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Legislation

Contents

(Continued overleaf)

EN

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

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

II *Acts whose publication is not obligatory*

Commission

(1) Text with EEA relevance

EN

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1814/98

of 20 August 1998

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,

Having regard to Council Regulation (EEC) No 3813/92 of 28 December 1992 on the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy [3], as last amended by Regulation (EC) No 150/95 [4], and in particular Article 3 (3) thereof,

Whereas 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;

Whereas, 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 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

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[1] OJ L 337, 24. 12. 1994, p. 66.
[2] OJ L 198, 15. 7. 1998, p. 4.
[3] OJ L 387, 31. 12. 1992, p. 1.
[4] OJ L 22, 31. 1. 1995, p. 1.

ANNEX

to the Commission Regulation of 20 August 1998 establishing the standard import values for determining the entry price of certain fruit and vegetables

(ECU/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	060	57,2
	999	57,2
0709 90 70	052	27,3
	999	27,3
0805 30 10	382	59,4
	388	65,7
	524	67,1
	528	65,5
	999	64,4
0806 10 10	052	87,7
	600	40,7
	624	160,0
	999	96,1
0808 10 20, 0808 10 50, 0808 10 90	388	62,9
	400	72,0
	508	93,5
	512	57,7
	524	30,3
	528	51,3
	804	83,7
	999	64,5
0808 20 50	052	83,0
	064	59,7
	388	57,5
	528	106,0
	999	76,6
0809 30 10, 0809 30 90	052	119,3
	400	124,4
	999	121,9
0809 40 05	052	58,0
	060	59,8
	064	65,5
	066	65,6
	093	65,9
	624	191,4
	999	84,4

(1) Country nomenclature as fixed by Commission Regulation (EC) No 2317/97 (OJ L 321, 22. 11. 1997, p. 19). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1815/98

of 20 August 1998

fixing the rates of the refunds applicable to certain cereal and rice-products exported in the form of goods not covered by Annex II to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organization of the market in cereals ([1]), as last amended by Commission Regulation (EC) No 923/96 ([2]), and in particular Article 13 (3) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organization of the market in rice ([3]), as amended by Regulation (EC) No 192/98 ([4]), and in particular Article 13 (3) thereof,

Whereas Article 13 (1) of Regulation (EEC) No 1766/92 and Article 13 (1) of Regulation (EC) No 3072/95 provide that the difference between quotations of prices on the world market for the products listed in Article 1 of each of those Regulations and the prices within the Community may be covered by an export refund;

Whereas Commission Regulation (EC) No 1222/94 of 30 May 1994 laying down common implementing rules for granting export refunds on certain agricultural products exported in the form of goods not covered by Annex II to the Treaty, and the criteria for fixing the amount of such refunds ([5]), as last amended by Regulation (EC) No 1352/98 ([6]), specifies the products for which a rate of refund should be fixed, to be applied where these products are exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to Regulation (EC) No 3072/95 as appropriate;

Whereas, in accordance with the first subparagraph of Article 4 (1) of Regulation (EC) No 1222/94, the rate of the refund per 100 kilograms for each of the basic products in question must be fixed for each month;

Whereas, now that a settlement has been reached between the European Community and the United States of America on Community exports of pasta products to the United States and has been approved by Council Decision 87/482/EEC ([7]), it is necessary to differentiate the refund on goods falling within CN codes 1902 11 00 and 1902 19 according to their destination;

Whereas Article 4 (5) (b) of Regulation (EC) No 1222/94 provides that, in the absence of the proof referred to in Article 4 (5) (a) of that Regulation, a reduced rate of export refund has to be fixed, taking account of the amount of the production refund applicable, pursuant to Commission Regulation (EEC) No 1722/93 ([8]), as last amended by Regulation (EC) No 1011/98 ([9]), for the basic product in question, used during the assumed period of manufacture of the goods;

Whereas the Management Committee for Cereals has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products appearing in Annex A to Regulation (EC) No 1222/94 and listed either in Article 1 of Regulation (EEC) No 1766/92 or in Article 1 (1) of Regulation (EC) No 3072/95, exported in the form of goods listed in Annex B to Regulation (EEC) No 1766/92 or in Annex B to amended Regulation (EC) No 3072/95 respectively, are hereby fixed as shown in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 21 August 1998.

([1]) OJ L 181, 1. 7. 1992, p. 21.
([2]) OJ L 126, 24. 5. 1996, p. 37.
([3]) OJ L 329, 30. 12. 1995, p. 18.
([4]) OJ L 20, 27. 1. 1998, p. 16.
([5]) OJ L 136, 31. 5. 1994, p. 5.
([6]) OJ L 184, 27. 6. 1998, p. 25.
([7]) OJ L 275, 29. 9. 1987, p. 36.
([8]) OJ L 159, 1. 7. 1993, p. 112.
([9]) OJ L 145, 15. 5. 1998, p. 11.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

ANNEX

to the Commission Regulation of 20 August 1998 fixing the rates of the refunds applicable to certain cereals and rice products exported in the form of goods not covered by Annex II to the Treaty

CN code	Description of products (1)	Rate of refund per 100 kg of basic product
1001 10 00	Durum wheat:	
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	—
	– in other cases	—
1001 90 99	Common wheat and meslin:	
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	1,901
	– in other cases:	
	– – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2)	0,303
	– – in other cases	2,924
1002 00 00	Rye	4,127
1003 00 90	Barley	4,759
1004 00 00	Oats	3,394
1005 90 00	Maize (corn) used in the form of:	
	– starch:	
	– – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2)	1,875
	– – in other cases	5,152
	– glucose, glucose syrup, maltodextrine, maltodextrine syrup of CN codes 1702 30 51, 1702 30 59, 1702 30 91, 1702 30 99, 1702 40 90, 1702 90 50, 1702 90 75, 1702 90 79, 2106 90 55 (3):	
	– – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2)	1,318
	– – in other cases	4,595
	– other (including unprocessed)	5,152
	Potato starch of CN code 1108 13 00 similar to a product obtained from processed maize:	
	– where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2)	0,875
	– in other cases	4,152
1006 20	Husked rice:	
	– round grain	—
	– medium grain	—
	– long grain	—
ex 1006 30	Wholly-milled rice:	
	– round grain	—
	– medium grain	—
	– long grain	—
1006 40 00	Broken rice used in the form of:	
	– starch of CN code 1108 19 10:	
	– – where pursuant to Article 4 (5) of Regulation (EC) No 1222/94 (2)	—
	– – in other cases	2,700
	– other (including unprocessed)	2,700

CN code	Description of products (1)	Rate of refund per 100 kg of basic product
1007 00 90	Sorghum	4,759
1101 00	Wheat or meslin flour:	
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of Amercia	2,338
	– in other cases	3,597
1102 10 00	Rye flour	5,654
1103 11 10	Groats and durum wheat meal:	
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	—
	– in other cases	—
1103 11 90	Common wheat groats and spelt:	
	– on exports of goods falling within CN codes 1902 11 and 1902 19 to the United States of America	2,338
	– in other cases	3,597

(1) As far as agricultural products obtained from the processing of a basic product or/and assimilated products are concerned, the coefficients shown in Annex E of amended Commission Regulation (EC) No 1222/94 shall be applied (OJ L 136, 31. 5. 1994, p. 5).

(2) The goods concerned are listed in Annex I of amended Regulation (EEC) No 1722/93 (OJ L 159, 1. 7. 1993, p. 112).

(3) For syrups of CN codes NC 1702 30 99, 1702 40 90 and 1702 60 90, obtained from mixing glucose and fructose syrup, the export refund may be granted only for the glucose syrup.

COMMISSION REGULATION (EC) No 1816/98

of 20 August 1998

fixing the maximum export refund on barley in connection with the invitation to tender issued in Regulation (EC) No 1078/98

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 923/96 [2],

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals [3], as last amended by Regulation (EC) No 2052/97 [4], and in particular Article 4 thereof,

Whereas an invitation to tender for the refund and/or the tax for the export of barley to all third countries was opened pursuant to Commission Regulation (EC) No 1078/98 [5];

Whereas Article 7 of Regulation (EC) No 1501/95 provides that the Commission may, on the basis of the tenders notified, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92, decide to fix a maximum export refund taking account of the criteria referred to in Article 1 of Regulation (EC) No 1501/95; whereas in that case a contract is awarded to any tenderer whose bid is equal to or lower than the maximum refund, as well as to any tenderer whose bid relates to an export tax;

Whereas the application of the abovementioned criteria to the current market situation for the cereal in question results in the maximum export refund being fixed at the amount specified in Article 1;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

For tenders notified from 14 to 20 August 1998, pursuant to the invitation to tender issued in Regulation (EC) No 1078/98, the maximum refund on exportation of barley shall be ECU 53,86 per tonne.

Article 2

This Regulation shall enter into force on 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

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[1] OJ L 181, 1. 7. 1992, p. 21.
[2] OJ L 126, 24. 5. 1996, p. 37.
[3] OJ L 147, 30. 6. 1995, p. 7.
[4] OJ L 287, 21. 10. 1997, p. 14.
[5] OJ L 154, 28. 5. 1998, p. 20.

COMMISSION REGULATION (EC) No 1817/98

of 20 August 1998

fixing the maximum export refund on common wheat in connection with the invitation to tender issued in Regulation (EC) No 1079/98

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 923/96 [2],

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals [3], as last amended by Regulation (EC) No 2052/97 [4], and in particular Article 4 thereof,

Whereas an invitation to tender for the refund and/or the tax for the export of common wheat to all third countries was opened pursuant to Commission Regulation (EC) No 1079/98 [5];

Whereas Article 7 of Regulation (EC) No 1501/95 provides that the Commission may, on the basis of the tenders notified, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92, decide to fix a maximum export refund taking account of the criteria referred to in Article 1 of Regulation (EC) No 1501/95; whereas in that case a contract is awarded to any tenderer whose bid is equal to or lower than the maximum refund, as well as to any tenderer whose bid relates to an export tax;

Whereas the application of the abovementioned criteria to the current market situation for the cereal in question results in the maximum export refund being fixed at the amount specified in Article 1;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

For tenders notified from 14 to 20 August 1998, pursuant to the invitation to tender issued in Regulation (EC) No 1079/98, the maximum refund on exportation of common wheat shall be ECU 32,98 per tonne.

Article 2

This Regulation shall enter into force on 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

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[1] OJ L 181, 1. 7. 1992, p. 21.
[2] OJ L 126, 24. 5. 1996, p. 37.
[3] OJ L 147, 30. 6. 1995, p. 7.
[4] OJ L 287, 21. 10. 1997, p. 14.
[5] OJ L 154, 28. 5. 1998, p. 24.

COMMISSION REGULATION (EC) No 1818/98

of 20 August 1998

fixing the maximum export refund on rye in connection with the invitation to tender issued in Regulation (EC) No 1746/98

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 923/96 [2],

Having regard to Commission Regulation (EC) No 1501/95 of 29 June 1995 laying down certain detailed rules for the application of Council Regulation (EEC) No 1766/92 on the granting of export refunds on cereals and the measures to be taken in the event of disturbance on the market for cereals [3], as last amended by Regulation (EC) No 2052/97 [4], and in particular Article 7 thereof,

Whereas an invitation to tender for the refund and/or the tax for the export of rye to all third countries was opened pursuant to Commission Regulation (EC) No 1746/98 [5];

Whereas Article 7 of Regulation (EC) No 1501/95 provides that the Commission may, on the basis of the tenders notified, in accordance with the procedure laid down in Article 23 of Regulation (EEC) No 1766/92, decide to fix a maximum export refund taking account of the criteria referred to in Article 1 of Regulation (EC) No 1501/95; whereas in that case a contract is awarded to any tenderer whose bid is equal to or lower than the maximum refund, as well as to any tenderer whose bid relates to an export tax;

Whereas the application of the abovementioned criteria to the current market situation for the cereal in question results in the maximum export refund being fixed at the amount specified in Article 1;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

For tenders notified from 14 to 20 August 1998, pursuant to the invitation to tender issued in Regulation (EC) No 1746/98, the maximum refund on exportation of rye shall be ECU 55,00 per tonne.

Article 2

This Regulation shall enter into force on 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

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[1] OJ L 181, 1. 7. 1992, p. 21.
[2] OJ L 126, 24. 5. 1996, p. 37.
[3] OJ L 147, 30. 6. 1995, p. 7.
[4] OJ L 287, 21. 10. 1997, p. 14.
[5] OJ L 219, 7. 8. 1998, p. 3.

COMMISSION REGULATION (EC) No 1819/98

of 20 August 1998

fixing the export refunds on products processed from cereals and rice

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organization of the market in cereals [1], as last amended by Commission Regulation (EC) No 923/96 [2], and in particular Article 13 (3) thereof,

Having regard to Council Regulation (EC) No 3072/95 of 22 December 1995 on the common organization of the market in rice [3], as amended by Regulation (EC) No 192/98 [4], and in particular Article 13 (3) thereof,

Whereas Article 13 of Regulation (EEC) No 1766/92 and Article 13 of Regulation (EC) No 3072/95 provide that the difference between quotations or prices on the world market for the products listed in Article 1 of those Regulations and prices for those products within the Community may be covered by an export refund;

Whereas Article 13 of Regulation (EC) No 3072/95 provides that when refunds are being fixed account must be taken of the existing situation and the future trend with regard to prices and availabilities of cereals, rice and broken rice on the Community market on the one hand and prices for cereals, rice, broken rice and cereal products on the world market on the other; whereas the same Articles provide that it is also important to ensure equilibrium and the natural development of prices and trade on the markets in cereals and rice and, furthermore, to take into account the economic aspect of the proposed exports, and the need to avoid disturbances on the Community market;

Whereas Article 4 of Commission Regulation (EC) No 1518/95 [5], as amended by Regulation (EC) No 2993/95 [6], on the import and export system for products processed from cereals and from rice defines the specific criteria to be taken into account when the refund on these products is being calculated;

Whereas the refund to be granted in respect of certain processed products should be graduated on the basis of the ash, crude fibre, tegument, protein, fat and starch content of the individual product concerned, this content being a particularly good indicator of the quantity of basic product actually incorporated in the processed product;

Whereas there is no need at present to fix an export refund for manioc, other tropical roots and tubers or flours obtained therefrom, given the economic aspect of potential exports and in particular the nature and origin of these products; whereas, for certain products processed from cereals, the insignificance of Community participation in world trade makes it unnecessary to fix an export refund at the present time;

Whereas the world market situation or the specific requirements of certain markets may make it necessary to vary the refund for certain products according to destination;

Whereas the refund must be fixed once a month; whereas it may be altered in the intervening period;

Whereas certain processed maize products may undergo a heat treatment following which a refund might be granted that does not correspond to the quality of the product; whereas it should therefore be specified that on these products, containing pregelatinized starch, no export refund is to be granted;

Whereas the Management Committee for Cereals has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1 (1) (d) of Regulation (EEC) No 1766/92 and in Article 1 (1) (c) of Regulation (EC) No 3072/95 and subject to Regulation (EC) No 1518/95 are hereby fixed as shown in the Annex to this Regulation.

[1] OJ L 181, 1. 7. 1992, p. 21.
[2] OJ L 126, 24. 5. 1996, p. 37.
[3] OJ L 329, 30. 12. 1995, p. 18.
[4] OJ L 20, 27. 1. 1998, p. 16.
[5] OJ L 147, 30. 6. 1995, p. 55.
[6] OJ L 312, 23. 12. 1995, p. 25.

Article 2

This Regulation shall enter into force on 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

ANNEX

to the Commission Regulation of 20 August 1998 fixing the export refunds on products processed from cereals and rice

(ECU/tonne)

Product code	Refund
1102 20 10 9200 (1)	72,13
1102 20 10 9400 (1)	61,82
1102 20 90 9200 (1)	61,82
1102 90 10 9100	71,39
1102 90 10 9900	48,54
1102 90 30 9100	61,09
1103 12 00 9100	61,09
1103 13 10 9100 (1)	92,74
1103 13 10 9300 (1)	72,13
1103 13 10 9500 (1)	61,82
1103 13 90 9100 (1)	61,82
1103 19 10 9000	41,27
1103 19 30 9100	73,76
1103 21 00 9000	29,82
1103 29 20 9000	48,54
1104 11 90 9100	71,39
1104 12 90 9100	67,88
1104 12 90 9300	54,30
1104 19 10 9000	29,82
1104 19 50 9110	82,43
1104 19 50 9130	66,98
1104 21 10 9100	71,39
1104 21 30 9100	71,39
1104 21 50 9100	95,18
1104 21 50 9300	76,14
1104 22 20 9100	54,30
1104 22 30 9100	57,70
1104 23 10 9100	77,28
1104 23 10 9300	59,25
1104 29 11 9000	29,82
1104 29 51 9000	29,24
1104 29 55 9000	29,24
1104 30 10 9000	7,31
1104 30 90 9000	12,88
1107 10 11 9000	52,05
1107 10 91 9000	84,71
1108 11 00 9200	58,48
1108 11 00 9300	58,48
1108 12 00 9200	82,43
1108 12 00 9300	82,43
1108 13 00 9200	66,43
1108 13 00 9300	66,43
1108 19 10 9200	41,04
1108 19 10 9300	41,04
1109 00 00 9100	0,00
1702 30 51 9000 (2)	96,04
1702 30 59 9000 (2)	73,52
1702 30 91 9000	96,04
1702 30 99 9000	73,52
1702 40 90 9000	73,52
1702 90 50 9100	96,04
1702 90 50 9900	73,52
1702 90 75 9000	100,63
1702 90 79 9000	69,84
2106 90 55 9000	73,52

(1) No refund shall be granted on products given a heat treatment resulting in pregelatinization of the starch.

(2) Refunds are granted in accordance with Council Regulation (EEC) No 2730/75 (OJ L 281, 1. 11. 1975, p. 20), amended.

NB: The product codes and the footnotes are defined in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24. 12. 1987, p. 1), amended.

COMMISSION REGULATION (EC) No 1820/98

of 20 August 1998

fixing the export refunds on cereal-based compound feedingstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organization of the market in cereals [1], as last amended by Commission Regulation (EC) No 923/96 [2], and in particular Article 13 (3) thereof,

Whereas Article 13 of Regulation (EEC) No 1766/92 provides that the difference between quotations or prices on the world market for the products listed in Article 1 of that Regulation and prices for those products within the Community may be covered by an export refund;

Whereas Regulation (EC) No 1517/95 of 29 June 1995 laying down detailed rules for the application of Regulation (EEC) No 1766/92 as regards the arrangements for the export and import of compound feedingstuffs based on cereals and amending Regulation (EC) No 1162/95 laying down special detailed rules for the application of the system of import and export licences for cereals and rice [3] in Article 2 lays down general rules for fixing the amount of such refunds;

Whereas that calculation must also take account of the cereal products content; whereas in the interest of simplification, the refund should be paid in respect of two categories of 'cereal products', namely for maize, the most commonly used cereal in exported compound feeds and maize products, and for 'other cereals', these being eligible cereal products excluding maize and maize products; whereas a refund should be granted in respect of the quantity of cereal products present in the compound feedingstuff;

Whereas furthermore, the amount of the refund must also take into account the possibilities and conditions for the sale of those products on the world market, the need to avoid disturbances on the Community market and the economic aspect of the export;

Whereas, however, in fixing the rate of refund it would seem advisable to base it at this time on the difference in the cost of raw inputs widely used in compound feedingstuffs as the Community and world markets, allowing more accurate account to be taken of the commercial conditions under which such products are exported;

Whereas the refund must be fixed once a month; whereas it may be altered in the intervening period;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Cereals,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the compound feedingstuffs covered by Regulation (EEC) No 1766/92 and subject to Regulation (EC) No 1517/95 are hereby fixed as shown in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 21 August 1998.

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

Done at Brussels, 20 August 1998.

For the Commission

Karel VAN MIERT

Member of the Commission

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[1] OJ L 181, 1. 7. 1992, p. 21.
[2] OJ L 126, 24. 5. 1996, p. 37.
[3] OJ L 147, 30. 6. 1995, p. 51.

ANNEX

to the Commission Regulation of 20 August 1998 fixing the export refunds on cereal-based compound feedingstuffs

Product code benefitting from export refund (1):

2309 10 11 9000, 2309 10 13 9000, 2309 10 31 9000, 2309 10 33 9000, 2309 10 51 9000, 2309 10 53 9000, 2309 90 31 9000, 2309 90 33 9000, 2309 90 41 9000, 2309 90 43 9000, 2309 90 51 9000, 2309 90 53 9000.

(ECU/tonne)

Cereal products (2)	Amount of refund (2)
Maize and maize products: CN codes 0709 90 60, 0712 90 19, 1005, 1102 20, 1103 13, 1103 29 40, 1104 19 50, 1104 23, 1904 10 10	51,52
Cereal products (2) excluding maize and maize products	38,42

(1) The product codes are defined in Sector 5 of the Annex to Commission Regulation (EEC) No 3846/87 (OJ L 366, 24. 12. 1987, p 1), amended.

(2) For the purposes of the refund only the starch coming from cereal products is taken into account.

Cereal products means the products falling within subheadings 0709 90 60 and 0712 90 19, Chapter 10, and headings Nos 1101, 1102, 1103 and 1104 (excluding subheading 1104 30) and the cereals content of the products falling within subheadings 1904 10 10 and 1904 10 90 of the combined nomenclature. The cereals content in products under subheadings 1904 10 10 and 1904 10 90 of the combined nomenclature is considered to be equal to the weight of this final product.

No refund is paid for cereals where the origin of the starch cannot be clearly established by analysis.

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 4 February 1998

declaring a concentration to be compatible with the common market and the functioning of the EEA Agreement

(Case No IV/M.950 — Hoffmann La Roche/Boehringer Mannheim)

(notified under document number C(1998) 70)

(Only the English text is authentic)

(Text with EEA relevance)

(98/526/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Agreement on the European Economic Area, and in particular Article 57(2)(a) thereof,

Having regard to Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings [1], as amended by the Act of Accession of Austria, Finland and Sweden, and in particular Article 8(2) thereof,

Having regard to the Commission decision of 2 October 1997 to initiate proceedings in this case,

Having given the undertakings concerned the opportunity to make known their views on the objections raised by the Commission,

Having regard to the opinion of the Advisory Committee on Concentrations [2],

Whereas:

(1) On 1 September 1997, the Hoffmann-La Roche Group (Roche) notified an acquisition, through its affiliate Roche Healthcare Ltd, of all of the shares of Corange Ltd from four family groups, by which Roche is acquiring sole control of Corange within the meaning of Article 3(1)(b) of Regulation (EEC) No 4064/89 (the Merger Regulation).

(2) By decision of 22 September 1997 the Commission ordered the continuation of the suspension of the notified concentration, pursuant to Article 7(2) and Article 18(2) of the Merger Regulation, until a final decision is reached in this case. On 2 October 1997, the Commission decided to initiate proceedings pursuant to Article 6(1)(c) of the Merger Regulation.

(3) During the investigation of the case, the Agreement between the European Community and the Government of the United States of America regarding the application of their competition law [3] has been activated.

[1] OJ L 395, 30. 12. 1989, p. 1; corrigendum OJ L 257, 21. 9. 1990, p. 13.
[2] OJ C 264, 21. 8. 1998.
[3] OJ L 95, 27. 4. 1995, p. 47.

I. THE PARTIES

(4) Roche is mainly active in the production and distribution of pharmaceuticals, vitamins and fine chemicals, diagnostics, flavours and fragrances.

(5) Corange Ltd (Corange) is a holding company with no operative business activities of its own which controls the whole of the Boehringer Mannheim Group (BM) and owns 84,2 % of the shares of DePuy Inc. BM is a manufacturer and distributor of diagnostics, pharmaceuticals and biochemicals. DePuy is a manufacturer and distributor of orthopaedic products and devices.

II. THE OPERATION

(6) The proposed operation consists in the acquisition of 100 % of the equity of Corange by Roche. Roche will assume sole control of Corange and thus of BM and DePuy.

III. COMMUNITY DIMENSION

(7) Roche and Corange have a combined aggregate worldwide turnover in excess of ECU 5 000 million (Roche: ECU 10 184 million, Corange: ECU 3 327 million). Both have a Community-wide turnover in excess of ECU 250 million (Roche: ECU 4 923 million, Corange: ECU 1 668 million) but do not achieve more than two thirds of their aggregate turnover within one and the same Member State. The notified operation therefore has a Community dimension.

IV. COMPETITIVE ASSESSMENT

(8) Roche and Corange (through BM) have partly overlapping business activities in *in vitro* diagnostics and pharmaceutical products.

(9) According to the information provided by the parties, there are no overlaps in orthopaedics, fragrances, flavours, fine chemicals, biochemicals, and vitamins (in bulk quantity). Vitamins in bulk quantity are sold in large quantities to the animal feed industry, food industry, cosmetics industry and pharmaceutical industry and are as such not substitutable with medicines (vitamin compounds).

A. PHARMACEUTICAL PRODUCTS

1. Relevant product markets

(10) The Commission has on many occasions dealt with the definition of the relevant market in the case of pharmaceutical products and has established a number of principles in its previous decisions (see decisions of 10 June 1991, Sanofi/Sterling Drug (Case IV/M.072), 29 April 1993, Procordia/Erbamont (Case IV/M.323), 18 April 1994, Rhône-Poulenc/Cooper (Case IV/M.426), 20 June 1994, La Roche/Syntex (Case IV/M.457), 19 September 1994, AHP/Cynamid (Case IV/M.500), 28 February 1995, Glaxo/Wellcome (Case IV/M.555), 3 April 1995, Behringwerke AG/Armour Pharmaceutical Co. (Case IV/M.495), 22 June 1995, Hoechst/Marion Merrell Dow (Case IV/M.587), 28 September 1995, Upjohn/Pharmacia (Case IV/M.631)). In those decisions, it noted that medicines may be subdivided into therapeutic classes by reference to the Anatomical therapeutic classification (ATC), which is recognised and used by the World Health Organisation. This classification allows medicines to be grouped together by reference to their composition and their therapeutic properties. The third level of the ATC classification allows medicines to be grouped in terms of their therapeutic indications, i.e. their intended use, and can therefore be used as an operational market definition. However, it may be appropriate to carry out analyses at other levels of the ATC classification.

(11) Medicines may, moreover, be subdivided into various segments on the basis of a variety of criteria, and in particular demand-related criteria. A possible distinction is that between medicines which can be issued only on prescription and those which can be sold over the counter. A further distinction is that between medicines which are refunded in whole or in part by sickness insurance schemes and those which are not reimbursed. These segments partly overlap. Most medicines issued only on prescription are reimbursed, whereas most of those which may be sold over the counter are not reimbursed. Furthermore, the allocation of a medicine to a particular segment is not permanent. It is based instead on decisions by the authorities, which may lead to changes between segments.

(12) The parties agree with the Commission that in most cases it is appropriate to base the market definition on the third-level of the ATC classification since the third level products generally serve the same treatment purpose and are not interchangeable with products from other classes. The parties have identified the following product markets as affected by the concentration: cephalosporins (J1D), anti-coagulants, non-injectable (B1A), antiacids, antiflatulents (A2A), laxatives (A6A), immunostimulants (L3A), non-steroids (M11A), vitamin B1 compounds (A11D), and hepatic protectors, lipotropics (A5B).

(13) In the pharmaceuticals industry, a full assessment of the competitive situation requires examination of the products which are not yet on the market but which are at an advanced stage of development (normally after extremely large sums of money have been invested). The potential for these products to enter into competition with other products which either are at the development stage or are already on the market can be assessed only by reference to their characteristics and intended therapeutic use. In so doing, it must be borne in mind that research and development cannot as a rule be traded between pharmaceutical companies, but are rather intended primarily for the development of a company's own active substances and products. On the other hand, cooperation takes place in the research field between pharmaceutical companies and public and private research institutes and small biotechnology undertakings which, although they have the relevant know-how, do not themselves have the resources and facilities for the clinical testing that must be carried out prior to market authorisation and for the manufacture of the pharmaceuticals. The Commission has to look at R&D potential in terms of its importance for existing markets, but also for future markets.

(14) In so far as research and development must be assessed in terms of its importance for future markets, the relevant product market must, in the nature of things, be defined in a less clear-cut manner than in the case of existing markets. Market definition can be based on the existing ATC classes only if existing products are to be replaced. Otherwise, it must be guided primarily by the indications to which the fixture products are to be applied.

2. **Relevant geographic markets**

(15) There are efforts at European standardisation as regards pharmaceutical products. The harmonisation of technical provisions within the Community and the entry into force of new registration procedures for medicines represent the completion of the programme for the single market in terms of the scientific and technical requirements applying to medicines. Since the beginning of 1995, pharmaceutical companies have had the option (and indeed, in the case of biotechnology products, the obligation) of submitting an application for registration of a new medicine to the European Agency for the Evaluation of Medicinal Products, which then issues a recommendation to the Commission, whose decision is binding on all Member States. At present, medicines can be registered in different Member States for different indications.

(16) The sale of medicines is influenced by the administrative procedures or purchasing policies which the national health authorities have introduced in the Member States. Some countries exercise a direct or indirect influence on prices, and there are different levels of reimbursement by the social-security system for different categories of medicines. For this reason, the prices for medicinal products may differ from one Member State to another. In addition, there are far-reaching differences in terms of brand and pack-size strategies and in distribution systems. These differences lead to national market characteristics.

(17) The markets for pharmaceutical products have therefore been defined as national markets in the decisions hitherto adopted by the Commission. This view is accepted by the parties in their notification. The markets affected by the concentration can thus be regarded as national.

(18) To the extent that future product markets can be considered on the basis of research and development in particular areas, the said national restrictions do not have the same degree of effectiveness. A characteristic of fixture markets is that no products have yet been registered. Because research and development is normally global, the consideration of future markets should therefore focus on the territory of the Community at least, and possibly on worldwide markets.

3. **Assessment**

(19) In most product markets affected by the concentration there will be no competitive problem, since the parties combined market share is below 25 % and since there are a number of strong international competitors.

(20) According to the parties, the only overlaps that will lead to market shares above 25 % are in Italy in antirheumatic non-steroids (M1A), vitamin B1 compounds (A11D), and hepatic protectors, lipotropics (A5B).

(21) In the Italian market for M1A (BM [< 30 %] [1], Roche [< 5 %]) and A5B (BM [< 30 %], Roche [< 5 %]), there are a number of other international competitors like Novartis, Pfizer, and Pharmacia & Upjohn.

(22) In Italy in A11D, where BM has a share of [< 20 %] and Roche of [< 50 %], the parties' combined market share will be [< 70 %]. One of Roche's products (Benerva) with a market share of [< 5 %] is not fully substitutable to BM's and Roche's other products as it is not a compound composed of vitamins B1, B6, and B12, but of B1 only. The major competitor is Bioindustria (Pfizer-Group) (21,6 %) Other competitors are Lepetit (Hoechst-Group), Angelini, Bracco, Guidotti, and Menarini. The market has a volume of ECU 10 million. All major products in this market were introduced several decades ago, with the exception of the Pfizer product Neuraben. This product has in the last six years almost doubled its market share and competed vigorously with Roche's and BM's products. This situation is unlikely to change after the merger. In addition, it is important to note that all products belonging to class A11D are patent-free and not reimbursed by the Italian National Health Service. It is therefore possible for the doctor and the patient to freely choose other brands. If BM/Roche were to raise its price, customers could easily switch to the competing products. They would have an incentive to do so, as A11D products are not reimbursed in Italy and thus need to be fully paid by the consumer. As the barriers to entry are low, other pharmaceutical companies could easily start production of A11D products or import products sold in other Member States if consumer demand increased or if prices were to rise. For these reasons, the concentration does not threaten to create or strengthen a dominant position in this product market.

(23) During the investigation it was suggested that the overlap between Roche and BM in the market for drugs used for the treatment, management and prevention of acute myocardial infarctions (heart attacks) could in the future be a cause for competitive concern. The investigation has, however, revealed that this problem is only related to the US market. In Europe the Genentech (Roche) product Activase is licensed to an independent third party (Boehringer Ingelheim). This company has its own production facility in Europe and is not dependent on Genentech for the supply of either raw materials or finished products. The competitive situation therefore does not change as a result of this concentration.

(24) Finally, in the fields of active substances, as well as research and development, the investigation has not revealed any significant overlaps, outside the field of tissue plasminogen activators, used for the production of the abovementioned heart attack medicines.

B. *IN VITRO* DIAGNOSTICS

1. **Relevant product markets**

(a) *Overview*

(25) The concentration concerns the area of diagnostic analysis. A diagnostic analysis is a procedure for monitoring the physiological condition of a subject. The analytical procedures differ, depending on whether they are designed for analysing the general health condition of a subject, a specific illness, a pre-birth pathology, or whether they concern the reaction of a subject to certain substances.

(26) Diagnostic tests can be performed either *in vitro* or *in vivo*. *In vitro* (literally in glass) diagnostic (IVD) tests are conducted outside the body and are used to identify and measure substances in patients' tissue, blood or urine samples which enable physicians to diagnose, treat and monitor patients. The *in vivo* method concerns the use of diagnostic substances directly in or on the human body. The two methods are complementary for some applications.

(27) Roche and BM are active only in the field of *in vitro* diagnostics. A large part of the *in vitro* diagnostics is sold in the form of multi-use diagnostics systems to hospitals, commercial laboratories, university laboratories or other institutions. In addition, a significant quantity of *in vitro* diagnostics is marketed as single-use products to general practitioners, public authorities, employers or others, and in some instances they are even sold as self-test kits over the counter (rapid tests, for example for pregnancy, diabetes and cholesterol). Self-test kits probably are complementary to multi-use test kits for some applications.

(28) The concentration between Roche and BM concerns primarily multi-use *in vitro* diagnostics (including DNA probes, see below), which are used on site. These diagnostics products generally form a system, composed of a measuring instrument which is designed for the automated operation of

[1] In the published version of this Decision, some information has been omitted or replaced by approximate figures, pursuant to Article 17(2) of the Merger Regulation (EEC) No 4064/89 concerning non-disclosure of business secrets.

several kinds of tests and reagents for that instrument. The reagents, i.e. the compounds and liquids used to perform tests, are supplied as part of a reagent kit which includes a control substance and a test serum to verify the smooth functioning of the measuring instrument. A calibrator serves for regular, often weekly, adjustments to the measuring instruments.

(29) The main part of the multi-use products business is characterised by a series of test kits which are adapted to a system. Most of the major suppliers offer a package consisting of a measuring instrument, a series of test kits and a comprehensive after-sales service including quality control. The development of a new system requires relatively large sums. The companies in the diagnostics industry spend about 10 % of their total turnover on R&D. Only up to 20 % of the turnover is achieved through the sale of instruments, while reagent kits account for most of the rest.

(30) This explains why competition in the diagnostics market is mainly focused on securing sales of reagents and why the suppliers have a strong interest in obtaining long-term orders for a continuous supply of reagent kits. Diagnostics manufacturers follow different strategies in the pursuit of this aim. There is a trend among diagnostic companies to market their products as closed systems which are designed for the exclusive use of their reagents. It is also a common feature of the industry that delivery contracts with customers are concluded for several years. Often, the instruments are only leased or otherwise put at the customer's disposal at a very low cost, or even without charge, on condition that the customer purchases a certain number of reagent kits over a certain time period (several years). These instruments are obviously not free of charge for the customers, as the instrument costs are included in the reagent price. In this respect, the Commission investigation indicates that a bought instrument would normally have an amortisation period of five years, but that the diagnostic industry in its internal calculations for a reagent-leasing contract would calculate a shorter amortisation. Within five years, the customer would thus have paid more for the instrument than he would have paid if he had purchased it directly. The rationale behind accepting such offers as this is that the customers, public and private laboratories, often prefer for budgetary or other reasons, to have the total cost of the system charged to them as running costs, rather than as long-term investments in instruments. The various suppliers, including the parties, have therefore designed several sales methods where the price for the instrument is not charged separately, but instead included in the price of reagents.

(31) The investigation has largely confirmed the parties' view that, from a technical viewpoint, the reagents of a certain supplier can be used on the instrument of another producer, provided that the technologies correspond to each other, and that this may apply even for closed systems, depending on the means employed to achieve the closeness of the system (specific container shapes, bar-codes, etc.). It appears, however, that the switch from one reagent supplier to the other requires a certain know-how and investment in terms of time and effort on the part of the customer. Whereas some large customers have indicated an unwillingness to become dependent on one specific supplier or on closed systems, the majority of customers contacted by the Commission have indicated that they generally have not used third-party reagents to any greater extent. This is also consistent with the fact that the capture rates, i.e. the extent to which diagnostic suppliers continue to sell reagents to customers that have purchased their instruments, of the parties (as well as most of their competitors) are generally high.

(32) The field of *in vitro* diagnostics can be divided into five main segments: clinical chemistry, immunochemistry, haematology/histology, microbiology (culture) and infectious immunology [1]. This corresponds to the first level of the product classification produced by the European Diagnostics Manufacturers Association, the EDMA classification, which seems to be generally accepted in the industry and which is used to compile sales data for individual reagents on a European scale. During the Commission's investigation, most customers, on the other hand, stated that they were not familiar with this classification. For the segments affected by that operation, however, they did confirm that it was a sensible way to classify diagnostics also from a demand-side point of view. In addition, DNA probes, which encompass tests in several areas (infectious diseases, oncology, genetic diseases and tissue typing) and are currently undergoing strong expansion, will be assessed below.

[1] See Cases IV/M.457 — Roche/Syntex, IV/M.954 — Bain/Hoechst — Dade Behring.

(33) The concentration between Roche and BM would lead to major overlaps in the fields of classical clinical chemistry and immunochemistry diagnostics. It would also have significant effects in the field of DNA probes.

(b) *Classical clinical chemistry reagents*

(34) Classical clinical chemistry diagnostics are primarily used to test for glucose, cholesterol, sodium and other substances found in large concentrations in the body. These tests are typically run for both routine and emergency patients to help doctors understand the performance of basic bodily functions.

(35) On its second level, the EDMA classification distinguishes seven different product groups in classical clinical chemistry. The parties, however, are of the opinion that the only relevant distinction for market definition purposes is that between rapid tests and clinical chemistry (CC) reagents. Rapid tests are primarily manual tests for glucose-monitoring, mostly carried out by patients themselves or by doctors. Reagents on the other hand are used to perform diagnostic tests on instruments in laboratories. The Commission's investigation has confirmed that rapid tests constitute a separate product market, due to differences in customers, distribution channels and competitive conditions. The question whether all rapid tests constitute one product market or whether there are separate product markets, e.g. for blood-test strips and urine-test strips, may be left open because in all alternative market definitions considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

(36) As regards reagents, the parties stated in the notification that all CC reagents can be grouped together since they have common characteristics, as customers regularly buy almost all of their requirements for such tests from one source and, on the supply side, all major suppliers offer the same range of instruments and reagents. The Commission's investigation has confirmed that the conditions of competition are indeed identical for the reasons invoked by the parties, and that it thus is possible to group these reagents in one product market, although they are strictly speaking not substitutable from a demand-side point of view.

(37) In later submissions, the parties extended this market definition by stating that some immunochemistry reagents, the homogenous immunoassays (HIA), should be included in the same product market with clinical chemistry reagents, since customers would buy CC and HIA reagents from the same source, since new clinical chemistry instruments, such as the Roche Integra, could also be used for HIA tests, and since all major suppliers would offer the same product range. The Commission's investigation has however found that the conditions of competition for HIAs are different from those for CC reagents, and that they therefore should not be included in the same product market. First, HIA reagents have different product characteristics from clinical chemistry reagents. Immunochemistry tests require a more complex detection technology. They measure other substances and are capable of detecting much lower concentrations. They are therefore more expensive than CC reagents. Secondly, the competitive constraints for suppliers of HIAs are different from those for suppliers of CC reagents. Even customers who can perform these tests partly on clinical chemistry instruments often buy their requirements for HIA reagents from sources other than their CC reagents, i.e. the suppliers of their immunochemistry instruments. Thus, they have different alternatives in the face of a small, but significant non-transitory price increase for HIA reagents, compared to the situation relating to CC reagents. Customers can switch to suppliers of HIA which are not active in CC (e.g. Abbott) and run these tests on their immunochemistry instruments. The importance of these different competitive alternatives can be seen in the different market share distributions for HIA and CC reagents. According to the parties, BM has a market share in the EEA of around 40 % in CC reagents, and of around 15 % for HIAs. Abbott on the other hand, has a market share of less than 2 % for CC reagents, but of more than 15 % for HIA reagents. Thirdly, on the supply-side, the major clinical chemistry suppliers offer different ranges of HIA tests to be run on clinical chemistry machines. The Commission therefore concludes that there is a separate product market for clinical chemistry reagents which does not include homogenous immunoassays.

(c) *Immunochemistry reagents*

(38) Immunochemistry involves the use of targeted antibodies to identify and test enzymes, drugs, hormones and other substances found in relatively small concentrations in the body. Depending on the condition monitored, a number of applications can be distinguished. If these were to be regarded as product markets, according to the parties, overlaps would exist in specific proteins, tumour markers, thyroid-function hormones, anaemia-related/vitamin tests, therapeutic drug monitoring, rheumatoid and autoimmune diseases, and standards and controls.

(39) The reasons for grouping together the immunochemistry reagents included in the different second-level EDMA groups are less strong than in the case of clinical chemistry. In immunochemistry, there seem to be significant differences relating to important technical differences for the users ([1]); customers do not regularly buy most of their requirements for such tests from one source, and on the supply side the major suppliers do not offer the same range of instruments and reagents. It may therefore be appropriate to view each such group as a relevant market. For the purpose of this case, this question may, however, be left open, because in all alternative market definitions considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

(d) *Classical clinical chemistry and immunochemistry instruments*

(40) Instruments are measuring instruments used to process the tests. There are different sizes ranging from small instruments to high end-high throughput instruments. All major reagent suppliers provide instruments. Most produce their own (e.g. Roche), but some source instruments from independent machine manufacturers. This is the case for BM which only produces some instruments and achieves the larger part of its instruments sales as exclusive distributor for Hitachi machines in Europe. These instruments are marketed as BM/Hitachi instruments.

(41) The EDMA classification did not separate instruments into further product groups until 1996. According to the notification, this approach is, however, too broad for market definition purposes, since the present generation of analytical instruments generally covers only diagnostic tests in one of the aforementioned segments (i.e. in clinical chemistry or immunochemistry). An instrument that is used to perform clinical chemistry tests would thus not be substitutable for an immunochemistry instrument. In later submissions, however, the parties pointed to the 'integration of IVD-segments', and especially to the integration of clinical chemistry tests and immunochemistry tests in one instrument. This integration currently expresses itself through the integration of some HIA tests in newly introduced clinical chemistry instruments, such as the Roche Integra. Even if this trend increases, and if it does become possible to run more immunochemistry tests on clinical chemistry instruments, it is important to note that it will only be possible in part to substitute immunochemistry instruments for classical chemistry instruments, and not vice versa. This one-way substitution implies that the clinical chemistry reagent trail generated by clinical chemistry instruments will not be reduced, and that any potential market power that a supplier may have in clinical chemistry instruments is not constrained by suppliers of immunochemistry instruments. It may, however, be an indication that any potential market power in immunochemistry instruments will be constrained by the possibility for customers to switch part of their tests to clinical chemistry instruments.

(42) A new, more detailed instrument classification, published in 1996 by EDMA, which will be used to assemble sales data in the future, follows on its first level the separation between the segments, clinical chemistry, immunochemistry, haematology, microbiology, and adds the categories 'other clinical instruments' and 'data management systems'.

(43) Within the segments, a further distinction can be drawn according to instrument sizes, as the throughput of the instruments varies widely. In clinical chemistry, for example, a common segmentation in the industry which is reflected in the EDMA classification distinguishes between manual instruments (throughput less than 50 tests per hour (tph)), small automated instruments (50 to 200 tph), medium automated instruments (200 to 450 tph), large automated instruments (450 to 1 000 tph), and extra-large automated instruments ($>1\,000$ tph). This segmentation is only relevant for market definition purposes to distinguish between manual instruments (photometers) and automated instruments. Manual instruments are mostly sold to doctors, who use them for occasional analyses in their office, and they thus serve a different demand from automated instruments, which are mostly sold to hospitals and private laboratories. Such customers demand one or several automated instruments depending on their size and have a certain degree of flexibility in choosing, for example, one extra-large instrument or two large instruments. The exact preferences of individual laboratories will vary according to numerous factors, including their size, daily throughput of tests, peak load, available space and personnel resources. Any attempt to define separate markets for certain sizes of automated clinical chemistry instruments would therefore not be generally applicable to the demand characteristics of individual laboratories. During the investigation neither the parties, nor any third party, have suggested such segmentation. The Commission therefore considers that automated clinical chemistry instruments

([1]) See, for example IV/M.954 — Bain/Hoechst — Dade Behring at paragraph 24.

constitute a separate product market, which should not be broken down into separate product markets for automated clinical chemistry instruments depending on their size.

(44) The overlap between the parties exists mainly in automated clinical chemistry instruments. For other instrument types, with the exception of DNA probes (see below), the concentration will not create any competitive problem. The definition of any other markets for instruments, including immunochemistry instruments, may be left open, because in all alternative market definitions considered, effective competition would not be significantly impeded in the EEA or any substantial part of that area.

(e) *DNA probes*

(45) Diagnostic tests using DNA probes are employed for the detection of infectious diseases, genetic disorders and cancer cells, by way of enzymatic amplification of a specific nucleic acid contained in a sample. Within its field of application this technique offers important advantages compared to older *in vitro* diagnostic methods, involving biologic amplification (growth in a culture). First, DNA probes offer the ability to copy minute fragments of genetic material millions of times in order to produce yields that are large enough for rapid and reliable detection of, for example, infectious diseases such as HIV. As such, DNA probes offer a methodology that is faster, less costly and potentially less hazardous than biologic amplification. Secondly, DNA probes offer a unique possibility for quantification of the viral load in a sample. The advantage of this is that it allows for more effective monitoring and therapeutic treatment of patients. Another advantage of DNA probes is that they offer unique possibilities to develop 'disease management', where a supplier (such as Roche) would offer a diagnostic test and a therapeutic drug as a package. Reimbursement of the drug may then be linked to having performed a certain diagnostic test. In summary, DNA probes offer significant possibilities for the end-user (a laboratory) to perform tests which either cannot be performed at all, or only at a lower degree of precision, using other diagnostic tests.

(46) DNA probes are presently mainly applied for the detection of HIV, hepatitis C (HCV), mycobacterium tuberculosis (MTB) and sexually transmitted diseases (STD), such as chlamydia. Until Roche introduced the first automated nucleic acid processor, the Cobas Amplicor, the DNA probe tests were only available as manual procedures. In addition to this automatisation process, the DNA probe market is currently undergoing strong expansion, and numerous research projects, aiming at employing DNA probes in other areas to enhance the diagnostic capabilities, are currently being carried out. The practical and technical limitation of the DNA probe technique is that it requires the presence of nucleic acids in the sample. This implies that the only area of *in vitro* diagnostics which in the future, for technical reasons, cannot be substituted by DNA probes is clinical chemistry.

(47) The abovementioned technological features, as well as the unique ability of DNA probes to provide certain diagnostic results, suggests an insignificant degree of substitutability between DNA probes and other diagnostic methods. This is confirmed by price data submitted by the parties, which indicate significant price differences between DNA probes and other *in vitro* diagnostic products (DNA probes are 30 times more expensive). In addition, data submitted by the parties indicate that the DNA probe market is in a very strong phase of expansion (Roche's sales in the Community doubled from 1995 to 1996), whereas the markets for other *in vitro* diagnostic products are growing at a much slower rate. The Commission has therefore concluded that DNA probes constitutes a separate market.

2. **Relevant geographic markets**

(48) In their notification the parties indicated that the markets for *in vitro* diagnostics are worldwide or at least the EEA. This statement was supported by the fact that reagents and instruments are generally marketed all over Europe in identical form and with identical design and labelling, that most of the products are produced in only one manufacturing site and that all major competitors are present on a worldwide basis.

(49) Even if, on the supply-side, production and R&D are carried out on a European or even worldwide scale, the Commission considers that the definition of the relevant product market

should be primarily based on demand-side considerations [1]. In its previous decisions in the IVD industry, the Commission has accordingly found that the geographic reference markets for the *in vitro* diagnostics concerned (TDM, DAT, haematology) remain essentially national as customers could not switch easily to suppliers located elsewhere [2].

(50) The Commission's investigation in this case confirmed these results. Almost all customers and competitors contacted by the Commission have indicated that they consider the markets as national or provided information supporting such a conclusion.

(51) For reagents, the customers stated that they do not buy these products outside their Member State and do not consider it a viable alternative to do so. Most customers also stressed the importance of rapid and reliable service to ensure the continuous availability of reagents and instruments. This service could only be provided by suppliers with a local presence.

(52) The Commission has also previously found that there are significant price differences for reagents between Member States. This has also been confirmed by most customers and competitors during the investigation. The price differences are further substantiated by the parties' own price data which show substantial price differences of up to 200 % for the same reagents between Member States. These price differences reflect the diversity among national medical cultures and in particular the divergences in national health policies, social security regulations and the technology used in laboratories. Particularly important are the different levels of reimbursement which exist for the same diagnostic test in different Member States. The pricing strategies of the IVD suppliers seem to be linked to these reimbursement levels, with higher prices demanded in those Member States where the customer (i.e. the laboratory) can also obtain higher prices through higher reimbursements.

(53) Other elements that point to the existence of national markets for reagents are the fact that all major competitors have national distribution systems and the existence of appreciable differences in the parties' market shares between neighbouring geographic areas (see below).

(54) For instruments, the parties claim to be unable to provide a meaningful price comparison. The other reasons cited above do however indicate that the markets for instruments are also national. As rapid and reliable service is especially important to reduce machine downtime, customers buy instruments locally. Differences in national medical systems lead to differences in the size of laboratories and thus to differences in the technology used. All competitors have national distribution systems and there are appreciable differences in the parties' market shares between neighbouring geographic areas.

(55) For both reagents and instruments, national regulation plays a certain role, but it is less stringent than in the case of pharmaceuticals. The Commission is preparing a directive for the harmonisation of national regulations on *in vitro* diagnostics. The directive, which may be adopted in 1998, will, however, not be effective immediately because a period of several years will be allowed for its implementation. It is also important to note that the harmonisation efforts only address the questions of product approval and not the question of reimbursement approval which will continue to be determined by each Member State. An independent market study, submitted by the parties, noted in that respect that '... consequently, a company could be allowed to sell a product in any EU country but not secure significant business because of limited reimbursement approval'.

(56) Based on the above, it is considered that the product markets are still essentially national.

3. **Assessment**

(57) It is the Commission's conclusion that the operation, in its notified form, would create or strengthen dominant positions in a number of national markets for clinical chemistry reagents and instruments, as described below. Furthermore, the operation would strengthen Roche's dominant position in DNA probes.

[1] See Commission notice on the definition of a relevant market for the purposes of Community competition law (OJ C 372, 9. 12. 1997, p. 5, paragraph 13).

[2] See Case IV/M.457 — Roche/Syntex; IV/M.954 — Bain/Hoechst — Dade Behring.

(a) *Classical clinical chemistry (reagents and instruments)*

1. Effects of the merger

(i) Market share additions

(58) The parties' activities overlap in clinical chemistry reagents (CCR), as well as in the instruments used to perform the tests. There is no overlap in rapid strip tests, as Roche is not active in this market.

(59) In CCR, the parties have a combined market share of [< 50 %] in the EEA (BM [< 40 %], Roche [< 5 %]). On a national basis, all Member States constitute affected markets. The following table, based on the parties' submission, shows their market shares in 1996:

Market shares in clinical chemistry reagents 1996

Market	Value (ECU million)	Market share BM (%)	Market share Roche (%)	Market share Roche + BM (%)	Important competitors (market share > 5 %) [1] (%)
Austria	19,9	[< 80]	[< 10]	[< 80]	J&J [< 10]
Belgium/Luxembourg	23,0	[< 40]	[< 10]	[< 40]	J&J [< 20], Beckman, Merck [< 10]
Denmark	7,2	[< 30]	[< 20]	[< 50]	J&J, Bayer [both < 20]
Finland	5,2	[< 50]	[< 10]	[< 50]	Bayer, Merck [< 20], Tamro, J&J [< 10]
France	80,1	[< 20]	[< 10]	[< 30]	Beckman, J&J [< 20], Biomerieux, Bayer, Dade Behring [< 10]
Germany	134,1	[< 60]	[< 10]	[< 60]	J&J, Beckman, Merck, Dade Behring [< 10]
Greece	9,8	[< 20]	[< 10]	[< 20]	Bayer, Dade/Behring [< 20]
Italy	94,3	[< 50]	[< 10]	[< 50]	Beckman [< 30], J&J [< 20], Instrumentation Laboratory, Bayer [< 10]
Netherlands	13,2	[< 40]	[< 10]	[< 40]	J&J [< 30], Beckman [< 20], Merck, Dade Behring [< 10]
Norway	6,9	[< 50]	[< 10]	[< 50]	J&J [< 30], Bayer, Nycomed [< 20]
Portugal	13,9	[< 40]	[< 10]	[< 50]	Beckman, J&J [< 20], Dade Behring [< 10]
Spain	98,4	[< 50]	[< 10]	[< 50]	Beckman, Bayer, J&J, Instrumentation Laboratory [< 10]
Sweden	8,7	[< 40]	[< 10]	[< 50]	J&J, Bayer [< 20], Beckman, Merck [< 10]
UK/Ireland [2]	39,3	[< 20]	[< 10]	[< 20]	J&J, Beckman [< 20], Bayer [< 10]
Total EU	547,0	[< 40]	[< 10]	[< 50]	J&J, Beckman [< 20], Bayer [< 10]
Total EEA	553,8	[< 40]	[< 10]	[< 50]	J&J, Beckman [< 20], Bayer [< 10]

[1] The exact market shares, based on information submitted by third parties, have been withheld for confidentiality reasons.

[2] The parties as well as most competitors stated that it is not possible to provide separate figures for Ireland. They believe, however, that the market shares in Ireland and the United Kingdom should be very similar.

(60) For instruments, statistical information is only available for all IVD instruments combined. On this basis all Member States would be affected markets. According to the parties, the overlaps for all instruments would be as follows: Austria (Roche [< 20 %], BM [< 50 %]), Belgium (Roche [< 10 %], BM [< 30 %]), Denmark (Roche [< 20 %], BM [< 20 %]), Finland (Roche [< 10 %], BM [< 20 %]), France (Roche [< 10 %], BM [< 10 %]), Germany (Roche [< 10 %], BM [< 20 %]), Greece (Roche [< 10 %], BM [< 20 %]), Italy (Roche [< 10 %], BM [< 20 %]), Netherlands (Roche n.a., BM [< 60 %]), Norway (Roche [< 10 %], BM [< 40 %]), Portugal (Roche n.a., BM [< 30 %]), Spain (Roche [< 10 %], BM [< 20 %]), Sweden (Roche [< 20 %], BM [< 30 %]), United Kingdom and Ireland (Roche [< 10 %], BM [< 20 %]).

(61) Since the parties have only limited positions in immunochemistry, haematology and microbiology, those overall market shares understate the parties' share in the market for clinical chemistry instruments. Given the close link between the sale of instruments and the sale of reagents, the Commission considers that the parties' shares in instruments should be closely related to those in reagents. If there are any discrepancies, logically the parties should have higher market shares for instruments, given that there are small reagent suppliers who do not sell instruments but whose products are used on the instruments of the major competitors. These competitors would thus reduce the parties' market share in reagents, but not in instruments. The parties have also stated in the notification that the market shares in instruments and reagents should correspond very closely to each other. The same view was taken by Dade and Behring in their notification in Case IV/M.954. The Commission therefore considers the market shares for clinical chemistry reagents set out above to be representative of the parties' market shares for clinical chemistry instruments. The parties have not contested this assumption during the proceedings.

(62) As can be seen from the above table, BM has high market shares and is the market leader in all Member States. There are a number of competitors ranging from international firms, with a presence in most Member States, to small reagent producers with less than 10 employees, which are only active in their country of origin. The market share of such competitors varies from Member State to Member State. The most important competitors overall are (in order of market share): Johnson & Johnson (J&J), Beckman, Bayer, Dade Behring, Merck KGaA (Merck), and Olympus.

(63) In the EEA as a whole, BM's market share is significantly higher than that of those competitors. It is as high as the market share of the five next largest competitors combined. Individually, it is more than three times as large as that of J&J and Beckman, and more than five times as large as that of Bayer, Dade Behring, or Merck. Olympus's market share is only half the size of these competitors. Roche's market share is smaller than that of J&J, Beckman, and Bayer, but about the same size as that of Merck and Dade Behring.

(64) An analysis of the above table reveals the position of the competitors in the different geographic markets and the importance of the market share additions created by the merger.

(65) In Austria and Germany, BM has a market share exceeding 50 %. The market share gap between it and the next largest competitor (Austria: > 60 %, Germany: > 40 %) already indicates that no competitor is able to challenge BM's position in these markets. For Germany, this is acknowledged by Roche, which in its 'Roche diagnostics chemistry laboratory systems international marketing plan 1997 to 1999' states that BM is dominant. The concentration would further strengthen this dominant position in Austria as it would remove the second biggest competitor from the market. In Germany, the addition of market share would widen the gap between BM and its competitors even further.

(66) In Spain, BM's market share is already four times as large as that of the next largest competitor. A special feature of this market is that the owner of Instrumentation Laboratory is also the distributor of J&J in Spain. But even the combined market share of these two companies combined would only be one third of BM's share. BM's position in this market thus can not be challenged by any competitor. The addition of Roche's share would widen this gap even further.

(67) In Portugal too, BM's market share is almost four times as large as that of the next largest competitor. The addition of Roche's market share of [< 10 %] would increase this lead further and would remove the competitive impact of one of the five biggest competitors from this market.

(68) In Finland, BM's market share is more than twice as large as that of the next largest competitor. Together with Roche, the combined market share would be close to 50 % and larger than that of the next three competitors combined.

(69) In Sweden, BM's market share is more than twice as large as that of J&J, the next largest competitor. Roche adds another [< 10 %] to this lead. Combined, Roche/BM would be as large as the next five competitors combined.

(70) In Italy, BM's market share is almost twice as large as that of the next largest competitor. Together with Roche, the combined market share would be close to 50 % and larger than that of the next two competitors combined.

(71) In Denmark, the situation is particular in so far as BM's market share is lower than its average European share, but Roche has an especially high market share. The combination Roche/BM would become the undisputed leader in this market with a share which is more than double that of the next largest competitor.

(72) In Norway, BM's market share is higher but there are two competitors which together are larger than Roche/BM combined.

(73) In Belgium, the Netherlands, France, Greece, the United Kingdom and Ireland the investigation does not indicate a competitive concern, since the parties' combined market shares are comparatively lower and there are competitors in these markets with comparable market positions.

(ii) Addition of installed bases

(74) In addition to high market shares, the investigation indicates that following the merger Roche and BM would have a strong advantage in terms of having the greatest installed bases of instruments, i.e. the number of instruments that have been sold over the years and are still in use. The installed base is of particular importance (and more important than the number of instruments that are placed in a given year) for two main reasons: first, it determines to a large extent the sales volume of reagents (the 'reagent trail') during the lifetime of the instrument (normally five to eight years). Secondly, the installed base strongly influences the future placements of instruments, since it is easier for a supplier to place an instrument with a current CC customer, where he knows all decision-makers as well as the replacement needs, than with a CC customer with whom the supplier has previously had no relationship. Since those decision-makers for CC instruments are often not the same as those who decide on purchases of other IVD instruments, even a supplier with a large installed base in other instruments, such as Abbott, will not have similar access to CC customers.

(75) The customers' choice of a certain instrument tends to have a lock-in effect, irrespective of whether they have bought the instrument or whether they received it from the supplier in exchange for the conclusion of a reagent delivery contract. This lock-in effect arises both out of contractual commitments and from the economic rationale of operating a laboratory business. If a customer has bought an instrument, it would normally not be replaced before the end of its depreciation period (normally five years). If the customer has received the instrument, the reagent delivery contracts used by Roche and BM will typically be concluded for a period of five years. During the contractual period the customer is committed to purchase reagents (expressed either in terms of a certain yearly value or as a certain minimum number of test-kits) from the instrument supplier for several years. The standard contracts submitted by Roche do not foresee any possibility of early termination of the contract. This yearly purchase obligation is calculated individually for each customer, on the basis of its projected annual consumption. Customers also have an economic incentive to concentrate as large a proportion of certain tests as possible on a specific instrument, as this is the most immediate way to reduce its per-test cost (optimal use of invested capital, minimising cost for training of personnel, etc.). The total price to be paid by the customer will also include a rental fee for the instrument. The calculation of the latter takes account of the initial price of the instrument, the contractual period, its value after that period and capital costs. Typically, the agreement will also include the provision of additional services, such as training of the customer's staff, maintenance and supplies of disposables.

(76) With an installed base of about [< 9 000] clinical chemistry instruments (BM [< 6 200] and Roche [< 2 400]), the total installed base of the parties in the EEA would be at least three times as large as that of the next largest competitors (J&J and Bayer, both less than 2 300 instruments) and would exceed that of the next largest competitor in all Member States. The following table shows the total installed base of the parties and of major competitors in those Member States where the addition of market shares indicates competitive concerns:

Total installed base of clinical chemistry instruments 1996

Market	Total installed base (estimate) (1)	BM	Roche	Roche + BM	Sum of two largest competitors	Sum of six largest competitors
Austria	800	[< 400]	[< 200]	[< 500]	134	166
Denmark	300	[< 100]	[< 100]	[< 200]	110	110
Finland	150	[< 100]	[< 100]	[< 100]	36	36
Germany	4 600	[< 2 000]	[< 500]	[< 2 400]	733	1 261
Italy	4 200	[< 1 200]	[< 500]	[< 1 700]	1 048	1 752
Norway	200	[< 100]	[< 100]	[< 100]	84	84
Portugal	400	[< 200]	[< 100]	[< 300]	74	112
Spain	2 300	[< 700]	[< 300]	[< 900]	652	913
Sweden	300	[< 100]	[< 100]	[< 200]	66	99

(1) An exact figure for the total installed base of all competitors combined is not available. Based on information in a study of an independent consultant specialised in monitoring the IVD industry, the Commission estimates that the combined installed base of the eight largest competitors in the EEA represents 80 % of the total installed base in the EEA.

(77) The large installed base, with the corresponding number of customers, would reinforce the market position of the parties. In this respect, one of the supporting documents submitted by Roche with the notification contains the following assessment: '... given [BM's] extensive installed base and high volume for reagent production BM is able to obtain significant economies of scale and very high operation margins for clinical chemistry ([...]), the mix of business between instrument and reagent sales is very good (75/25) [75 % reagents] and though an open system, the quality of BM reagents permits a high capture rate on instruments placed, thus allowing BM to maintain these margins'.

(78) It is important to note that the concentration would not only combine the two largest installed bases in Europe in numerical terms. The two companies' respective activities are also largely complementary in the sense that they together would create a unique coverage across all sizes of instrument. Whereas BM's traditional focus is in the medium- to high-throughput end of the market, Roche has traditionally been strongest in the segment for small instruments with its 'Cobas Mira' instrument. This suggests that existing competitors would face increasing difficulties in challenging Roche/BM's strong combined position either in general, or by focusing on certain segments of the market.

(79) A comparison of BM's and Roche's installed base with that of the six biggest competitors in Europe (J&J, Beckman, Bayer, Dade Behring, Merck, Olympus) shows the advantages that the merged entity would enjoy in those Member States where the combined market shares suggest that Roche/BM would have a dominant position. The comparison focuses on two aspects: it first looks at the total installed base of all instruments combined, irrespective of instrument size. This number gives an indication of the customer base and contacts of a supplier. Secondly, it looks at the installed base by instrument size. This gives an indication of the reagent 'trail' generated by the different instrument sizes and ensures the comparability of the different instruments.

(80) In Austria, BM has the largest total installed base, and Roche the second largest. Their combined total installed base would be almost three times as large as that of the six largest competitors combined. BM also has the largest installed base in each of the instrument segments with the exception of small instruments, where Roche is the leader. In each segment, their combined installed base would be significantly larger than that of the six competitors combined.

(81) In Germany, BM has the largest total installed base, and Roche the second largest. Their combined total installed base would be almost twice as large as that of the six competitors combined. BM also has the largest installed base in each of the instrument segments. Together with Roche, it would have an installed base in each segment which is larger than the combined installed base of the six competitors combined, with the exception of the medium-size segment where the competitors' combined base exceeds Roche/BM.

(82) In Spain, BM has the largest installed base overall, and in every segment except small instruments. Roche is strong in small instruments and fourth in large instruments. Combined they would be as large as the six competitors combined overall and in all segments, except medium-sized instruments.

(83) In Portugal and in Finland, BM has the largest installed base overall and in every segment. Roche has the second largest installed base (almost exclusively small instruments). Together, they would be larger than the six competitors in every segment.

(84) In Sweden, Roche is the leader in small instruments and BM the leader in medium-sized and large instruments. Bayer is the only supplier in this market that has placed an extra-large instrument. Roche/BM combined would be as large as or larger than the competitors combined overall and in every segment, except extra-large.

(85) In Denmark, Roche has the largest total installed base and BM the third largest (after Bayer). Their combined installed base would be the largest overall and in every segment, exceeding that of the six competitors combined in every segment, except medium-sized instruments where J&J has placed the largest number of instruments.

(86) In Italy, BM has the largest total installed base and Roche the third largest. BM leads in every segment, except medium-sized instruments (where Beckman is the leader). Roche/BM would exceed each competitor, but not the six competitors combined.

(87) In Norway, Roche is the leader in small instruments. J&J is as large as Roche/BM in medium-sized and large instruments and Bayer is larger than Roche/BM in extra-large instruments. Overall, Roche/BM's installed base would not be larger than that of J&J and Bayer combined.

(88) The comparison shows that in those countries, where BM had a dominant position prior to the merger (i.e. Austria, Germany, Spain), it clearly controls the majority of the installed base. This position would be further strengthened through the addition of Roche's base with its focus on small instruments. In Portugal, Finland, Sweden, and Denmark, the combined installed bases of BM and Roche would be as large or larger than that of the six competitors combined. In Italy, it would be as large as the combined total of the four largest competitors. In the case of Norway, the comparison of the installed bases suggest that Roche/BM will not have a dominant position, since J&J and Bayer will be in a position to challenge the market leader effectively.

(89) It can thus be concluded that for reagents as well as instruments, the combination of Roche's and BM's installed bases would strengthen BM's dominant position in Austria, Germany, and Spain, and would facilitate the creation of a dominant position in Portugal, Finland, Sweden, Denmark, and Italy.

(iii) Removal of Roche as a competitor

(90) The concentration will remove Roche as a competitor from the market. In Austria and Denmark, this is in itself a substantial reduction of competition, as Roche was among the leading challengers of BM in these markets (second in Austria, third in Denmark).

(91) In those markets, where Roche is not among the three biggest competitors, account has to be taken of the fact that in recent years Roche has been one of the most dynamic competitors in the IVD industry. An independent market study submitted by the parties notes that Roche has been among the companies with the highest growth in IVD, with a growth in revenue of 7 % for CC in Europe from 1995 to 1996. The competitive importance of Roche in clinical chemistry has been increased by the successful launch of its new instrument family, the Roche Integra. While historically concentrating on small instruments, it launched this new large instrument in 1995. With this instrument, it had just begun to challenge BM in an area where the latter has traditionally had its main focus.

(iv) Increased bundling possibilities

(92) The competitive importance of a broad product range and the resulting possibility to bundle products from several fields of the IVD industry has clearly been recognised by Roche. The head of the Roche diagnostic division noted in that respect: 'We believe there are advantages to establishing a leadership position in a broad range of diagnostic disciplines: firstly, from the ability to bundle products and services to the same customer base, and secondly, in order to offer a consolidated solution to the laboratories needs. . .'.

(93) The unique potential of Roche/BM to do that, has also been recognised by the head of Roche's diagnostic division. When assessing the merits of acquiring a competitor other than BM, he concluded that, in combination with this competitor, Roche would be '. . .the only company, with the exception of BMD [BM], which could successfully bundle chemistry and immunochemistry'.

(94) The above assessment that BM currently is the only supplier successfully able to bundle CC and immunochemistry is confirmed by the weak position of all existing competitors in the field of CC, and by the fact that Abbott, the market leader in immunochemistry, is presently not active in CC. Furthermore, Roche/BM would also be uniquely placed in that it is the only competitor that could successfully bundle classical chemistry and/or immunochemistry with DNA probes (see below.)

2. Contestability

(95) The Commission's investigation has shown that neither actual nor potential competitors nor countervailing power on the demand side can be regarded as able to contest Roche/BM's dominant position for the following reasons.

(i) Existing competitors

(96) The market shares of the most important competitors have already been analysed above in relation to Roche/BM's shares. As noted there, the main competitors are J&J, Beckman, Bayer, Dade Behring, Merek and Olympus. When analysing the competitive impact of the competitors, it is also important to note, in addition to the weak position of these companies (in terms of market share and installed base), that two of the five biggest competitors in Europe, Bayer and Merck, are in a steadily declining market position. Even the commitment of J&J to the IVD industry has been questioned by industry observers.

(97) As has been stated above, the parties have submitted that all leading diagnostic companies have developed or are developing new generation modular instrument systems, which will cover clinical chemistry, immunochemistry and infectious immunology ([1]). The parties are of the opinion that this would provide a strong challenge to BM's existing market leadership in clinical chemistry.

(98) The parties have submitted that, in addition to themselves, Abbott, Beckman, Dade Behring and Bayer are also developing such 'integrated instrument systems'. Whereas it is true that some such development projects are in progress, the Commission does not find the parties' arguments convincing. As the term 'modular' implies, these new generation instruments will consist of several modules that are adapted to work together as a system. Thus, there would be one module that would carry out clinical chemistry testing, another one that would carry out immunochemistry testing and so on.

(99) None of these modular instrument systems have yet been marketed in the EEA, or indeed elsewhere in the world. It appears that the first system that could be described as a modular one, the Dade Behring RXL, does not yet incorporate the module for heterogeneous immunochemistry testing. The other module, which covers clinical chemistry and HIA, has been marketed in the USA. The parties have not advanced any argument why the eventual launch of the RXL instrument in Europe would significantly improve Dade Behring's market position in the clinical chemistry market. They also have not shown why any other future modular instrument system introduced by Beckmann, Bayer or any other company already active in the market for clinical chemistry would improve the market position of such suppliers. Therefore, while in no way ruling out the introduction of modular instrument systems in the European markets in the future, the Commission finds that the parties have not demonstrated that this development is likely to significantly alter the market characteristics of the clinical chemistry market, i.e. the importance of having a large installed base to secure future reagent sales and replacement of instruments (see above). Moreover, the parties' statements concerning the modular instrument systems fail to take account of the fact that it cannot be presumed that all customers would be interested in these new

([1]) The first step in this integration development can be observed in the introduction of homogeneous immunoassays on clinical chemistry instruments. The limited impact of this on the conditions of competition in CC has been discussed above, under market definition, and will not be repeated here.

systems, even if they were to become widely accessible in the foreseeable future. This is evidenced by the customers' answers in the Commission investigation as well as by the fact that the current installed base in clinical chemistry clearly indicates that customers have significantly varying needs in terms of size, test menu and throughput of the instrument. Finally, and not least importantly, the parties' submission concerning the imminent impact of modular instrument systems would seem to contradict the rationale of Roche's proposed acquisition of BM. If these new instruments were to constitute such a threat to BM's position as is submitted by the parties, it would arguably make little sense for Roche to pay USD 11 billion for BM, as its major strength lies in the field of clinical chemistry. The above indicates that the possible introduction of modular instrument systems will not fundamentally change the main characteristics of the markets for clinical chemistry diagnostics (reagents and instruments) in the foreseeable future.

(100) On the basis of the above, it can be concluded that in those countries where the concentration would threaten to create or strengthen a dominant position, existing competitors are already not in a position in terms of market share and installed base to effectively challenge the leadership of Roche/BM. Nor can it be expected that the possible development and marketing of modular instrument systems by any of these companies would significantly improve their ability to challenge the position of Roche/BM.

(ii) Buying power

(101) The demand side can be segmented along several dimensions, the most important being ownership (public laboratories/private laboratories), volume/throughput requirement (small laboratories/large laboratories), and status (hospital laboratories/dedicated reference laboratories/doctors' practices). The number and size of these customers differs from Member State to Member State and depends on the organisation of the national healthcare system. In some Member States there is a certain concentration of demand through joint purchasing by public laboratories. Such joint purchasing, however, is never done at a national level. Instead, it merely combines the demand of local or regional authorities. As a result, in every Member State, irrespective of national specificities, the demand side is much more dispersed than the supply side.

(102) According to the notification, that dispersal on the demand side is reflected in Roche and BM's customer base. In no case does the largest customer of the parties account for a substantial amount of either party's sales of CC reagents in any of the countries where the investigation indicates competitive concerns. The highest proportion (13 %) is found for Roche sales in Finland and Portugal. Otherwise BM's largest customer accounts for between 1 % and 8 % in those Member States. The corresponding figure for Roche is between 1 % and 10 %.

(103) Thus, the parties are not faced with powerful customers which concentrate an important percentage of the total demand in any country. It can not therefore be expected that even the biggest customers have countervailing power. This assessment is confirmed by the fact that not even the owner of the largest group of private laboratories in the EEA (based in Germany) considers itself to be in a position to negate the market power of Roche/BM.

(104) The use of calls for tender does not increase the countervailing power of the customers to a large extent. According to a submission by the parties, calls for tender play a significant role (i.e. account for more than 20 % of the total volume demanded) only in Italy, Spain, Portugal, Greece and the United Kingdom. In Greece and the United Kingdom, the concentration will not create a dominant position. In the other countries, calls for tender cannot be expected to counterbalance Roche/BM's position. This would only be the case if there was a limited number of large calls for tender issued by centralised purchasing organisations. However, in Italy the large diagnostic companies participated in around 2 000 tenders which were issued in 1996 by several regional authorities. In Portugal and Spain, for the same period, Roche participated in 150 to 200 tenders in each country, BM in 300 to 600. Less than 3 % of these were issued by a centralised authority.

(105) On the basis of the above, it can be concluded that structural factors indicate that the parties' market position would not be constrained by countervailing purchasing power on the demand side.

(iii) Potential competition

(106) The barriers to entry into the market for clinical chemistry diagnostics are high. Entry on a significant scale would require large investments. The development costs for a new system (instrument and corresponding reagents) are estimated by the German Diagnostic Manufacturers Association (of which both Roche and BM are members), to be between ECU 25 million and ECU 150 million. An independent market study submitted by the parties estimates those costs to be in excess of ECU 250 million. In addition, a new entrant would have to bear the cost of setting up the necessary sales and service organisations. Documents submitted by the parties also indicate the existence of significant economies of scale. Moreover, any new entrant would be faced with a situation where its potential customers are largely locked in by their existing instrument base, and, thus, reluctant to replace these instruments before they have been written off.

(107) The height of the barriers to entry is demonstrated by the fact that the only entrant of some significance over the last five years in Europe would seem to be Olympus. It should, however, be noted that, prior to entering the market as a full-line supplier, Olympus had for 20 years already produced instruments which were sold by Merck and Eppendorf.

(108) The parties have submitted that Abbott, the worldwide leader in immunochemistry, is about to enter the clinical chemistry market. Abbott currently has only a very limited presence in classical chemistry, based on instrument placements done in the 1970s and early 1980s. It has been confirmed that Abbott is indeed planning to re-enter the market. This will be done through an alliance with the Japanese instrument manufacturer Toshiba (for large and extra-large instruments) and through the acquisition of the French instrument manufacturer Alcyon (small instruments). The parties have also put forward the argument analysed above relating to the introduction of a new generation modular instrument systems relating to Abbott.

(109) In the first stage, Abbott's entry into this field will, however, not be achieved through the introduction of a modular system but by offering Alcyon clinical chemistry instruments. Alcyon currently has a very limited position on any of the markets for clinical chemistry in Europe. The alliance with Toshiba is aiming at producing the clinical chemistry module of Abbott's planned Architect system, which will combine such instruments with immunochemistry instruments produced by Abbott. The introduction of the clinical chemistry module is, however, not foreseen until the year 2000, at the earliest.

(110) While Abbott has the access to customers and the financial means to attempt to overcome the high barriers to entry, it cannot be expected to challenge Roche/BM's dominant position in the short to medium term. Abbott will take over the sales of the small Alcyon instruments immediately. While the financial strength of Abbott may to some degree increase the sales of such instruments from its current level, the effect of this may be expected to be relatively limited. The large and potentially modular Toshiba instrument will be launched later. Abbott accordingly does not expect to reach significant market shares (> 5 %) within the foreseeable future.

(111) It can thus be concluded that potential competition would not effectively constrain the market behaviour of Roche/BM after the merger.

3. Conclusion

(112) The concentration of the classical clinical chemistry businesses of Roche and BM would result in the creation of dominant positions in Portugal, Finland, Sweden, Denmark, and Italy, and the strengthening of BM's pre-existing dominant positions in Austria, Germany, and Spain. This conclusion is based not only on the high combined market shares attained by Roche/BM, but also on their advantages in terms of installed base, their unmatched product portfolio, the relative weakness of existing competitors, the insufficient countervailing power of the demand side and the high barriers to entry.

(b) *Immunochemistry (reagents and instruments)*

(113) In a market for all immunochemistry diagnostics, the parties would have a combined market share in the EEA of [< 20 %] (BM [< 20 %], Roche [< 10 %]). On that basis affected markets would be found in the following countries: Austria (combined market share [< 40 %] (BM [< 30 %], Roche [< 10 %])), Norway (combined market share [< 30 %] (BM [< 30 %], Roche [< 10 %])), Germany (combined market share < 20 % (BM < 20 %, Roche < 10 %)) and Spain (combined market share < 20 % (BM < 20 %, Roche < 10 %)). In all of these markets there are important competitors, notably Abbott, the world leader in immunochemistry, which has comparable market shares to BM in these countries, Dade Behring, which has considerably larger shares than Roche, but lower shares than BM, and Beckman.

(114) On the second level of the EDMA classification, the notified operation leads to significant overlaps in certain specific product groups within the overall immunochemistry field. The following table shows those product groups in which, based only on the parties' combined shares, an indication of competitive concerns exists:

Product	Country	Market value (ECU million)	Market share BM (%)	Market share Roche (%)	Market share Roche + BM (%)	Important competitors (> 5 %) [1] (%)
Tumour markers	Italy	35,7	[< 30]	[< 20]	[< 40]	Abbott [< 30]
Anaemia rel./vit. tests	Austria	2,2	[< 40]	[< 10]	[< 50]	Abbott [< 30]
Rheumatoid and Autoimmune Disease [2]	Austria	5,4	[< 60]	[< 10]	[< 70]	Dade Behring [< 20], Beckman [< 10]
	Belgium	4,6	[< 10]	[< 40]	[< 40]	Dade Behring [< 30], Beckman [< 10]
	Portugal	0,9	[< 50]	[< 10]	[< 50]	Dade Behring [< 40]
Standards and controls	Austria	1,8	[< 50]	[< 10]	[< 60]	Dade Behring [< 30], Beckman [< 10]
	Germany	14,1	[< 40]	[< 10]	[< 40]	Dade Behring [< 30], Beckman [< 20]
	Portugal	0,7	[< 30]	[< 20]	[< 40]	Dade Behring [< 20]

[1] The exact market shares, based on information submitted by third parties, have been withheld for confidentiality reasons.

[2] The above market shares of Roche/BM include a combination of two specific EDMA level 2 groups of reagents (rheumatoid diseases, EDMA 12.10 and autoimmune diseases EDMA 12.11). These groups have only recently been separated in the EDMA classification and statistical information is only available for Germany. As neither party is active in 12.10 to any significant extent, but both are strong in 12.11, their market share in autoimmune disease in the countries mentioned above is higher than indicated in the table. This is however also true for the major competitors Dade Behring and Beckman. The competitive relation between these competitors would thus remain unchanged, if this segment was analysed separately.

(115) The table shows that Roche/BM would attain market shares of a similar size to those discussed in relation to clinical chemistry also in some segments of the immunochemistry field. This position is, however, not as consolidated as their position in the market for clinical chemistry. As indicated above, in most markets there are substantial competitors that will constrain the parties' market behaviour. Even in the two markets where the parties' share is particularly high (rheumatoid and autoimmune diseases, and standards and controls in Austria), the investigation has confirmed that the operation will not create competitive concerns. Neither of those two products is used on instruments dedicated for such purposes. The ability of the parties to exploit their strength in these segments will therefore be constrained by their much weaker position in other immunochemistry reagents used on the same instrument. In addition, although the markets for immunochemistry diagnostics remain essentially national, Dade Behring, which has comparable market shares to the parties in rheumatoid and autoimmune diseases in the EEA and in Germany and which is already present to a significant degree in Austria, would be able to react to any attempt by Roche/BM to exploit their position in Austria. Dade Behring has a sufficient production capacity and sales force to counter the behaviour of Roche/BM.

(116) It can be concluded that Roche/BM will face powerful competitors in the overall immunochemistry field. These competitors (primarily Abbott, Dade/Behring and Beckman) are also significantly active in the immunochemistry products mentioned in the above table. For this reason the investigation has confirmed that the concentration would not create or strengthen a dominant position in any market for immunochemistry diagnostics.

(c) *DNA probes*

1. Market structure

(117) For DNA probes, statistical information from EDMA is still only partly available, as the classification does not yet contain a specific chapter containing all such tests. Therefore the parties have not been able to provide market share data broken down to the Member State level. The aggregated data provided for the Community as a whole shows that the total value of the market in 1996 was ECU 76 million, an increase of 42 % since 1995 (in the same period Roche's sales almost doubled). The data also shows that Roche has a very strong position, with a market share of [< 70 %] for the four main fields of application (HIV, hepatitis C (HCV), mycobacterium tuberculosis (MTB) and sexually transmitted diseases (STD)). In 1996, these four applications represented [< 80 %] of the total DNA probe market ([< 60 %] in 1995). In particular the areas of HIV and HCV tests increased significantly between those years ([< 400 %] for HIV and [< 50 %] for HCV).

(118) Roche is the only company which is able to supply reagents for all of those four main applications, and thus offers the broadest range of tests available. Moreover it was the first company to launch a test for the quantitative measurement of the viral load (amount of virus) in a patient's blood. Roche was also the first company to introduce an automated instrument for DNA probe testing, the Cobas Amplicor. This instrument allows 20 DNA probe tests to be performed in one hour. Thus, from a customer point of view, instruments are advantageous as they significantly lower the processing time compared to manual tests. An additional advantage of automated instruments is that they reduce the risk of contamination of the sample. Other instruments have subsequently been developed by other companies (Abbot LCx and Organon Nasba QR). None of these, however, provide a test menu as wide as the Amplicor.

(119) The extent to which DNA probe tests are employed, and the level of automation of such tests, would seem to vary significantly between Member States, with Germany, Austria, Italy, Spain and France having a relatively high number of automated systems installed, whereas other Member States (the United Kingdom, Ireland and Greece) do not yet have any such systems installed. One explanation for this is that, as has been stated above, the national reimbursement systems have a strong impact on the development of the *in vitro* diagnostics industry as a whole. However, even for the Member States where DNA probes have not yet reached a high degree of automatisation, the parties have not indicated that their market share would differ significantly from the reported figure for the Community as a whole. For the purposes of the present assessment the Commission therefore considers that Roche's existing market share in all Member States is of the same order as that for the Community as a whole.

2. Position of the parties

(i) Roche

(120) As has been stated above, Roche has a very strong position on the market for DNA probes. This position is based on Roche's extensive patent portfolio relating to the main DNA probe technology, the polymerase chain reaction (PCR) technique, which has developed into the industry standard in both scientific and commercial applications. The PCR technology was acquired by Roche from the US company Cetus in 1991, and has over the last six years been employed in a steadily increasing number of commercial applications. In addition to three fundamental enabling patents issued in the United States between 1987 and 1990, Roche has large number of patents (at least 81) covering improvements to the technology, the key enzymes used in the process, specific pathogens, detection methods, target information on cancer cells, etc. Many of these additional patents have beer issued in the latter half of this decade. For example, in November 1996 the European Patent Office (EPO) granted Roche a patent for key enzymes used in the PCR technology (taq polymerase). According to Roche this enzyme plays an '... extremely important role in the PCR technique ...' and the decision by the EPO '... significantly enhances the division's strong patent portfolio in the field of DNA amplification ...'. It can therefore be concluded that Roche will retain a significant

patent protection on the PCR technology well into the 21st century.

(121) Since its acquisition of the PCR technology Roche has, in addition to the successful commercialisation of a number of PCR tests, been very successful in spreading the technology within the research community, through the granting of more than 450 research licences worldwide (150 in Europe). Such licences have been granted both to research institutions (universities etc.) and to competing diagnostic manufacturers (such as BM) [1]. The fact that PCR was the first DNA probe technology to be successfully commercialised, in combination with Roche's policy of extensively granting research licences, has led to the situation where the majority of all published material on DNA probes deals primarily with PCR. All such published material submitted by the parties during the investigation confirms the opinion that the PCR technology will continue to be by far the most commercially important DNA probe technology for the foreseeable future. This assessment has also been confirmed by other IVD companies during the Commission's investigation.

(122) The abovementioned research licences do not give the licensees any right to commercialise products or equipment using the patented PCR technology. Roche has actively and successfully pursued this limitation in its research licences by taking legal action against licensees when required. It can therefore be concluded that none of the companies holding a research licence for PCR will be in a position, on the basis of that licence, to market its own DNA probe products and thus to counter the strong position held by Roche.

(ii) BM

(123) BM has since 1993 had a licence from Roche for PCR in the research field, and has produced and sold the abovementioned key enzymes used in the PCR technology (taq polymerase) to research laboratories. Apart from this, the parties stated in the notification that BM is not active on the DNA probe market and has no pipeline products.

(124) The investigation has, however, revealed that BM, prior to the proposed transaction, has invested substantial efforts in positioning itself on this market. BM has made such efforts both independently and in collaboration with Roche.

(125) BM's independent activities include a programme under which it has developed and acquired a substantial portfolio of patents (at least 126) relating to the DNA probe market. In a list submitted to the Commission these patents have been divided into three groups (46 patents developed to circumvent the PCR technology, 60 general patents relating to analyte-specific formats and improvements to the amplification process and sample preparation, and 20 patents relating to an alternative technology, 'PNA', acquired from a Danish company in 1994).

(126) Further, the investigation has also revealed a number of other examples of BM's interest in positioning itself for an independent entry on the DNA probe market, relating to both reagents and instruments. In relation to reagents, BM has concluded collaboration agreements with 10 different independent parties, all of whom are developing DNA probe products for BM. All of these collaboration agreements relate to both research and commercial applications, and five of the collaboration agreements give BM exclusive rights to the product concerned. Finally, BM is also currently conducting in-house work on the development of DNA probe tests for, *inter alia,* HIV. In terms of instruments, BM has entered into an agreement with an American company, Idaho Technologies, by which BM would distribute a DNA probe instrument to research laboratories. BM has also developed in-house a programme for the production of a DNA probe instrument. The parties have stated that BM's development projects would be terminated if the proposed transaction was to be consummated.

(127) It can be concluded from the above that BM, prior to the proposed transaction, had initiated several projects with a view to positioning itself for an entry into the DNA probe market independently of Roche. It is, however, also significant that BM, in parallel to those independent preparations for market entry, has also invested four years of R&D and so forth on the DNA probe market on the PCR technology. This not only confirms the strength of the PCR technology compared with alternative technologies (see below), but also indicates that BM, in the absence of the proposed transaction, would have had a strong incentive either to reach an agreement with Roche to grant it a licence to commercialise the PCR products, or to expand further its efforts to develop and/or acquire a competing technology. Indeed, the head of Roche's Diagnostic Division has confirmed that, prior to the proposed transaction, an agreement in principle had been reached to license BM to commercialise products using the PCR technology and that it had only not been concluded because of the merger.

[1] In addition, Roche has licensed BM and 22 other companies to produce and sell taq polymerase and other reagents for the PCR process in the research field.

(128) Thus, in contrast to what was implied by the parties in the notification, it must be concluded that BM, prior to the proposed transaction, had significant pipeline projects relating to the DNA probe market, and would have entered this market in the absence of Roche's proposed acquisition.

3. The weak position of alternative technologies

(129) The parties have submitted that Abbott, Chiron, Organon, Genprobe and a group referred to as 'Others' operate in the DNA probe market, supplying products which '... while differing in some features and ease of use, are essentially equivalent'. However, the investigation has shown that none of these companies are currently able to produce DNA probe products equivalent to those produced by Roche (as confirmed by the above-mentioned market share).

(130) Abbott, Organon, and Genprobe each have an overall market share of less than 5 % in the overall DNA probe market in the EEA. They offer only a limited number of tests and the alternative technologies used by them are regarded by most industry observers as inferior to the PCR technology. It must therefore be concluded that these companies are currently not in a position to challenge seriously. Roche's position in the DNA probe market. Nor is there any evidence suggesting that they would be able to do so in the foreseeable future.

(131) Chiron is a US company which has its traditional focus on infectious-disease diagnostics. Its DNA probe technology is called 'Branched DNA'. According to the notification, Chiron's activities on the DNA probe market relate exclusively to HIV and hepatitis C (HCV), where Chiron holds significant patent rights. In these two fields, Chiron holds a relatively strong position in the EEA (23 % and 25 % of these two segments respectively). On the overall DNA probe market these activities translate into a total market share for Chiron of 14 % (20 % if non-automated tests in the group of 'other tests' are excluded, see below). Although Chiron is not an insignificant player on the DNA probe market, it has a serious disadvantage in that it does not have an instrument for the automated operation of its tests. In addition, the fact that it has no activities in two of the four main areas of the DNA probe market (mycobacterium tuberculosis (MTB) and sexually transmitted diseases (STD)) further decreases its ability to act as a significant constraint on Roche's market position. This is confirmed by a consultant report submitted by Roche which provides the following assessment of Chiron's Branched DNA technology '[it] is well suited for certain application signal thresholds, but will not expand much further into IVD application suited for nucleic acid amplification'.

(132) Finally, the group of 'other tests', which according to the data provided by the parties constitute about 30 % of the overall DNA probe market, consists mainly of diagnostic parameters with a distinctly lower turnover than the four main tests included on the Roche Amplicor instrument. It includes viral tests, such as THLV I/II or enterovirus, genetic tests and cancer tests. In addition the category includes sales of instruments and disposables. With the exception of Roche, none of the four abovementioned companies achieve any sales in this category. According to the parties, more than 80 % of the products in this category are based on Roche's PCR technology. Instruments and disposals are likely to make up the major part of the remaining 20 %.

(133) Therefore, as these 'other tests' are mainly still at the research stage and are supplied by a large number of smaller companies or research institutions which have concluded a research licence with Roche, it must be concluded that none of these tests could be commercialised without Roche's participation.

(134) As has been stated above, the fact that most of the research on DNA probes is done on Roche's PCR technology underlines the fact that this technology has become the industry standard. The fact that all this research is done using the PCR technology is of great value to Roche, in that it alone will be able to participate in any commercialisation of products flowing from these activities. To the extent that products within this category, due to their research-related nature, should be included when calculating market shares on the DNA probe market, it would therefore be logical to include these activities in Roche's market share, since Roche, through its patent rights, is able to control any commercialisation of these products. If these 'other tests' were to be included in the market and in Roche's share of that market, Roche's share would be even higher than estimated above (66 %).

4. Market dynamics

(135) Since DNA probes constitute a relatively young market with high growth rates, it is necessary to determine whether Roche's dominant position is sustainable. The parties have argued in this respect that the DNA probes market is in the infant stage of a developing market and that, therefore, market share figures have only a low probative value in assessing a competitive situation. The Commission agrees that in technology-driven markets a careful

analysis must be made of the likely development of market dynamics. Such an assessment, however, clearly indicates that Roche's market position will continue to be secure for the reasons outlined above. In contrast to other cases, where the Commission found that high market shares would be eroded in the future through competition [1], the DNA probe markets have not experienced volatile market share movements, and there has not been a change in market leadership since Roche's acquisition of the PCR technology in 1991. Nor has the investigation revealed any indication that the market structure will change fundamentally in the future. On the contrary, all documents submitted by the parties as well as by all third parties show that all industry players consider that the PCR technology will continue to be the dominant technology in the future. For example, one of the market studies submitted by the parties estimates that the market share of PCR technology will increase to 75 % by the year 2002 and to 80 % by the year 2005. Thus, it must be concluded that the market, although growing at a fast rate, has left the infant stage, where significant uncertainty remains as to which technology will become the industry standard. The Commission therefore concludes that the market position of Roche in DNA probes will not be eroded by market dynamics in the foreseeable future.

(136) In the light of the above, it has to be concluded that Roche has a dominant position on the DNA probe market in all Member States. Furthermore, it must be concluded that none of the available alternative technologies has any prospect of seriously challenging the PCR technology in the foreseeable future.

5. Effects of the proposed transaction

(137) Prior to this concentration, Roche had, during the last three years studied a number of other possible candidates for acquisition (virtually all major *in vitro* diagnostic companies except Abbott). It is clear from the documents submitted by Roche that its strategic plans for such a transaction focused on getting access to a larger sales force to maximise the marketing of PCR products, and to create possibilities of successfully bundling sales of clinical chemistry, immunochemistry and DNA probe products.

(138) BM's position as Europe's leading supplier of clinical chemistry products and one of the major suppliers of immunochemistry products, with a presence in most laboratories and a sales and marketing organisation to match these activities, will fit these objectives. It can therefore be assumed that Roche's direct access to BM's sales and marketing network will allow Roche further to consolidate and strengthen its dominant position on the DNA probe market.

(139) Although from a technical point of view, it will not be possible for the foreseeable future to combine DNA probes with clinical chemistry tests on a combined instrument, it is clear from Roche's own submission that it considers commercial bundling of clinical chemistry, immunochemistry and DNA probe products feasible and advantageous. It must therefore be presumed that, following the acquisition of BM, Roche would adopt such a marketing strategy. Although Roche, as explained above, already has a presence in clinical chemistry and immunochemistry, the very strong position of BM, in particular in clinical chemistry, would lead to significantly increased possibilities of successful bundling with DNA probe products. This effect of the proposed transaction would significantly consolidate and strengthen its dominant position on the DNA probe market.

(140) Finally, it is clear that BM, in the absence of the proposed transaction, would have entered the DNA probe market independently and/or through a licence from Roche. BM's interest in doing so is evidenced by the fact that the DNA probe market is the only market in the field of *in vitro* diagnostics that is rapidly expanding. BM, as one of the world top players in the diagnostic field, would have had a very strong incentive to enter the market, since a strategy of staying outside the DNA probe market could, in the long term, have eroded its existing positions in other markets. Had BM followed such a strategy of independent entry into the DNA probe market, it can be presumed that, for the reasons stated above (existing sales force and customer base, and ability to bundle its product offering), it would have been the best placed potential competitor of Roche on the European markets. It must therefore be concluded that the acquisition of BM would further consolidate and strengthen Roche's dominant position on the DNA probe market by eliminating the best placed potential entrant to the European markets.

(141) Customers and competitors of Roche and BM have largely confirmed that the proposed transaction would be likely to bring about the results indicated above. In particular, a number of customers and

[1] See, for example, Cases IV/M.057 — Digital/Kienzle, paragraph 20, or IV/M.354 — American Cyanamid/Shell, paragraph 33.

competitors have expressed fears that the transaction would increase the already dominant position of Roche on the DNA probe market. As an example of possible exploitation of Roche's strong position in the DNA probe market, several customers have referred to Roche's unique system of charging its customers (the laboratories) a fixed percentage of their turnover on PCR tests as a 'royalty', and stated that Roche's access to the BM sales network and the increased bundling possibilities would facilitate the use of similar tactics.

(142) In conclusion, Roche has already, prior to the proposed transaction, a market share of [< 70 %] on the DNA probe markets in the EEA, which, in particular in combination with the weakness of all alternative DNA probe technologies, gives Roche a dominant position on these markets. The acquisition of BM would strengthen this position by giving Roche increased access to market its DNA probe products through BM's existing organisation, as well as the possibility of successfully bundling the products of the two companies. Also the loss of BM as the most likely potential competitor of Roche on the DNA probe market in the Community would serve to consolidate and strengthen Roche's dominant position.

V. **CONCLUSION**

(143) On the basis of the above, the Commission has reached the conclusion that the proposed concentration would lead to the creation or strengthening of a dominant position as a result of which effective competition would be significantly impeded, within the meaning of Article 2(3) of the Merger Regulation, on the following markets: clinical chemistry reagents and clinical chemistry instruments in Austria, Germany, Finland, Portugal, Spain, Sweden, Denmark, and Italy; and DNA probes in all Member States of the EEA.

VI. **UNDERTAKINGS SUBMITTED BY THE PARTIES**

(144) With a view to removing the competition concerns, Roche has offered to enter into the following commitments:

A. CLINICAL CHEMISTRY REAGENTS AND INSTRUMENTS

(145) For clinical chemistry reagents and instruments, Roche undertakes to divest its Cobas Mira business in Austria, Germany, Denmark, Finland, Sweden, Italy, Portugal and Spain. The purchaser will also be given the opportunity to purchase the Cobas Mira business in Norway and an option to extend the geographic scope of the transaction to all Member States of the Community. The assets included in the transaction will comprise title and ownership to Cobas Mira instruments, as far as not yet assigned to the customers, the customer list, all respective supply agreements for reagents and disposables, all respective service agreements, a stock of spare parts, all necessary service software and tools. The purchaser, will, on request, also be granted a non-exclusive licence covering Roche's patent rights, and all its documented know-how (including design know-how such as blueprints) used by Roche for the manufacture of Cobas Mira instruments. In addition, Roche would be ready to sell to the buyer new Cobas Mira instruments, the necessary spare parts, and, if needed, reagents, all at a favourable transfer price.

(146) Roche undertakes to use its best efforts to sell this business in its entirety to one single purchaser, who will be a viable competitor in the clinical chemistry business and independent from Roche, the satisfaction of such conditions being subject to approval by the Commission. Roche will seek the Commission's consent to sell the business on a national basis to different purchasers, if a single purchaser for the entire business cannot be found.

(147) Roche undertakes to use its best efforts for completing such a divestiture within a period of [. . .] following the Commission's decision. After such [. . .] period a trustee, approved by the Commission, will be entitled to sell the business at best price within a period of another [. . .]. The trustee will already within the first [. . .] review that the business will be continued by Roche as an ongoing viable business and that no measures are taken which would have a substantial adverse impact on the business.

B. DNA PROBES

(148) As regards DNA probes, Roche undertakes to give access to PCR technology, for all *in vitro* diagnostic applications, to all interested market participants. Given the different needs and resources of potential licensees, Roche will offer both broad and targeted licences. It will offer three categories of broad licences. The first (Option A) covers the fundamental PCR patents. The second (Option B1) covers, in addition, the full Roche present patent portfolio in PCR. Finally, under Option B2 the licensee will, in addition to the fundamental PCR patents, have the choice, of additional patents from Roche's present patent portfolio, depending on the needs of the licensee. Roche is also prepared to grant every licensee a licence on the future PCR

patents of Roche. In addition, Roche will offer targeted licences for single parameters to those competitors that only have an interest in a specific disease, with as yet unmet medical needs, for example, HLA or cystic fibrosis.

(149) Roche will offer these licences on non-discriminatory terms to all interested third parties. For the purpose of ensuring the non-discriminatory treatment of all licensees Roche will grant to each licensee a 'most-favoured-customer' clause. In addition, Roche agrees to the appointment of a trustee, who will be approved by the Commission, and who will be informed of every executed licence agreement and can be contacted by every licensee for reviewing compliance with the principle of non-discrimination. Such trustee will report his conclusions to the Commission.

(150) To ensure the timely implementation of this undertaking, Roche undertakes to conclude binding licence agreements with at least one licensee for a broad licence (Option B1) within [...] from the Commission's Decision in the present case. Furthermore, Roche undertakes to conclude a binding agreement for a targeted licence within [...] of the same date.

(151) In order to ensure that Roche does not obtain sensitive business information on the activities of its licensees, Roche agrees to ensure that sales volumes and values of licensees will not be reported to Roche before the expiration of [...] from the end of the period, covered by such sales figures. For the purpose of the calculation of the payment and the review of the royalties during the [...] period, the licensees shall report to an independent auditor, who will be approved by the Commission, and obliged not to disclose such figures to Roche before the end of the [...] period.

VII. ASSESSMENT OF THE UNDERTAKINGS

A. CLINICAL CHEMISTRY REAGENTS AND INSTRUMENTS

(152) The commitment offered by Roche with regard to the Cobas Mira range of instruments will have an important effect on the addition of installed bases after the merger and will significantly reduce the increase in BM's market share related to the concentration.

(153) The Cobas Mira line of instruments represents the most important part of Roche's total installed base. In those Member States where the merger would have created a competitive problem, the merger will thus only add a limited number of instruments to BM's installed base. In Germany, Spain, and Italy [< 100] instruments will be added, in Austria, Sweden, Denmark [< 50] instruments, and, in Finland and Portugal [< 20]. These numbers have to be compared to the large installed base that BM already controls in these countries (see above). Roche/BM will thus not increase its advantages in terms of access to customers, since most Roche customers have been using the Cobas Mira. In addition, the undertaking ensures that the merger will not combine Roche's strength in small instruments with BM's strength in the other instrument segments, since Roche's strength in this segment was entirely based on the Cobas Mira range of instruments. It will thus be as easy for competitors to challenge Roche/BM in certain segments of the market as it was prior to the concentration.

(154) In the market for reagents, the purchaser would, with the access to this installed base, be put into a position to effectively compete in the market by offering its own reagents for the whole installed base of such instruments. Since the Cobas Mira is an open instrument, the purchaser can provide its own reagents for this instrument without any costs or adaptations. It can therefore immediately serve all customers using the Cobas Mira.

(155) Further, Roche's undertaking to sell new Cobas Mira instruments to the purchaser will enable it to act immediately as a full-range supplier (instruments and reagents) in the small instruments segment. The purchaser will also therefore be able to offer its customers new or replacement instruments in the period before it could provide an instrument of its own (through own production or sub-contracting). The undertaking to grant it a non-exclusive licence covering all patent rights and know-how necessary to manufacture Cobas Mira instruments even enables the purchaser to start producing this specific instrument type.

(156) For these reasons, the Commission considers, that the parties' undertaking resolves the competition concerns outlined above in the markets for clinical chemistry reagents and instruments.

B. DNA PROBES

(157) The undertaking to license the PCR technology to all interested competitors should ensure that there will be several entries from large IVD producers into this market. These companies, which have already, during the Commission proceedings, expressed their interest in obtaining a commercial PCR licence, have the same incentives to enter this high-growth market within the IVD industry as BM had prior to the merger.

(158) The scope of the licensing programme as well as the differentiation between broad licences and targeted licences for specific parameters should also ensure that not only large competitors will enter this market, but also small companies that have an interest in a specific disease with as yet unmet medical needs, but who do not have an interest in the full breadth of PCR applications. Until now, the small companies that were active in the R&D of new tests using a research licence from Roche could not market these tests themselves but had to sell their development results to Roche or another company with a commercial PCR licence.

(159) The commitment to conclude at least one broad licence and one targeted licence within the periods specified above ensures that market entry will be timely.

(160) Since the broad licences will be given to suppliers which are already active in the IVD-industry, any concern about Roche's unique potential ability to bundle DNA probes with other IVD products will also be removed by the undertaking. The undertaking will place the licensees in a similar competitive position as regards the ability to offer DNA probes combined with other IVD products.

(161) As a result of these commitments, the Commission considers that the abovementioned reinforcement of a dominant position in DNA probes arising from the notified merger will effectively be removed.

(162) In order for the Commission to deal with requests from Roche relating to the divestiture of the Cobas Mira business, as indicated in paragraph 146, as well as with requests relating to the appointment of a trustee and an auditor, as indicated in paragraphs 147, 149 and 151 in a timely fashion, and in order to reduce any hardship to Roche, a non-opposition procedure should apply to the Commission's treatment of such requests. Roche should provide the Commission with all relevant data demonstrating the independence of the proposed trustee, auditor or purchaser, as the case may be. In relation to a proposed purchaser, Roche should also provide sufficient information to show that the proposed party will be a viable competitor in the clinical chemistry business. If the Commission does not, within two weeks of Roche's submission, object to the request or require that further information be submitted, it shall be deemed to have approved the request.

VIII. **FINAL CONCLUSION**

(163) Consequently, the Commission concludes that, subject to full compliance with the commitments made by Roche, as set out in its letter to the Commission of 19 January 1998, and in recitals 145 to 151, the proposed concentration will not create or strengthen a dominant position, as a result of which effective competition would be significantly impeded in the common market or a substantial part of it,

HAS ADOPTED THIS DECISION:

Article 1

Subject to full compliance with the commitments made by F. Hoffmann-La Roche Ltd, as set out in recitals 145 to 151 of this Decision, the concentration by which the Hoffmann-La Roche group acquires control of the whole of Corange Ltd. is declared compatible with the common market and the functioning of the EEA Agreement.

Article 2

Whenever F. Hoffmann-La Roche Ltd, in accordance with its commitments, submits to the Commission for approval a proposal for a trustee, an auditor or a purchaser of the Cobas Mira business, it shall provide the Commission with all relevant data demonstrating the independence of the proposed trustee, auditor or purchaser, as the case may be. In relation to a proposed purchaser, F. Hoffmann-La Roche Ltd should also provide sufficient information to show that the proposed party will be a viable competitor in the clinical chemistry business. If the Commission does not, within two weeks of submission of the request, object to it or require that further information be submitted, it shall be deemed to have approved the request.

Article 3

This Decision is addressed to:

F. Hoffmann-La Roche Ltd
Grenzacherstraße 124
CH-4070 Basel.

Done at Brussels, 4 February 1998.

For the Commission
Karel VAN MIERT
Member of the Commission

COMMISSION DECISION

of 24 July 1998

on the treatment for national accounts purposes of VAT fraud (the discrepancies between theoretical VAT receipts and actual VAT receipts)

(notified under document number C(1998) 2202)

(Text with EEA relevance)

(98/527/EC, Euratom)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty establishing the European Atomic Energy Community,

Having regard to Council Directive 89/130/EEC, Euratom, of 13 February 1989 on the harmonisation of the compilation of gross national product at market prices [1], and in particular Article 1 thereof,

Whereas Commission Decision 94/168/EC, Euratom, of 22 February 1994 on measures to be taken for the implementation of Council Directive 89/130/EEC, Euratom on the harmonization of the compilation of gross national product at market prices [2], relates in particular to tax evasion but does not explicitly describe how VAT evasion should be treated; whereas it is therefore appropriate to describe how such evasion should be treated;

Whereas, in order to ensure the exhaustiveness of their GDP and GNP estimates in accordance with Directive 89/130/EEC, Euratom, the Member States need to adjust those estimates so as to take VAT evasion into account;

Whereas such adjustment relates to that component of the discrepancies between theoretical VAT receipts and actual VAT receipts which is attributable to evasion not involving the connivance of the buyer ('without complicity');

Whereas the measures provided for in this Decision are compatible with the opinion of the committee set up by Article 6 of Directive 89/130/EEC, Euratom,

HAS ADOPTED THIS DECISION:

Article 1

The Member States shall calculate the value of VAT evasion 'without complicity' by applying the methods set out in the Annex to this Decision.

For the purposes of the above-mentioned calculation, the Member States shall determine theoretical VAT receipts and actual VAT receipts and calculate the discrepancy between these two amounts, by applying the following formula:

Evasion 'without complicity'	= Theoretical VAT receipts *less* actual VAT receipts *less* time differences *less* insolvencies *less* missing revenue (evasion 'with complicity')

The Member States shall adjust, if necessary, the amount of value added included in their GDP and GNP estimates made in accordance with Directive 89/130/EEC, Euratom by adding to it the value, calculated using the above formula, of evasion 'without complicity'.

Article 2

In order to make the adjustment described in Article 1, the Member States may apply a method which is equivalent to that described in the first subparagraph of Article 1, and which produces comparable results.

[1] OJ L 49, 21. 2. 1989, p. 26.
[2] OJ L 77, 19. 3. 1994, p. 51.

Article 3

The Member States shall, no later than 1 October 1998, provide the Commission with an explanation of the sources and methods applied and state the value of the adjustments made. The Commission shall, in accordance with Article 19 of Council Regulation (EEC, Euratom) No 1552/89 [1], examine the validity of the sources and methods used and the adjustments made, and the comparability of the results obtained, particularly in cases where, in accordance with Article 2, the method described in the first subparagraph of Article 1 has not been used.

The time limit for the new Member States (Austria, Finland and Sweden) is fixed at 1 October 1999.

Article 4

If a Member State can demonstrate to the Commission that the equivalent calculation is already implicit in its accounts, Article 1 shall have no effect. Any Member State wishing to follow this route shall supply full documentation to the Commission by 1 October 1998 (for Austria, Finland and Sweden: 1 October 1999).

The Commission shall inform the GNP Committee on the outcome of the implementation of this Decision and, in particular, on the methods used by the Member States.

Article 5

This Decision is addressed to the Member States.

Done at Brussels, 24 July 1998.

For the Commission
Yves-Thibault DE SILGUY
Member of the Commission

[1] OJ L 155, 7. 6. 1989, p. 1.

ANNEX

The value of VAT evasion not involving the connivance of the buyer ('without complicity') is calculated using the two following variables:

1. The value of theoretical VAT receipts;

2. The discrepancies between theoretical VAT receipts and VAT receipts actually collected during the period.

Calculation of theoretical VAT receipts

The theoretical VAT receipts are the amounts of VAT which would be collected if all units subject to VAT were to pay it as required by law.

In order to calculate theoretical VAT receipts, the first step is to bring the VAT base into line with current legislation: in other words, to identify all the transactions which are subject to non-deductible VAT. Final household consumption is treated as wholly subject to non-deductible VAT, whereas other categories of uses have to be broken down in order to determine a rate of non-deductibility. This calculation is made using the most highly disaggregated national accounts data available. The VAT base is calculated in the light of all current legislation and rules governing VAT.

The second step is to apply the appropriate rate of VAT to each transaction constituting the VAT base as defined in the previous paragraph. The VAT rates applied must be those in force during the year for which the VAT base has been calculated. Theoretical VAT receipts are calculated in the light of all current legislation and rules governing VAT.

Calculation of the discrepancies between theoretical VAT receipts and VAT receipts actually collected during the reference period

The discrepancies between theoretical VAT receipts (calculated in the light of all current legislation and rules) and actual VAT receipts comprises four components:

1. Time differences between treasury data and national accounts data;

2. *Ad hoc* cancellations by the tax authorities of certain VAT claims in cases of insolvency;

3. Evasion involving the buyers' connivance (with complicity) (cases where the buyer does not pay VAT to the seller);

4. Evasion not involving the buyers' connivance (without complicity) (cases where the buyer pays VAT to the seller, but the latter fails to remit it to the tax authorities).

As a result, the value of evasion 'without complicity' is arrived at by deducting evasion 'with complicity' and insolvency-related cancellations from the discrepancies between theoretical VAT receipts and actual VAT receipts, taking into account time differences between the transaction giving rise to the VAT and the collection of VAT receipts by the tax authorities.

Evasion 'without complicity' =	Theoretical VAT receipts *less* actual VAT receipts *less* time differences *less* insolvencies *less* missing receipts (evasion 'with complicity')

Actual VAT receipts are the amounts actually collected by the tax authorities during the period to which the calculation of theoretical VAT receipts relates.

Adjustments for time differences are intended to correct receipts so as to allow for the fact that some payments of VAT made in the current year *(n)* relate to the previous year *(n − 1)* and that some VAT payable in respect of year *n* is not actually collected until the following year *(n + 1)*.

There may be instances where current legislation entitles the tax authorities to make *ad hoc* cancellations of VAT claims in cases of insolvency. In such cases, the value of the cancellations must be deducted from the difference between theoretical VAT receipts and actual VAT receipts (unless it has already been taken into account in the calculation of theoretical VAT receipts).

In order to calculate the value of evasion 'with complicity', only those activities should be taken into account in respect of which an adjustment for undeclared work (non-recording in statistical files of economically active units) has been made.

By using this method, applying the adjustments for undeclared work previously made to the output of branches of economic activity and multiplying the corresponding amounts for additional sales (undeclared sales) by the appropriate rates of VAT, it is possible to estimate the value of 'missing' VAT receipts which the tax authorities have been denied because of VAT evasion 'with complicity'.

By way of example: if, following an adjustment for undeclared work, the estimate of the household consumption of a given product, excluding VAT, is increased by 15 %, and if the rate of VAT applying to purchases of that product is 18,6 %, the amount owing to the tax authorities can be calculated as follows:

Missing VAT receipts due to evasion 'with complicity' = value of sales of the product before adjustment × 15 % × 18,6 %.