	ex 0809 40 05	Plums	— 11 June to 30 September	41 539'

**COMMISSION REGULATION (EC) No 2714/2000
of 12 December 2000**

**determining the revised estimate of production of unginned cotton for the 2000/01 marketing year
and the relevant percentage increase**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Act of Accession of Greece, and in particular Protocol 4 on cotton, as last amended by Council Regulation (EC) No 1553/95 ⁽¹⁾,

Having regard to Council Regulation (EC) No 1554/95 of 29 June 1995 laying down general rules for the system of aid for cotton and repealing Regulation (EEC) No 2169/81 ⁽²⁾, as last amended by Regulation (EC) No 1419/98 ⁽³⁾, and in particular Article 8(2) thereof,

Whereas:

- (1) In accordance with Article 8(1) of Regulation (EC) No 1554/95, Commission Regulation (EC) No 1842/2000 ⁽⁴⁾ lays down the estimated production of unginned cotton for the 2000/01 marketing year.
- (2) Article 8(2) of Regulation (EC) No 1554/95 lays down that the revised estimate of production of unginned cotton and the percentage increase used in calculating the advance applicable from 16 December of the current marketing year must be determined by 1 December of each marketing year, account being taken of the progress of the harvest. Those figures should be fixed for the 2000/01 marketing year as indicated below on the basis of the information available. In order to ensure

that the new level of advance may be applied from the deadline laid down, this Regulation should enter into force on the day following its publication.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Flax and Hemp,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the 2000/01 marketing year, the revised estimate of production of unginned cotton is:

- 1 250 000 tonnes for Greece,
- 295 000 tonnes for Spain,
- 0 tonnes for other Member States.

2. For the 2000/01 marketing year, the percentage increase referred to in the second subparagraph of Article 5(3a) of Regulation (EC) No 1554/95 shall be 8,5 % for Greece and 7,5 % for Spain.

Article 2

This Regulation shall enter into force on the 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, 12 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 148, 30.6.1995, p. 45.

⁽²⁾ OJ L 148, 30.6.1995, p. 48.

⁽³⁾ OJ L 190, 4.7.1998, p. 4.

⁽⁴⁾ OJ L 220, 31.8.2000, p. 14.

COMMISSION REGULATION (EC) No 2715/2000
of 12 December 2000
on the authorisation of transfers between the quantitative limits of textiles and clothing products
originating in the People's Republic of China

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 3030/93 of 12 October 1993 on common rules for imports of certain textile products from third countries ⁽¹⁾, as last amended by Regulation (EC) No 2474/2000 ⁽²⁾, and in particular Article 7 thereof,

Whereas:

- (1) Article 5 of the Agreement between the Community and the People's Republic of China on trade in textiles products, initialled on 9 December 1988 ⁽³⁾ and as last amended and extended by an Agreement in the form of an Exchange of Letters, initialled on 15 May 2000, and Article 8 of the Agreement between the Community and the People's Republic of China initialled on 19 January 1995 on trade in textile products not covered by the MFA bilateral agreement ⁽⁴⁾ and as last amended by an Agreement in the form of an Exchange of Letters, initialled on 15 May 2000, provide that transfers may be agreed between quota years.
- (2) The People's Republic of China made a request on 30 May 2000.
- (3) The transfers requested by the People's Republic of China fall within the limits of the flexibility provisions referred to in Article 5 of the Agreement between the

Community and the People's Republic of China on trade in textiles products, initialled on 9 December 1988, and as set out in Annex VIII to Regulation (EEC) No 3030/93.

- (4) It is appropriate to grant the request.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Textile Committee provided for in Article 17 of Regulation (EEC) No 3030/93,

HAS ADOPTED THIS REGULATION:

Article 1

Transfers between the quantitative limits for textile goods originating in the People's Republic of China are authorised for the quota year 2000 as detailed in the Annex to this Regulation.

Article 2

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

It shall apply to the quota year 2000.

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

Done at Brussels, 12 December 2000.

For the Commission

Pascal LAMY

Member of the Commission

⁽¹⁾ OJ L 275, 8.11.1993, p. 1.

⁽²⁾ OJ L 286, 11.11.2000, p. 1.

⁽³⁾ OJ L 367, 31.12.1988, p. 75.

⁽⁴⁾ OJ L 104, 6.5.1995, p. 1.

ANNEX

Category 1:	carry over of 157 720 kilograms from year 1999 quantitative limits.
Category 2:	carry over of 160 335 kilograms from year 1999 quantitative limits.
Category 2A:	carry over of 66 880 kilograms from year 1999 quantitative limits.
Category 3:	carry over of 236 720 kilograms from year 1999 quantitative limits.
Category 3A:	carry over of 29 720 kilograms from year 1999 quantitative limits.
Category 4:	carry over of 1 951 817 pieces from year 1999 quantitative limits.
Category 5:	carry over of 50 882 pieces from year 1999 quantitative limits.
Category 6:	carry over of 22 665 pieces from year 1999 quantitative limits.
Category 6S:	carry over of 12 615 pieces from year 1999 quantitative limits.
Category 7:	carry over of 335 708 pieces from year 1999 quantitative limits.
Category 8:	carry over of 19 741 pieces from year 1999 quantitative limits.
Category 9:	carry over of 233 680 kilograms from year 1999 quantitative limits.
Category 10:	carry over of 1 696 860 pairs from year 1999 quantitative limits.
Category 12:	carry over of 2 470 pairs from year 1999 quantitative limits.
Category 13:	carry over of 781 728 pieces from year 1999 quantitative limits.
Category 14:	carry over of 51 941 pieces from year 1999 quantitative limits.
Category 15:	carry over of 92 843 pieces from year 1999 quantitative limits.
Category 16:	carry over of 626 720 pieces from year 1999 quantitative limits.
Category 17:	carry over of 427 960 pieces from year 1999 quantitative limits.
Category 18:	carry over of 4 702 kilograms from year 1999 quantitative limits.
Category 19:	carry over of 3 983 520 pieces from year 1999 quantitative limits.
Category 20/39:	carry over of 309 264 kilograms from year 1999 quantitative limits.
Category 21:	carry over of 666 000 pieces from year 1999 quantitative limits.
Category 22:	carry over of 649 200 kilograms from year 1999 quantitative limits.
Category 23:	carry over of 439 960 kilograms from year 1999 quantitative limits.
Category 24:	carry over of 1 700 320 pieces from year 1999 quantitative limits.
Category 26:	carry over of 7 624 pieces from year 1999 quantitative limits.
Category 28:	carry over of 127 405 pieces from year 1999 quantitative limits.
Category 29:	carry over of 453 720 pieces from year 1999 quantitative limits.
Category 31:	carry over of 139 759 pieces from year 1999 quantitative limits.
Category 32:	carry over of 160 240 kilograms from year 1999 quantitative limits.
Category 33:	carry over of 1 054 920 kilograms from year 1999 quantitative limits.
Category 37:	carry over of 542 120 kilograms from year 1999 quantitative limits.
Category 37A:	carry over of 160 680 kilograms from year 1999 quantitative limits.
Category 68:	carry over of 221 081 kilograms from year 1999 quantitative limits.
Category 73:	carry over of 11 206 pieces from year 1999 quantitative limits.
Category 76:	carry over of 55 720 kilograms from year 1999 quantitative limits.
Category 78:	carry over of 43 596 kilograms from year 1999 quantitative limits.
Category 83:	carry over of 131 614 kilograms from year 1999 quantitative limits.
Category 97:	carry over of 80 400 kilograms from year 1999 quantitative limits.
Category X13:	carry over of 28 560 pieces from year 1999 quantitative limits.

Category X18:	carry over of 37 840 kilograms from year 1999 quantitative limits.
Category X20:	carry over of 1 720 kilograms from year 1999 quantitative limits.
Category X24:	carry over of 7 200 pieces from year 1999 quantitative limits.
Category X39:	carry over of 16 120 kilograms from year 1999 quantitative limits.
Category X118:	carry over of 49 560 kilograms from year 1999 quantitative limits.
Category X120:	carry over of 19 520 kilograms from year 1999 quantitative limits.
Category X122:	carry over of 6 800 kilograms from year 1999 quantitative limits.
Category X123:	carry over of 3 320 kilograms from year 1999 quantitative limits.
Category X124:	carry over of 36 440 kilograms from year 1999 quantitative limits.
Category X125A:	carry over of 640 kilograms from year 1999 quantitative limits.
Category X127A:	carry over of 1 040 kilograms from year 1999 quantitative limits.
Category X127B:	carry over of 600 kilograms from year 1999 quantitative limits.
Category X136A:	carry over of 15 560 kilograms from year 1999 quantitative limits.
Category X140:	carry over of 5 000 kilograms from year 1999 quantitative limits.
Category X145:	carry over of 1 040 kilograms from year 1999 quantitative limits.
Category X146A:	carry over of 6 080 kilograms from year 1999 quantitative limits.
Category X146B:	carry over of 9 240 kilograms from year 1999 quantitative limits.
Category X151B:	carry over of 94 080 kilograms from year 1999 quantitative limits.
Category X156:	carry over of 122 920 kilograms from year 1999 quantitative limits.
Category X157:	carry over of 407 691 kilograms from year 1999 quantitative limits.
Category X159:	carry over of 166 080 kilograms from year 1999 quantitative limits.
Category X160:	carry over of 1 960 kilograms from year 1999 quantitative limits.
Category X161:	carry over of 594 560 kilograms from year 1999 quantitative limits.

**COMMISSION REGULATION (EC) No 2716/2000
of 12 December 2000
prohibiting fishing for cod by vessels flying the flag of a Member State**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2847/93 of 12 October 1993 establishing a control system applicable to the common fisheries policy ⁽¹⁾, as last amended by Regulation (EC) No 2846/98 ⁽²⁾, and in particular Article 21(3) thereof,

Whereas:

- (1) Council Regulation (EC) No 2742/1999 of 17 December 1999 fixing for 2000 the fishing opportunities and associated conditions for certain fish stocks and groups of fish stocks, applicable in Community waters and, for Community vessels, in waters where limitations in catch are required and amending Regulation (EC) No 66/98 ⁽³⁾, as last amended by Regulation (EC) No 2579/2000 ⁽⁴⁾, lays down quotas for cod for 2000.
- (2) In order to ensure compliance with the provisions relating to the quantity limits on catches of stocks subject to quotas, the Commission must fix the date by which catches made by vessels flying the flag of a Member State are deemed to have exhausted the quota allocated to the Community.

- (3) According to the information received by the Commission, catches of cod in the waters of ICES zones I and II (Norwegian waters) by vessels flying the flag of a Member State or registered in a Member State have exhausted the quota allocated to the Community for 2000,

HAS ADOPTED THIS REGULATION:

Article 1

Catches of cod in the waters of ICES zones I and II (Norwegian waters) by vessels flying the flag of a Member State or registered in a Member State are hereby deemed to have exhausted the quota allocated to the Community for 2000.

Fishing for cod in the waters of ICES zones I and II (Norwegian waters) by vessels flying the flag of a Member State or registered in a Member State is hereby prohibited, as are the retention on board, transshipment and landing of this stock caught by the above vessels after the date of application of this Regulation.

Article 2

This Regulation shall enter into force on the 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, 12 December 2000.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 261, 20.10.1993, p. 1.

⁽²⁾ OJ L 358, 31.12.1998, p. 5.

⁽³⁾ OJ L 341, 31.12.1999, p. 1.

⁽⁴⁾ OJ L 298, 25.11.2000, p. 3.

DIRECTIVE 2000/69/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 November 2000
relating to limit values for benzene and carbon monoxide in ambient air

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

After consultation of the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) On the basis of principles enshrined in Article 174 of the Treaty, the European Community programme of policy and action in relation to the environment and sustainable development (the Fifth Environment Action Programme) ⁽⁴⁾, supplemented by Decision No 2179/98/EC of the European Parliament and the Council ⁽⁵⁾ on its review, envisages in particular amendments to legislation on air pollutants. That programme recommends the establishment of long-term objectives on air quality. Article 174 of the Treaty requires the precautionary principle to be applied in relation to the protection of human health and the environment.
- (2) Article 152 of the Treaty provides that health-protection requirements are to form a constituent part of the Community's other policies. Article 3(1)(p) of the Treaty provides that the activities of the Community are to include a contribution to the attainment of a high level of health protection.
- (3) Pursuant to Article 4(5) of Council Directive 96/62/EC of 27 September 1996 on ambient air quality assessment and management ⁽⁶⁾, the Council is to adopt the legislation provided for in paragraph 1 as well as the provisions laid down in paragraphs 3 and 4 of that Article.
- (4) Directive 96/62/EC requires that action plans be developed for zones within which concentrations of pollutants in ambient air exceed limit values, plus any temporary margins of tolerance applicable in order to ensure compliance with limit values by the dates laid down.

(5) Directive 96/62/EC provides that the numerical values for limit values are to be based on the findings of work carried out by international scientific groups active in the field. The Commission is to take account of the most recent scientific research data in the epidemiological and environmental fields concerned and of the most recent advances in metrology for re-examining the elements on which limit values are based.

(6) 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 ⁽⁷⁾.

(7) The amendments necessary for adaptation to scientific and technical progress may relate solely to criteria and techniques for the assessment of concentrations of benzene and carbon monoxide or detailed arrangements for forwarding information to the Commission, and may not have the effect of modifying limit values either directly or indirectly.

(8) The limit values laid down in this Directive are minimum requirements; in accordance with Article 176 of the Treaty, Member States may maintain or introduce more stringent protective measures; in particular, stricter limit values may be introduced to protect the health of particularly vulnerable categories of the population, such as children and hospital patients. A Member State may require that limit values be attained before the dates laid down in this Directive.

(9) Benzene is a human genotoxic carcinogen and there is no identifiable threshold below which there is no risk to human health.

(10) However, when limit values for benzene as set by this Directive are difficult to achieve because of site-specific dispersion characteristics or relevant climatic conditions and if the application of the measures would result in severe socio-economic problems, Member States may ask the Commission for one time-limited extension under specific conditions.

(11) In order to facilitate the review of this Directive in 2004, the Commission and the Member States should consider encouraging research into the effects of benzene and carbon monoxide, taking air pollution in enclosed spaces into account as well as that in outside air.

⁽¹⁾ OJ C 53, 24.2.1999, p. 8.

⁽²⁾ OJ C 138, 18.5.1999, p. 42.

⁽³⁾ Opinion of the European Parliament of 2 December 1999 (OJ C 194, 11.7.2000, p. 56), Council Common Position of 10 April 2000 (OJ C 195, 11.7.2000, p. 1) and Decision of the European Parliament of 6 July 2000 (not yet published in the Official Journal). Council Decision of 24 October 2000.

⁽⁴⁾ OJ C 138, 17.5.1993, p. 5.

⁽⁵⁾ OJ L 275, 10.10.1998, p. 1.

⁽⁶⁾ OJ L 296, 21.11.1996, p. 55.

⁽⁷⁾ OJ L 184, 17.7.1999, p. 23.

- (12) Standardised accurate measurement techniques and common criteria for the location of measuring stations are an important element in the assessment of ambient air quality with a view to obtaining comparable information across the Community.
- (13) Information on concentrations of benzene and carbon monoxide should be forwarded to the Commission as a basis for regular reports.
- (14) Up-to-date information on concentrations of benzene and carbon monoxide in ambient air should be readily available to the public,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Objectives

The objectives of this Directive shall be:

- (a) to establish limit values for concentrations of benzene and carbon monoxide in ambient air intended to avoid, prevent or reduce harmful effects on human health and the environment as a whole;
- (b) to assess concentrations of benzene and carbon monoxide in ambient air on the basis of common methods and criteria;
- (c) to obtain adequate information on concentrations of benzene and carbon monoxide in ambient air and ensure that it is made available to the public;
- (d) to maintain ambient air quality where it is good and improve it in other cases with respect to benzene and carbon monoxide.

Article 2

Definitions

The definitions in Article 2 of Directive 96/62/EC shall apply.

For the purposes of this Directive:

- (a) 'upper assessment threshold' shall mean a level specified in Annex III, below which a combination of measurements and modelling techniques may be used to assess ambient air quality, in accordance with Article 6(3) of Directive 96/62/EC;
- (b) 'lower assessment threshold' shall mean a level specified in Annex III, below which modelling or objective estimation techniques alone may be used to assess ambient air quality in accordance with Article 6(4) of Directive 96/62/EC;
- (c) 'fixed measurements' shall mean measurements taken in accordance with Article 6(5) of Directive 96/62/EC.

Article 3

Benzene

1. Member States shall take the measures necessary to ensure that concentrations of benzene in ambient air, as assessed in accordance with Article 5, do not exceed the limit

value laid down in Annex I according to the dates mentioned therein.

The margin of tolerance laid down in Annex I shall apply in accordance with Article 8 of Directive 96/62/EC.

2. When the limit value laid down in Annex I is difficult to achieve because of site-specific dispersion characteristics or relevant climatic conditions, such as low windspeed and/or conditions conducive to evaporation, and if the application of the measures were to result in severe socio-economic problems, a Member State may ask the Commission for a time-limited extension. The Commission, acting in accordance with the procedure laid down in Article 12(2) of Directive 96/62/EC, may, at the request of a Member State and without prejudice to Article 8(3) of this Directive, grant one extension for a period of up to five years if the Member State concerned:

- designates the zones and/or agglomerations concerned;
- provides the necessary justification for such an extension;
- demonstrates that all reasonable measures have been taken to lower the concentrations of the pollutants concerned and to minimise the area over which the limit value is exceeded, and
- outlines the future developments with regard to the measures which it will take according to Article 8(3) of Directive 96/62/EC.

The limit value for benzene to be granted during that time-limited extension shall, however, not exceed 10 µg/m³.

Article 4

Carbon monoxide

Member States shall take the measures necessary to ensure that concentrations of carbon monoxide in ambient air, as assessed in accordance with Article 5, do not exceed the limit value laid down in Annex II according to the dates mentioned therein.

The margin of tolerance laid down in Annex II shall apply in accordance with Article 8 of Directive 96/62/EC.

Article 5

Assessment of concentrations

1. The upper and lower assessment thresholds for benzene and carbon monoxide shall be those laid down in Section I of Annex III.

The classification of each zone or agglomeration for the purposes of Article 6 of Directive 96/62/EEC shall be reviewed at least every five years in accordance with the procedure laid down in Section II of Annex III to this Directive. Classification shall be reviewed earlier in the event of significant change in activities relevant to ambient concentrations of benzene or carbon monoxide.

2. The criteria for determining the location of sampling points for the measurement of benzene and carbon monoxide in ambient air shall be those listed in Annex IV. The minimum number of sampling points for fixed measurements of concentrations of each relevant pollutant shall be as laid down in Annex V, and they shall be installed in each zone or agglomeration within which measurement is required if fixed measurement is the sole source of data on concentrations within it.

3. For zones and agglomerations within which information from fixed measurement stations is supplemented by information from other sources, such as emission inventories, indicative measurement methods and air quality modelling, the number of fixed measuring stations to be installed and the spatial resolution of other techniques shall be sufficient for the concentrations of air pollutants to be established in accordance with Section I of Annex IV, and Section I of Annex VI.

4. For zones and agglomerations within which measurement is not required, modelling or objective-estimation techniques may be used.

5. The reference methods for the analysis and the sampling of benzene and carbon monoxide shall be as laid down in Sections I and II of Annex VII. Section III of Annex VII will set out reference techniques for air quality modelling when such techniques are available.

6. The date by which Member States shall inform the Commission of the methods used for the preliminary assessment of air quality under point (d) of Article 11(1) of Directive 96/62/EC shall be the date set out in Article 10 of this Directive.

7. Any amendments necessary to adapt the provisions of this Article and Annexes III to VII to scientific and technical progress shall be adopted in accordance with the procedure referred to in Article 6(2) but may not result in any direct or indirect changes to limit values.

Article 6

Committee

1. The Commission shall be assisted by the committee referred to in Article 12(2) of Directive 96/62/EC, hereinafter referred to as 'the Committee'.

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

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

3. The Committee shall adopt its rules of procedure.

Article 7

Public information

1. Member States shall ensure that up-to-date information on ambient concentrations of benzene and carbon monoxide is routinely made available to the public as well as to appropriate

organisations, such as environmental organisations, consumer organisations, organisations representing the interests of sensitive populations and other relevant health-care bodies, by means, for example, of broadcast media, press, information screens or computer-network services, teletext, telephone or fax.

Information on ambient concentrations of benzene, as an average value over the last 12 months, shall be updated on at least a three-monthly basis and, wherever practicable, information shall be updated on a monthly basis. Information on ambient concentrations of carbon monoxide, as a maximum running average over eight hours, shall be updated on at least a daily basis and, wherever practicable, information shall be updated on an hourly basis.

The information referred to in the second subparagraph shall at least indicate any exceedances of the concentrations stated in the limit values over the averaging periods laid down in Annexes I and II. It shall also provide a short assessment in relation to limit values and appropriate information regarding effects on health.

2. When making plans or programmes available to the public under Article 8(3) of Directive 96/62/EC, Member States shall also make them available to the organisations referred to in paragraph 1 of this Article. This also includes the documentation required by Annex VI(II) of this Directive.

3. Information made available to the public and to organisations under paragraphs 1 and 2 shall be clear, comprehensible and accessible.

Article 8

Report and review

1. No later than 31 December 2004 the Commission shall submit to the European Parliament and the Council a report based on the experience acquired in the application of this Directive and, in particular, on the results of the most recent scientific research concerning the effects on human health, paying particular attention to sensitive populations, and on ecosystems of exposure to benzene and carbon monoxide, and on technological developments including the progress achieved in methods of measuring and otherwise assessing concentrations of benzene and carbon monoxide in ambient air.

2. The report referred to in paragraph 1 shall take into account in particular as regards benzene and carbon monoxide:

- (a) current air quality and trends up to and beyond the year 2010;
- (b) the scope for making further reductions to polluting emissions across all relevant sources, taking account of their technical feasibility and cost-effectiveness;
- (c) the relationships between pollutants and opportunities for combined strategies for achieving Community air quality and related objectives;

- (d) current and future requirements for informing the public and for the exchange of information between Member States and Commission;
- (e) the experience acquired in the application of this Directive in Member States including, in particular, the conditions laid down in Annex IV under which measurement has been carried out.

3. With a view to maintaining a high level of protection of human health and the environment, the report referred to in paragraph 1 shall be accompanied, if appropriate, by proposals for the amendment of this Directive which could include further extensions to the timetable for meeting the limit value for benzene in Annex I which may be agreed under Article 3(2).

Article 9

Penalties

Member States shall determine the penalties applicable to breaches of the national provisions adopted pursuant to this Directive. The penalties shall be effective, proportionate and dissuasive.

Article 10

Implementation

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this

Directive by 13 December 2002 at the latest. They shall forthwith inform the Commission thereof.

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

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

Article 11

Entry into force

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

Article 12

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 16 November 2000.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

R. SCHWARTZENBERG

ANNEX I

LIMIT VALUE FOR BENZENE

The limit value must be expressed in $\mu\text{g}/\text{m}^3$, standardised at a temperature of 293 K and a pressure of 101,3 kPa.

	Averaging period	Limit value	Margin of tolerance	Date by which limit value is to be met
Limit value for the protection of human health	Calendar year	5 $\mu\text{g}/\text{m}^3$	5 $\mu\text{g}/\text{m}^3$ (100 %) on 13 December 2000, reducing on 1 January 2006 and every 12 months thereafter by 1 $\mu\text{g}/\text{m}^3$ to reach 0 % by 1 January 2010	1 January 2010 ⁽¹⁾

⁽¹⁾ Except within zones and agglomerations within which a time-limited extension has been agreed in accordance with Article 3(2).

ANNEX II

LIMIT VALUE FOR CARBON MONOXIDE

The limit value must be expressed in mg/m^3 . The volume must be standardised at a temperature of 293 K and a pressure of 101,3 kPa.

	Averaging period	Limit value	Margin of tolerance	Date by which limit value is to be met
Limit value for the protection of human health	Maximum daily 8-hour mean	10 mg/m^3	6 mg/m^3 on 13 December, reducing on 1 January 2003 and every 12 months thereafter by 2 mg/m^3 to reach 0 % by 1 January 2005	1 January 2005

The maximum daily 8-hour mean concentration will be selected by examining 8-hour running averages, calculated from hourly data and updated each hour. Each 8-hour average so calculated will be assigned to the day on which it ends, i.e. the first calculation period for any one day will be the period from 17:00 on the previous day to 01:00 on that day; the last calculation period for any one day will be the period from 16:00 to 24:00 on that day.

ANNEX III

DETERMINATION OF REQUIREMENTS FOR ASSESSMENT OF CONCENTRATIONS OF BENZENE AND CARBON MONOXIDE IN AMBIENT AIR WITHIN A ZONE OR AGGLOMERATION**I. Upper and lower assessment thresholds**

The following upper and lower assessment thresholds will apply:

(a) Benzene

	Annual average
Upper assessment threshold	70 % of limit value (3,5 µg/m ³)
Lower assessment threshold	40 % of limit value (2 µg/m ³)

(b) Carbon Monoxide

	Eight-hour average
Upper assessment threshold	70 % of limit value (7 mg/m ³)
Lower assessment threshold	50 % of limit value (5 mg/m ³)

II. Determination of exceedances of upper and lower assessment thresholds

Exceedances of upper and lower assessment thresholds must be determined on the basis of concentrations during the previous five years where sufficient data are available. An assessment threshold will be deemed to have been exceeded if it has been exceeded during at least three separate years out of those previous five years.

Where fewer than five years' data are available, Member States may combine measurement campaigns of short duration during the period of the year and at locations likely to be typical of the highest pollution levels with results obtained from information from emission inventories and modelling to determine exceedances of the upper and lower assessment thresholds.

ANNEX IV

LOCATION OF SAMPLING POINTS FOR THE MEASUREMENT OF CONCENTRATIONS OF BENZENE AND CARBON MONOXIDE IN AMBIENT AIR

The following considerations will apply to fixed measurement.

I. Macroscale siting

Sampling points directed at the protection of human health should be sited:

- (i) to provide data on the areas within zones and agglomerations where the highest concentrations occur to which the population is likely to be directly or indirectly exposed for a period which is significant in relation to the averaging period of the limit value(s);
- (ii) to provide data on levels in other areas within the zones and agglomerations which are representative of the exposure of the general population.

Sampling points should in general be sited to avoid measuring very small micro-environments in their immediate vicinity. As a guideline, a sampling point should be sited to be representative of air quality in a surrounding area of no less than 200 m² at traffic-orientated sites and of several square kilometres at urban-background sites.

Sampling points should also, where possible, be representative of similar locations not in their immediate vicinity.

Account should be taken of the need to locate sampling points on islands, where that is necessary for the protection of human health.

II. Microscale siting

The following guidelines should be met as far as practicable:

- the flow around the inlet sampling probe should be unrestricted, without any obstructions affecting the airflow in the vicinity of the sampler (normally some metres away from buildings, balconies, trees and other obstacles and at least 0,5 m from the nearest building in the case of sampling points representing air quality at the building line);
- in general, the inlet sampling point should be between 1,5 m (the breathing zone) and 4 m above the ground. Higher positions (up to 8 m) may be necessary in some circumstances. Higher siting may also be appropriate if the station is representative of a large area;
- the inlet probe should not be positioned in the immediate vicinity of sources in order to avoid direct intake of emissions unmixed with ambient air;
- the sampler's exhaust outlet should be positioned so that recirculation of exhaust air to the sample inlet is avoided;
- location of traffic-orientated samplers:
 - for all pollutants, such sampling points should be at least 25 metres from the edge of major junctions and at least 4 m from the centre of the nearest traffic lane;
 - for carbon monoxide, inlets should be no more than 5 m from the kerbside;
 - for benzene, inlets should be sited so as to be representative of air quality near to the building line.

The following factors may also be taken into account:

- interfering sources;
- security;
- access;
- availability of electrical power and telephone communications;
- visibility of the site in relation to its surroundings;
- safety of public and operators;
- the desirability of co-locating sampling points for different pollutants;
- planning requirements.

III. Documentation and review of site selection

The site selection procedures should be fully documented at the classification stage by such means as compass-point photographs of the surrounding area and a detailed map. Sites should be reviewed at regular intervals with repeated documentation to ensure that selection criteria remain valid over time.

ANNEX V

CRITERIA FOR DETERMINING NUMBERS OF SAMPLING POINTS FOR FIXED MEASUREMENT OF CONCENTRATIONS OF BENZENE AND CARBON MONOXIDE IN AMBIENT AIR

Minimum number of sampling points for fixed measurement to assess compliance with limit values for the protection of human health in zones and agglomerations where fixed measurement is the sole source of information:

(a) Diffuse sources

Population of agglomeration or zone (thousands)	If concentrations exceed the upper assessment threshold ⁽¹⁾	If maximum concentrations are between the upper and lower assessment thresholds
0-249	1	1
250-499	2	1
500-749	2	1
750-999	3	1
1 000-1 499	4	2
1 500-1 999	5	2
2 000-2 749	6	3
2 750-3 749	7	3
3 750-4 749	8	4
4 750-5 999	9	4
≥ 6 000	10	5

⁽¹⁾ To include at least one urban-background station and one traffic-oriented station provided this does not increase the number of sampling points.

(b) Point sources

For the assessment of pollution in the vicinity of point sources, the number of sampling points for fixed measurement should be calculated taking into account emission densities, the likely distribution patterns of ambient air pollution and potential exposure of the population.

ANNEX VI

DATA QUALITY OBJECTIVES AND COMPILATION OF RESULTS OF AIR QUALITY ASSESSMENT

I. Data quality objectives

The following data quality objectives, for allowed uncertainty of assessment methods, and of minimum time coverage and of data capture of measurement are provided to guide quality-assurance programmes.

	Benzene	Carbon monoxide
<i>Fixed measurements</i> ⁽¹⁾		
Uncertainty	25 %	15 %
Minimum data capture	90 %	90 %
Minimum time coverage	35 % urban background and traffic sites (distributed over the year to be representative of various conditions for climate and traffic) 90 % industrial sites	
<i>Indicative measurements</i>		
Uncertainty	30 %	25 %
Minimum data capture	90 %	90 %
Minimum time coverage	14 % (one day's measurement a week at random, evenly distributed over the year, or 8 weeks evenly distributed over the year)	14 % (one measurement a week at random, evenly distributed over the year, or 8 weeks evenly distributed over the year)
<i>Modelling</i>		
Uncertainty:		
Eight-hour averages	—	50 %
Annual averages	50 %	—
<i>Objective estimation</i>		
Uncertainty	100 %	75 %

⁽¹⁾ Member States may apply random measurements instead of continuous measurements for benzene if they can demonstrate to the Commission that the uncertainty, including the uncertainty due to random sampling, meets the quality objective of 25 %. Random sampling must be evenly distributed over the year in order to avoid skewing of results.

The uncertainty (on a 95 % confidence interval) of the assessment methods will be evaluated in accordance with the principles of the ISO Guide to the Expression of Uncertainty in Measurement (1993) or the methodology of ISO 5725:1994 or equivalent. The percentages for uncertainty in the above table are given for individual measurements averaged over the period considered by the limit value, for a 95 % confidence interval. The uncertainty for the fixed measurements should be interpreted as being applicable in the region of the appropriate limit value. Until such time as CEN standards with detailed test protocols are fully adopted, the Commission will issue, before the adoption of this Directive, the guidelines for use developed by CEN.

The uncertainty for modelling and objective estimation is defined as the maximum deviation of the measured and calculated concentration levels, over the period considered, by the limit value, without taking into account the timing of the events.

The requirements for minimum data capture and time coverage do not include losses of data due to the regular calibration or the normal maintenance of the instrumentation.

II. Results of air quality assessment

The following information should be compiled for zones or agglomerations within which sources other than measurement are employed to supplement information from measurement or as the sole means of air quality assessment:

- a description of assessment activities carried out;
- the specific methods used, with references to descriptions of the method;
- the sources of data and information;
- a description of results, including uncertainties and, in particular, the extent of any area or, if relevant, the length of road within the zone or agglomeration over which concentrations exceed limit value(s) or, as may be, limit value(s) plus applicable margin(s) of tolerance and of any area within which concentrations exceed the upper assessment threshold or the lower assessment threshold;
- for limit values the object of which is the protection of human health, the population potentially exposed to concentrations in excess of the limit value.

Where possible, Member States should compile maps showing concentration distributions within each zone and agglomeration.

III. Standardisation

For benzene and carbon monoxide the measurement result must be standardised at a temperature of 293 K and a pressure of 101,3 kPa.

ANNEX VII

REFERENCE METHODS FOR ASSESSMENT OF CONCENTRATIONS OF BENZENE AND CARBON MONOXIDE

I. Reference method for the sampling/analysis of benzene

The reference method for the measurement of benzene will be the pumped sampling method on a sorbent cartridge followed by gas chromatographic determination that is currently being standardised by CEN. In the absence of a CEN standardised method, Member States are allowed to use national standard methods based on the same measurement method.

A Member State may also use any other method which it can demonstrate gives results equivalent to the above method.

II. Reference method for the analysis of carbon monoxide

The reference method for the measurement of carbon monoxide will be the non-dispersive infra-red spectrometric (NDIR) method, that is currently being standardised by CEN. In the absence of a CEN standardised method, the Member States are allowed to use national standard methods based on the same measurement method.

A Member State may also use any other method which it can demonstrate gives results equivalent to the above method.

III. Reference modelling techniques

Reference modelling techniques cannot be specified at present. Any amendments to adapt this point to scientific and technical progress must be adopted in accordance with the procedure laid down in Article 6(2).

**DIRECTIVE 2000/70/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 November 2000**

**amending Council Directive 93/42/EEC as regards medical devices incorporating stable derivatives of
human blood or human plasma**

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

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

Having regard to the proposal from the Commission ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽³⁾,

Whereas:

- (1) In addition to being directed at medical devices for *in vitro* diagnosis, the Commission proposal sought to amend Council Directive 93/42/EEC of 14 June 1993 concerning medical devices ⁽⁴⁾ in order to extend its scope to medical devices manufactured by using non-viable tissues or substances of human origin derived from those tissues. This amendment was not included in Directive 98/79/EC ⁽⁵⁾ when it was adopted.
- (2) This Directive accordingly aims at amending Directive 93/42/EEC so as to include in its scope only devices which incorporate, as an integral part, substances derived from human blood or plasma. However, medical devices incorporating other substances derived from human tissues remain excluded from the scope of the said Directive.
- (3) The essential aim of any rules governing the production, distribution or use of medical devices must be to safeguard public health.
- (4) Furthermore, national provisions for the safety and health protection of patients, users and, where appropriate, other persons, with regard to the use of medical devices must be harmonised in order to guarantee free movement of such devices within the internal market.
- (5) Medical devices incorporating, as an integral part, substances derived from human blood or plasma have the same purposes as other medical devices. There is therefore no reason to treat them differently as regards their free circulation.

- (6) Medical devices incorporating, as an integral part, a substance derived from human blood or plasma and which is liable to act upon the body with action ancillary to that of the device must comply with the provisions of Directive 93/42/EEC and other instruments supplementing the said Directive.
- (7) A human blood derivative, if used separately, may be considered to be a medicinal product constituent within the meaning of Council Directive 89/381/EEC ⁽⁶⁾. When it is incorporated into a medical device, the substance must be subject to appropriate checks by analogy with Council Directives 75/318/EEC ⁽⁷⁾ and 89/381/EEC. These checks will be carried out by the authorities empowered to implement the aforesaid Directives,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 93/42/EEC is hereby amended as follows:

1. Article 1 shall be amended as follows:

(a) the following paragraph shall be inserted:

'4 a. Where a device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of Article 1 of Directive 89/381/EEC ^(*) and which is liable to act upon the human body with action ancillary to that of the device, hereinafter referred to as a "human blood derivative", that device must be assessed and authorised in accordance with this Directive.

^(*) Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma (OJ L 181, 28.6.1989, p. 44).';

⁽¹⁾ OJ C 172, 7.7.1995, p. 21 and

OJ C 87, 18.3.1997, p. 9.

⁽²⁾ OJ C 18, 22.1.1996, p. 12.

⁽³⁾ Opinion of the European Parliament of 12 March 1996 (OJ C 96, 1.4.1996, p. 31), Council Common Position of 29 June 2000 (OJ C 245, 25.8.2000, p. 19) and European Parliament Decision of 24 October 2000.

⁽⁴⁾ OJ L 169, 12.7.1993, p. 1. Directive as amended by Directive 98/79/EC of the European Parliament and of the Council (OJ L 331, 7.12.1998, p. 1).

⁽⁵⁾ Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

⁽⁶⁾ Council Directive 89/381/EEC of 14 June 1989 extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma (OJ L 181, 28.6.1989, p. 44).

⁽⁷⁾ Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of Member States relating to analytical, pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products (OJ L 147, 9.6.1975, p. 1). Directive as last amended by Commission Directive 1999/83/EC (OJ L 243, 15.9.1999, p. 9).

- (b) in paragraph 5, point (e) shall be replaced by the following:

‘(e) human blood, blood products, plasma or blood cells of human origin with the exception of human blood derivatives;’

2. Annex I shall be amended as follows:

- (a) in section 7.4, the following subparagraphs shall be added:

‘Where a device incorporates, as an integral part, a human blood derivative, the notified body shall seek a scientific opinion from the European Agency for the Evaluation of Medicinal Products (EMA) on the quality and safety of the derivative, taking account of the appropriate Community provisions and, in particular, by analogy with the provisions of Directives 75/318/EEC and 89/381/EEC. The usefulness of the derivative as a part of the medical device shall be verified, taking account of the intended purpose of the device.

In accordance with Article 4(3) of Directive 89/381/EEC, a sample from each batch of bulk and/or finished product of the human blood derivative shall be tested by a State laboratory or a laboratory designated for that purpose by a Member State.’

- (b) in section 13.3, the following subparagraph shall be added:

‘(n) in the case of a device within the meaning of Article 1(4a), an indication that the device contains a human blood derivative.’

3. Annex II shall be amended as follows:

- (a) in section 3.2(c), the fifth indent shall be replaced by the following:

‘— a statement indicating whether or not the device incorporates, as an integral part, a substance or a human blood derivative referred to in section 7.4 of Annex I and the data on the tests conducted in this connection required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device.’;

- (b) in section 4.3, the second and third subparagraphs shall be replaced by the following subparagraphs:

‘In the case of devices referred to in Annex I, section 7.4, first subparagraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 65/65/EEC before taking a decision. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, section 7.4, second subparagraph, the scientific opinion of the EMA must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the EMA when making its decision. The notified body may not deliver the certificate if the EMA's scientific opinion is unfavourable. It will convey its final decision to the EMA.’;

- (c) the following section shall be added:

‘8. Application to the devices referred to Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device, issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.’

4. Annex III shall be amended as follows:

- (a) in section 3, the sixth indent shall be replaced by the following:

‘— a declaration stating whether or not the device incorporates, as an integral part, a substance or human blood derivative, referred to in section 7.4 of Annex I, and the data on the tests conducted in this connection which are required to assess the safety, quality and usefulness of that substance or human blood derivative, taking account of the intended purpose of the device.’;

- (b) in section 5, the second and third subparagraphs shall be replaced by the following subparagraphs:

‘In the case of devices referred to in Annex I, section 7.4, first subparagraph, the notified body shall, as regards the aspects referred to in that section, consult one of the competent bodies designated by the Member States in accordance with Directive 65/65/EEC before taking a decision. The notified body will give due consideration to the views expressed in this consultation when making its decision. It will convey its final decision to the competent body concerned.

In the case of devices referred to in Annex I, section 7.4, second subparagraph, the scientific opinion of the EMA must be included in the documentation concerning the device. The notified body will give due consideration to the opinion of the EMA when making its decision. The notified body may not deliver the certificate if the EMA's scientific opinion is unfavourable. It will convey its final decision to the EMA.’

5. In Annex IV, the following section shall be added:

‘9. Application to devices referred to in Article 1(4a):

In the case of section 5, upon completing the manufacture of each batch of devices referred to in Article 1(4a), and in the case of verification under section 6, the manufacturer shall inform the notified body of the release of this batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.’

6. In Annex V, the following section shall be added:

‘7. Application to devices referred to in Article 1(4a):

Upon completing the manufacture of each batch of devices referred to in Article 1(4a), the manufacturer shall inform the notified body of the release of the batch of devices and send to it the official certificate concerning the release of the batch of human blood derivative used in the device issued by a State laboratory or a laboratory designated for that purpose by a Member State in accordance with Article 4(3) of Directive 89/381/EEC.’

7. In Annex IX, Part III, section 4.1, the following subparagraph shall be added:

‘All devices incorporating, as an integral part, a human blood derivative are in Class III.’

Article 2

Implementation, transitional provisions

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

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

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

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

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 16 November 2000.

For the European Parliament

The President

N. FONTAINE

For the Council

The President

R. SCHWARZENBERG

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 27 November 2000

on the grant of funds to the Hellenic Republic in order to compensate partially for the interest paid on European Investment Bank loans for the reconstruction of the region which was devastated by the earthquake of September 1999

(2000/786/EC)

THE COUNCIL OF THE EUROPEAN UNION,

HAS DECIDED AS FOLLOWS:

Having regard to the Treaty establishing the European Community, and in particular Article 308 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Whereas:

- (1) A subsidy to compensate partially for the interest paid on the European Investment Bank loans for the reconstruction of the region of the Hellenic Republic which was devastated by the earthquake of September 1999 should be granted to the Hellenic Republic.
- (2) This subsidy should be chargeable to the general budget of the European Union.
- (3) The Treaty provides for no powers other than those in Article 308 thereof for the adoption of this Decision,

Article 1

The Community shall make available to the Hellenic Republic funds of EUR 2 million in order to compensate partially for the interest paid in 2000 on loans received from the EIB for the reconstruction of buildings, infrastructure and industrial installations (including small and medium enterprises) in the Attica region affected by the earthquake of September 1999. The Commission is hereby empowered to pay these funds in one instalment on terms which it shall agree with the Hellenic Republic and the EIB.

Article 2

This Decision shall take effect on the day of its publication in the *Official Journal of the European Communities*.

Done at Brussels, 27 November 2000.

For the Council

The President

L. FABIUS

⁽¹⁾ Opinion delivered on 15 November 2000 (not yet published in the Official Journal).