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Legislation

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[1] Text with EEA relevance

(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.

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[1] Text with EEA relevance

I

(Acts whose publication is obligatory)

COUNCIL REGULATION (EC) No 583/2004

of 22 March 2004

amending Regulations (EC) No 1782/2003 establishing common rules for direct support schemes under the common agricultural policy and establishing certain support schemes for farmers, (EC) No 1786/2003 on the common organisation of the market in dried fodder and (EC) No 1257/1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the European Union

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community,

Having regard to the Treaty concerning the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the European Union [1], signed in Athens on 16 April 2003, and in particular Article 2(3) thereof,

Having regard to the Act concerning the conditions of accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic and the adjustments to the Treaties on which the European Union is founded (hereinafter 'the Act of Accession') [2], and in particular Article 57(2) thereof,

Having regard to the proposal from the Commission,

Whereas:

(1) Council Regulation (EC) No 1782/2003 of 29 September 2003 [3] introduced common rules for direct support schemes under the common agricultural policy and established certain support schemes for farmers.

(2) The said common rules and support schemes should be amended to allow their implementation in the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia (hereinafter 'the new Member States').

(3) With a view to the introduction of modulation in the new Member States, the Commission should establish national ceilings for the additional amount of aid for the new Member States.

(4) The farmers in the new Member States will receive direct payments, following a phasing-in mechanism. In order to achieve the proper balance between policy tools designed to promote sustainable agriculture and those designed to promote rural development, the system of modulation should not be applied in the new Member States until the level of direct payments applicable in the new Member States is at least equal to the level applicable in the Community as constituted on 30 April 2004.

(5) Taking into account the levels of direct payments for farmers in the new Member States as a result of phasing-in, it should be foreseen that in the framework of the application of the schedule of increments provided for in Article 143a to all direct payments granted in the new Member States, the instrument of financial discipline should not apply in the new Member States until the level of direct payments applicable in the new Member States is at least equal to the level applicable in the Community as constituted on 30 April 2004.

(6) Direct payments under the single payment scheme are based on reference amounts of direct payments that were received in the past or on regionalised per hectare payments. Farmers in the new Member States did not receive Community direct payments and have no historical references for the calendar years 2000, 2001 and 2002. Therefore, the single payment scheme in the new Member States should be based on regionalised per hectare payments, subdivided between regions according to objective criteria and divided by the farmers whose holdings are located in the region concerned and that meet the eligibility criteria.

(7) The amount of direct payments, described in national ceilings, under the single payment scheme for the new Member States should be based on the quota, ceilings and quantities that were agreed in the accession negotiations multiplied by the relevant aid amounts per hectare, head or tonne.

[1] OJ L 236, 23.9.2003, p. 17.
[2] OJ L 236, 23.9.2003, p. 33.
[3] OJ L 270, 21.10.2003, p. 1.

(8) As of 1 April 2005 the market measure benefiting the production of dried fodder, as provided for in Council Regulation (EC) No 1786/2003 of 29 September 2003 on the common organisation of the market in dried fodder [1], is amended. From that date the market support is partially turned into a direct payment which will benefit farmers. In order to avoid a decrease in overall support in 2005 for the new Member States, it is appropriate to derogate from the general principle of phasing-in of direct payments. Therefore, the dried-fodder-related component in the single payment scheme national ceiling should be calculated at the 100 % aid level instead of at the phasing-in aid level.

(9) Under the regionalised option for the single payment scheme the new Member States should have the possibility of adjusting the premium per hectare on the basis of objective criteria in order to ensure equal treatment between farmers and to avoid market distortions.

(10) The new Member States should have the possibility of partially implementing and/or to exclude certain sectors from the single payment scheme.

(11) The sectoral ceilings for partial implementation and/or the exclusion of certain sectors of the single payment scheme should be based on the quota, ceilings and quantities that were agreed in the accession negotiations.

(12) The transition from the single area payment scheme to the single payment scheme and other aid schemes may give rise to difficulties of adaptation which are not dealt with in this Regulation. In order to deal with this eventuality, a general provision should be included in Regulation (EC) No 1782/2003 enabling the Commission to adopt the transitional measures necessary for a certain period.

(13) In view of the short programming period, the Act of Accession introduced the possibility of integrating a 'LEADER + (Community initiative for rural development) type measure' in the mainstream programmes, instead of having separate LEADER + programming. Therefore the measure 'management of integrated rural development strategies by local partnerships' introduced in Council Regulation (EC) No 1257/1999 of 17 May 1999 on support for rural development from the European Agricultural Guidance and Guarantee Fund (EAGGF) [2] is not needed for the new Member States, as it is covered by the LEADER + type measure.

(14) Regulations (EC) No 1782/2003, (EC) No 1786/2003 and (EC) No 1257/1999 should therefore be amended accordingly,

HAS ADOPTED THIS REGULATION:

Article 1

Council Regulation (EC) No 1782/2003 is amended as follows:

1. In Article 5(2) the following sentence is added at the end of the first subparagraph:

'The new Member States shall ensure that land which was under permanent pasture on 1 May 2004 is maintained under permanent pasture.'

2. In Article 12 the following paragraph is added:

'5. For the new Member States, the ceilings referred to in paragraph 2 shall be fixed by the Commission in accordance with the procedure referred to in Article 144(2).'

3. After Article 12 the following Article is added:

'*Article 12a*

Application to new Member States

1. Articles 10 and 12 shall not apply to the new Member States until the beginning of the calendar year, in respect of which the level of direct payments applicable in the new Member States is at least equal to the then applicable level of such payments in the Community as constituted on 30 April 2004.

2. In the framework of the application of the schedule of increments provided for in Article 143a to all direct payments granted in the new Member States, Article 11 shall not apply to the new Member States until the beginning of the calendar year, in respect of which the level of direct payments applicable in the new Member States is at least equal to the then applicable level of such payments in the Community as constituted on 30 April 2004.'

4. In Article 54(2) the following sentence is added at the end of the first subparagraph:

'For the new Member States, the reference to the date provided for the area aid applications for 2003 shall be construed as a reference to 30 June 2003.'

[1] OJ L 270, 21.10.2003, p. 114.
[2] OJ L 160, 26.6.1999. p. 80. Regulation as last amended by Regulation (EC) No 1783/2003 (OJ L 270, 21.10.2003, p. 70).

5. In Title III the following Chapter is added:

'CHAPTER 6

IMPLEMENTATION IN THE NEW MEMBER STATES

Article 71a

1. Save as otherwise provided for in this Chapter, the provisions of this Title shall apply to the new Member States.

Articles 33, 34, 37, 38, 39, 40(1), (2), (3) and (5), 41, 42, 43, 47 to 50, 53 and 58 to 63 shall not apply.

2. Any new Member State applying the single area payment scheme shall take the decisions referred to in Articles 64(1) and 71(1) by 1 August of the year preceding that in respect of which it will apply the single payment scheme for the first time.

Article 71b

Application for support

1. Farmers shall apply for support under the single payment scheme by a date, to be fixed by the new Member States, but not later than 15 May.

2. Except in case of *force majeure* and exceptional circumstances within the meaning of Article 40(4), no entitlements shall be allocated to farmers if they do not apply for the single payment scheme by 15 May of the first year of application of the single payment scheme.

3. The amounts corresponding to entitlements not allocated shall revert to the national reserve referred to in Article 71d and shall be available for reallocation.

Article 71c

Ceiling

The national ceilings of the new Member States shall be those listed in Annex VIIIa.

Article 71d

National reserve

1. Each new Member State shall proceed to a linear percentage reduction of its national ceiling in order to constitute a national reserve. This reduction shall not be greater than 3 %, without prejudice to the application of Article 71b(3).

2. The new Member States shall use the national reserve for the purpose of allocating, according to objective criteria and in such a way as to ensure equal treatment between farmers and to avoid market and competition distortions, payment entitlements to farmers finding themselves in a special situation, to be defined by the Commission in accordance with the procedure referred to in Article 144(2).

3. During the first year of application of the single payment scheme, the new Member States may use the national reserve for the purpose of allocating payment entitlements, according to objective criteria and in such a way as to ensure equal treatment between farmers and to avoid market and competition distortions, to farmers in specific sectors, finding themselves in a special situation as a result of the transition to the single payment scheme. Such payment entitlements shall be distributed according to rules to be defined by the Commission in accordance with the procedure referred to in Article 144(2).

4. In application of paragraphs 2 and 3, new Member States may increase the unit value of entitlements within the limit of EUR 5 000, and/or the number of entitlements allocated to farmers.

5. The new Member States shall proceed to linear reductions of the entitlements where their national reserve is not sufficient to cover the cases referred to in paragraphs 2 and 3.

6. Except in case of transfer by actual or anticipated inheritance and by way of derogation from Article 46, the entitlements established using the national reserve shall not be transferred for a period of five years starting from their allocation.

By way of derogation from Article 45(1), any entitlement which has not been used during each year of the five-year period shall revert immediately to the national reserve.

Article 71e

Regional allocation of the ceiling referred to in Article 71c

1. The new Member States shall apply the single payment scheme at regional level.

2. The new Member States shall define the regions according to objective criteria.

New Member States with less than three million eligible hectares may be considered as one single region.

3. Each new Member State shall subdivide its national ceiling referred to in Article 71c after any reduction according to Article 71d between the regions according to objective criteria.

Article 71f

Regionalisation of the single payment scheme

1. All farmers whose holdings are located in a given region shall receive entitlements, whose unit value is calculated by dividing the regional ceiling established pursuant to Article 71e by the number of eligible hectares within the meaning of Article 44(2), established at regional level.

2. The number of entitlements per farmer shall be equal to the number of hectares he/she declares in accordance with Article 44(2) for the first year of application of the single payment scheme, except in case of *force majeure* or exceptional circumstances within the meaning of Article 40(4).

3. The payment entitlements per hectare shall not be modified save as otherwise provided.

Article 71g

Use of the land

1. Farmers may, by way of derogation from Article 51 and in accordance with the provisions of this Article, also use the parcels declared according to Article 44(3) for the production of products referred to in Article 1(2) of Regulation (EC) No 2200/96 (*) and in Article 1(2) of Regulation (EC) No 2201/96 (**) and potatoes other than those intended for the manufacture of potato starch for which aid is granted pursuant Article 93 of this Regulation, except permanent crops.

2. The new Member States shall establish the number of hectares that may be used according to paragraph 1 by subdividing, according to objective criteria, the average of the number of hectares that were used for the production of the products referred to in paragraph 1 at national level during the three-year period 2000 to 2002 amongst the regions defined pursuant to Article 71e(2). The average number of hectares at national level and the number of hectares at regional level shall be fixed by the Commission in accordance with the procedure referred to in Article 144(2) on the basis of the data communicated by the new Member State.

3. Within the limit established according to paragraph 2 for the region concerned, a farmer shall be allowed to make use of the option referred to in paragraph 1:

(a) within the limit of the number of hectares that he/she used for the production of the products referred to in paragraph 1 in 2003;

(b) by way of derogation from Article 71a(1), second subparagraph, in case of application, *mutatis mutandis*, of Articles 40 and 42(4), within the limit of a number of hectares to be established according to objective criteria and in such a way as to ensure equal treatment between farmers and to avoid market and competition distortions.

4. Within the limit of the number of hectares that remain available after application of paragraph 3, farmers shall be allowed to produce the products referred to in paragraph 1 on a number of hectares other than the number of hectares falling under paragraph 3 within the limit of a number of hectares used for the production of the products referred to in paragraph 1 in 2004 and/or 2005, whereby priority shall be given to the farmers who produced the products already in 2004 within the limit of the number of hectares used in 2004.

In case of application of Article 71 or Article 143b, 2004 and 2005 shall be replaced by, respectively, the year previous to the year of application of the single payment scheme and the year of application itself.

5. In order to establish the individual limits referred to in paragraphs 3 and 4, new Members States shall use the farmer's individual data, where available, or any other evidence provided by the farmer to their satisfaction.

6. The number of hectares for which the authorisation has been established according to paragraphs 3 and 4 shall in no case exceed the number of eligible hectares as defined in Article 44(2) declared in the first year of application of the single payment scheme.

7. The authorisation shall be used, within the region concerned, with the corresponding payment entitlement.

8. The report referred to in Article 60 shall also concern implementation by the new Member States.

Article 71h

Grassland

The new Member States may also, according to objective criteria, fix, within the regional ceiling or part of it, different per unit values of entitlements to be allocated to farmers referred to in Article 71f(1), for hectares of grassland as identified on 30 June 2003 and for any other eligible hectare or alternatively for hectares of permanent pasture as identified on 30 June 2003 and for any other eligible hectare.

Article 71i

Dairy premium and additional payments

Starting from 2007, the amounts resulting from dairy premium and additional payments provided for in Articles 95 and 96 and to be granted in 2007 shall be included in the single payment scheme.

However, new Member States may decide that the amounts resulting from dairy premiums and additional payments, provided for in Articles 95 and 96, shall be included, in part or in full, in the single payment scheme starting from 2005. Entitlements established according to this paragraph shall be modified accordingly.

The amount used for the establishment of entitlements in respect of those payments shall be equal to the amounts to be granted according to Articles 95 and 96, calculated on the basis of the individual reference quantity for milk available on the holding on 31 March of the year of inclusion, in part or in full, of those payments in the single payment scheme.

By way of derogation from Article 71a(1), Articles 48, 49 and 50 shall apply *mutatis mutandis*.

Article 71j

Set-aside entitlements

1. Farmers shall receive part of their payment entitlements in the form of set-aside entitlements.

2. The number of set-aside entitlements shall be established by multiplying the farmer's eligible land within the meaning of Article 54(2) declared in the first year of application of the single payment scheme with the applicable set-aside rate.

The set-aside rate shall be calculated by multiplying the basic rate of compulsory set-aside of 10 % by the proportion, in the region concerned, between the regional base area or areas referred to in the third paragraph of Article 101 and the eligible land within the meaning of Article 54(2).

3. The value of the set-aside entitlements shall be the regional value for payment entitlements as established according to Article 71f(1).

4. Paragraphs 1 to 3 shall not apply to farmers who declare less than a number of hectares within the meaning of Article 54(2) which would be needed to produce a number of tonnes equal to 92 tonnes of cereals as defined in Annex IX on the basis of the reference yield referred to in Annex XIb applicable to the new Member State where the holding is located, divided by the proportion referred to in the second subparagraph of paragraph 2.

Article 71k

Conditions for the entitlements

1. By way of derogation from Article 46(1), entitlements established in accordance with this chapter may only be transferred within the same region or between regions where the entitlements per hectare are the same.

2. New Member States may also decide, by 1 August of the year preceding the first year of application of the single payment scheme at the latest, and acting in compliance with the general principle of Community law, that entitlements established in accordance with this chapter shall be subject to progressive modifications according to pre-established steps and objective criteria.

Article 71l

Optional implementation

1. Sections 2, 3 and 4 of Chapter 5 shall apply to the new Member States under the conditions laid down in this Article. However, Section 4 shall not apply to new Member States applying the single area payment scheme referred to in Article 143b.

2. Any reference in Sections 2 and 3 of Chapter 5 to Article 41, in particular with regard to the national ceiling(s), shall be construed as a reference to Article 71c.

3. The report referred to in Article 64(3) shall include the options laid down in this chapter.

(*) OJ L 297, 21.11.1996, p. 1.
(**) OJ L 297, 21.11.1996, p. 29.'

6. Article 74(1) is replaced by the following:

'1. The aid shall be granted for national base areas in the traditional production zones listed in Annex X.

The base area shall be as follows:

Greece	617 000 ha
Spain	594 000 ha
France	208 000 ha
Italy	1 646 000 ha
Cyprus	6 183 ha
Hungary	2 500 ha
Austria	7 000 ha
Portugal	118 000 ha'

7. Article 78(1) is replaced by the following:

'1. A maximum guaranteed area of 1 600 000 ha for which the aid may be granted is hereby established.'

8. Article 80(2) is replaced by the following:

'2. The aid shall be as follows, according to the yields in the Member States concerned:

	Marketing year 2004/05 and in case of application of Article 71 (EUR/ha)	Marketing year 2005/06 and onward (EUR/ha)
Greece	1 323,96	561,00
Spain	1 123,95	476,25
France		
— metropolitan territory	971,73	411,75
— French Guiana	1 329,27	563,25
Italy	1 069,08	453,00
Hungary	548,70	232,50
Portugal	1 070,85	453,75'

9. Article 81 is replaced by the following:

'*Article 81*

Areas

A national base area for each producing Member State is hereby established. However, for France two base areas are established. The base areas shall be as follows:

Greece	20 333 ha
Spain	104 973 ha
France:	
— metropolitan territory	19 050 ha
— French Guiana	4 190 ha
Italy	219 588 ha
Hungary	3 222 ha
Portugal	24 667 ha

A Member State may subdivide its base area or areas into sub-base areas in accordance with objective criteria.'

10. Article 84 is replaced by the following:

'*Article 84*

Areas

1. A Member State shall grant the Community aid within the limit of a ceiling calculated by multiplying the number of hectares of its NGA as fixed in paragraph 3 by the average amount of EUR 120,75.

2. A maximum guaranteed area of 812 400 ha is hereby established.

3. The maximum guaranteed area referred to in paragraph 2 shall be divided into the following NGAs:

National guaranteed areas (NGA)

Belgium	100 ha
Germany	1 500 ha
Greece	41 100 ha
Spain	568 200 ha
France	17 300 ha
Italy	130 100 ha
Cyprus	5 100 ha
Luxembourg	100 ha
Hungary	2 900 ha
Netherlands	100 ha
Austria	100 ha
Poland	1 000 ha
Portugal	41 300 ha
Slovenia	300 ha
Slovakia	3 100 ha
United Kingdom	100 ha

4. A Member State may subdivide its NGA into subareas in accordance with objective criteria, in particular at regional level or in relation to the production.'

11. Article 90 is replaced by the following:

'*Article 90*

Conditions for eligibility

The aid shall be granted only in respect of areas whose production is covered by a contract between the farmer and the processing industry, except in case of processing undertaken by the farmer himself/herself on the holding.

Areas which have been subject to an application for energy crops scheme may not be counted as being set aside for the purposes of the set-aside requirement indicated in Article 6(1) of Regulation (EC) No 1251/1999 and in Articles 54(2), 63(2), 71j and 107(1) of this Regulation.'

12. Article 94 is replaced by the following:

'*Article 94*

Conditions

The aid shall be paid only in respect of the quantity of potatoes covered by a cultivation contract between the potato producer and the starch manufacturer within the limit of the quota allocated to such undertaking, as referred to in Article 2(2) or (4) of Regulation (EC) No 1868/94.'

13. Article 99(3) is replaced by the following:

'3. The amount of aid claimed shall not exceed a ceiling, fixed by the Commission in accordance with Article 64(2), corresponding to the component of seed aids for the species concerned in the national ceiling referred to in Article 41. However, for the new Member States, this ceiling shall correspond to the amounts mentioned in Annex XIa.

When the total amount of aid claimed exceeds the fixed ceiling, the aid per farmer shall be reduced proportionately in that year.'

14. In Article 101, the following paragraph is inserted after the second paragraph:

'However, the regional base area or areas in the new Member States shall be fixed by the Commission in accordance with the procedure referred to in Article 144(2) and within the limits of the national base areas listed in Annex XIb.'

15. In Article 103, the following paragraph is inserted after the first paragraph:

'Alternatively, for any new Member State applying the single area payment scheme referred to in Article 143b in 2004 and opting for the application of Article 66, the regionalisation plan shall be established, according to objective criteria, not later than 1 August of the last year of application of the single area payment scheme. Where this is done, the combined regional base areas and the weighted average reference yield in the regions shall respect the limits of the national base area and reference yield as listed in Annex XIb.'

16. Article 105 is replaced by the following:

'*Article 105*

Durum wheat supplement

1. A supplement to the area payment of

— EUR 291/ha for the marketing year 2005/06,

— EUR 285/ha for the marketing year 2006/07 and onwards

shall be paid for the area down to durum wheat in the traditional production zones listed in Annex X, subject to the following limits:

Greece	617 000 ha
Spain	594 000 ha
France	208 000 ha
Italy	1 646 000 ha
Cyprus	6 183 ha
Hungary	2 500 ha
Austria	7 000 ha
Portugal	118 000 ha.

2. Should the total of the areas for which a supplement to the area payment is claimed be greater than the limit referred to in paragraph 1 during the course of a marketing year, the area per farmer for which the supplement may be paid shall be reduced proportionately.

However, subject to the limits per Member State laid down in paragraph 1, Member States may distribute the areas indicated in that paragraph among the production zones as defined in Annex X, or, for the Member States of the Community as constituted on 30 April 2004, if necessary, the production regions of the regionalisation plan, according to the extent of the production of durum wheat during the period 1993 to 1997. Where this is done, should the total of the areas within a region for which a supplement to the area payment is requested be greater than the corresponding regional limit during the course of a marketing year, the area per farmer in that production region for which the supplement may be paid shall be reduced proportionately. The reduction shall be made when, within a Member State, the areas in regions which have not reached their regional limits have been distributed to regions in which those limits have been exceeded.

3. In regions where the production of durum wheat is well established, other than those referred to in Annex X, special aid amounting to EUR 46/ha for the marketing year 2005/06 shall be granted up to a limit of the following number of hectares:

Germany	10 000 ha
Spain	4 000 ha
France	50 000 ha
Italy	4 000 ha
Hungary	4 305 ha
Slovakia	4 717 ha
United Kingdom	5 000 ha.'

17. Article 108 is replaced by the following:

'*Article 108*

Eligible land

Applications for payments may not be made in respect of land which, at the date provided for the area aid applications for 2003, was under permanent pasture, permanent crops or trees or was used for non-agricultural purposes.

For the new Member States, applications for payments may not be made in respect of land which, on 30 June 2003, was under permanent pasture, permanent crops or trees or was used for non-agricultural purposes.

Member States may, on terms to be determined in accordance with the procedure referred to in Article 144(2), derogate from the first or second subparagraph of this Article provided that they take action to prevent any significant increase in the total eligible agricultural area.'

18. Article 116(2) is replaced by the following:

'2. Member States shall take the necessary measures to ensure that the sum of premium rights on their territory does not exceed the national ceilings set out in paragraph 4 and that the national reserves referred to in Article 118 may be maintained.

Except in cases where Article 143b is applied, the new Member States shall allocate individual ceilings to producers and shall set up the national reserves from the overall number of rights to the premium reserved for each of these new Member States as set out in paragraph 4, no later than one year after the date of accession.

After the end of the period of application of the single area payment scheme according to Article 143b and where Article 67 is applied, the allocation of the individual ceilings to producers and the setting up of the national reserve referred to in the second subparagraph shall take place no later than the end of the first year of the application of the single payment scheme.'

19. Article 116(4) is replaced by the following:

'4. The following ceilings shall apply:

Member State	Rights (× 1 000)
Belgium	70
Czech Republic	66,733
Denmark	104
Germany	2 432
Estonia	48
Greece	11 023
Spain	19 580
France	7 842
Ireland	4 956
Italy	9 575
Cyprus	472,401
Latvia	18,437
Lithuania	17,304
Luxembourg	4
Hungary	1 146
Malta	8,485
Netherlands	930
Austria	206
Poland	335,88
Portugal (*)	2 690
Slovenia	84,909
Slovakia	305,756
Finland	80
Sweden	180
United Kingdom	19 492
Total	81 667,905

(*) To be adjusted on the expiry of Regulation (EC) No 1017/94.'

20. Article 119(3) is replaced by the following:

'3. The following global amounts shall apply:

(EUR 1 000)

Belgium	64
Czech Republic	71
Denmark	79
Germany	1 793
Estonia	51
Greece	8 767
Spain	18 827
France	7 083
Ireland	4 875
Italy	6 920
Cyprus	441
Latvia	19
Lithuania	18
Luxembourg	4
Hungary	1 212
Malta	9
Netherlands	743
Austria	185
Poland	355
Portugal	2 275
Slovenia	86
Slovakia	323
Finland	61
Sweden	162
United Kingdom	20 162'

21. In Article 119, the following paragraph is added:

'4. In the new Member States, the global amounts shall be applied in accordance with the schedule of increments as set out in Article 143a.'

22. Article 123(8) is replaced by the following:

'8. The following regional ceilings shall apply:

Belgium	235 149
Czech Republic	244 349
Denmark	277 110
Germany	1 782 700
Estonia	18 800
Greece	143 134
Spain	713 999 (*)
France	1 754 732 (**)
Ireland	1 077 458
Italy	598 746
Cyprus	12 000
Latvia	70 200
Lithuania	150 000
Luxembourg	18 962
Hungary	94 620
Malta	3 201
Netherlands	157 932
Austria	373 400
Poland	926 000
Portugal	175 075 (***) (****)
Slovenia	92 276
Slovakia	78 348
Finland	250 000
Sweden	250 000
United Kingdom	1 419 811 (*****)

(*) Without prejudice to the specific rules laid down in Regulation (EC) No 1454/2001.
(**) Without prejudice to the specific rules laid down in Regulation (EC) No 1452/2001.
(***) Without prejudice to the specific rules laid down in Regulation (EC) No 1453/2001.
(****) To be adjusted on the expiry of Regulation (EC) No 1017/94.
(*****) This ceiling shall be temporarily increased by 100 000 to 1 519 811 until such time as live animals under six months of age may be exported.'

23. Article 126(1) is replaced by the following:

'1. An aid shall be granted to each farmer of suckler cows within the limit of the individual ceilings established in application of Article 7 of Regulation (EC) No 1254/1999 or of the second subparagraph of paragraph 2.'

24. Article 126(2) is replaced by the following:

'2. Member States shall take the necessary steps to ensure that the sum of premium rights on their territory does not exceed the national ceilings set out in paragraph 5 and that the national reserves referred to in Article 128 may be maintained.

Except in cases where Article 143b is applied, the new Member States shall allocate individual ceilings to producers and shall set up the national reserves from the overall number of rights to the premium reserved for each of these Member States as set out in paragraph 5, no later than one year after the date of accession.

After the end of the period of application of the single area payment scheme according to Article 143b and where Article 68(2)(a)(i) is applied, the allocation of the individual ceilings to producers and the setting up of the national reserve referred to in the second subparagraph shall take place no later than the end of the first year of the application of the single payment scheme.'

25. Article 126(5) is replaced by the following:

'5. The following national ceilings shall apply:

Belgium	394 253
Czech Republic (*)	90 300
Denmark	112 932
Germany	639 535
Estonia (*)	13 416
Greece	138 005
Spain (**)	1 441 539
France (***)	3 779 866
Ireland	1 102 620
Italy	621 611
Cyprus (*)	500
Latvia (*)	19 368
Lithuania (*)	47 232
Luxembourg	18 537
Hungary (*)	117 000
Malta (*)	454
Netherlands	63 236
Austria	375 000
Poland (*)	325 581
Portugal (****) (*****)	416 539
Slovenia (*)	86 384
Slovakia (*)	28 080
Finland	55 000
Sweden	155 000
United Kingdom	1 699 511

(*) Applicable from the date of accession.
(**) Without prejudice to the specific rules laid down in Regulation (EC) No 1454/2001.
(***) Without prejudice to the specific rules laid down in Regulation (EC) No 1452/2001.
(****) Without prejudice to the specific rules laid down in Regulation (EC) No 1453/2001.
(*****) To be increased on the expiry of Regulation (EC) No 1017/94 by the premiums resulting from the application of that Regulation in 2003 and 2004.'

26. In Article 130(3) the following subparagraph is added:

'For the new Member States the national ceilings shall be those contained in the following table:

	Bulls, steers, cows and heifers	Calves more than 1 and less than 8 months old and of carcase weight up to 185 kg
Czech Republic	483 382	27 380
Estonia	107 813	30 000
Cyprus	21 000	—
Latvia	124 320	53 280
Lithuania	367 484	244 200
Hungary	141 559	94 439
Malta	6 002	17
Poland	1 815 430	839 518
Slovenia	161 137	35 852
Slovakia	204 062	62 841'

27. Article 133(3) is replaced by the following:

'3. The following global amounts shall apply:

(EUR million)

Belgium	39,4
Czech Republic	8,776017
Denmark	11,8
Germany	88,4
Estonia	1,13451
Greece	3,8
Spain	33,1
France	93,4
Ireland	31,4
Italy	65,6
Cyprus	0,308945
Latvia	1,33068
Lithuania	4,942267
Luxembourg	3,4
Hungary	2,936076
Malta	0,0637
Netherlands	25,3
Austria	12,0
Poland	27,3
Portugal	6,2
Slovenia	2,964780
Slovakia	4,500535
Finland	6,2
Sweden	9,2
United Kingdom	63,8'

28. In Article 135(1), the following indent is added to the first subparagraph:

'— for the new Member States: equal to the ceilings set out in Article 123(8) or equal to the average number of slaughterings of male bovine animals during the years 2001, 2002 and 2003 deriving from Eurostat statistics for these years or any other published official statistical information for these years accepted by the Commission.'

29. In Article 135(4), the following sentence is added:

'For the new Member States the reference years shall be 2001, 2002 and 2003.'

30. In Article 136(2), the following sentence is added to the second subparagraph:

'For the new Member States the reference years shall be 1999, 2000 and 2001.'

31. After Article 136, the following Article is inserted:

'*Article 136a*

Conditions of application in the new Member States

In the new Member States, the global amounts referred to in Article 133(3) and the maximum area payment per hectare at EUR 350 referred to in Article 136(3) shall be applied in accordance with the schedule of increments as set out in Article 143a.'

32. In Article 139, the following sentence is added to the first subparagraph:

'However, for the new Member States, the ceiling fixed by the Commission in accordance with Article 64(2) shall correspond to the component of each of the direct payments concerned in the ceiling referred to in Article 71c.'

33. Article 143 is replaced by the following:

'*Article 143*

Ceiling

The sum of the aid claimed shall not be higher than a ceiling fixed by the Commission in accordance with Article 64(2), corresponding to the component of grain legumes area payments referred to in Annex VI in the national ceiling referred to in Article 41. However, for the new Member States, the ceiling fixed by the Commission in accordance with Article 64(2) shall correspond to the component of grain legumes area payments referred to in Annex VI in the national ceiling referred to in Article 71c.

When the total amount of aid claimed exceeds the fixed ceiling, the aid per farmer shall be reduced proportionately in that year.'

34. In Article 145, point (d) is replaced by the following:

'(d) with regard to the single payment scheme, detailed rules relating in particular to the establishment of national reserve, the transfer of entitlements, the definition of permanent crops, permanent pastures, agricultural land and grassland, the options provided for in Chapters 5 and 6 of Title III and the list of crops allowed on the set-aside land as well as detailed rules relating to compliance with the Memorandum of Understanding on certain oil seeds between the European Economic Community and the United States of America within the framework of the GATT approved by Decision 93/355/EEC (*).

(*) OJ L 147, 18.6.1993, p. 25.'

35. In Article 145, point (i) is replaced by the following:

'(i) such amendments to Annexes II, VI, VII, IX, X and XI as may become necessary, taking into account in particular new Community legislation and, as far as it concerns Annexes VIII and VIIIa, in case of application of Articles 62 and 71i respectively and, as the case may be, in function of the information communicated by the Member States in relation to the part of the reference amounts corresponding to the payments for arable crops, as well as the amounts of the ceilings themselves, to be increased in function of the difference between the area actually determined and the area for which premiums were paid for arable crops in 2000 and 2001, in application of Article 9(2) and (3) of Commission Regulation (EEC) No 3887/92 (**), within the limit of the base areas (or maximum guaranteed area for durum wheat) and taking into account the average national yield used for the calculation of Annex VIII.

(**) OJ L 327, 12.12.2001, p. 11.'

36. In Article 145, point (q) is replaced by the following:

'(q) measures which are both necessary and duly justified to resolve, in an emergency, practical and specific problems, in particular those related to the implementation of Chapter 4 of Title II and Chapters 5 and 6 of Title III. Such measures may derogate from certain parts of this Regulation, but only to the extent that, and for such a period as, is strictly necessary.'

37. Article 146 is replaced by the following:

'*Article 146*

Transmission of information to the Commission

Member States shall inform the Commission in detail of the measures taken to implement this Regulation and, in particular, those relating to Articles 5, 13, 42, 58, 71d and 71e.'

38. After Article 154, the following Article is added:

'*Article 154a*

Transitional arrangements for new Member States

1. Where transitional measures are necessary in order to facilitate, for the new Member States, the transition from the single area payment scheme to the single payment scheme and other aid schemes referred to in Titles III and IV, such measures shall be adopted in accordance with the procedure laid down in Article 144(2).

2. The measures referred to in paragraph 1 may be adopted during a period starting on 1 May 2004 and expiring on 30 June 2009 and shall not apply beyond that date. The Council, acting by a qualified majority on a proposal from the Commission, may extend that period.'

39. After Annex VIII, the following Annex is added:

'*ANNEX VIIIA*

National ceilings referred to in Article 71c

The ceilings have been calculated taking account of the schedule of increments provided for in Article 143a, and therefore do not need to be reduced.

(EUR million)

Calendar year	Czech Republic	Estonia	Cyprus	Latvia	Lithuania	Hungary	Malta	Poland	Slovenia	Slovakia
2005	227,9	23,4	8,9	33,9	92,0	350,8	0,67	724,3	35,5	97,6
2006	265,7	27,3	10,4	39,6	107,3	408,7	0,78	845,0	41,4	113,6
2007	342,4	40,4	13,9	55,6	146,9	495,1	1,59	1 098,8	55,5	144,5
2008	427,8	50,5	17,4	69,5	183,6	618,5	1,99	1 373,4	69,4	180,5
2009	513,2	60,5	20,9	83,4	220,3	741,9	2,38	1 648,0	83,3	216,6
2010	598,5	70,6	24,4	97,3	257,0	865,2	2,78	1 922,5	97,2	252,6
2011	683,9	80,7	27,8	111,2	293,7	988,6	3,18	2 197,1	111,0	288,6
2012	769,3	90,8	31,3	125,1	330,4	1 111,9	3,57	2 471,7	124,9	324,6
subsequent years	854,6	100,9	34,8	139,0	367,1	1 235,3	3,97	2 746,3	138,8	360,6'

40. Annex X is completed by the following entries:

'CYPRUS

HUNGARY

Regions

Dél Dunamenti síkság

Dél-Dunántúl

Közép-Alföld

Mezőföld

Berettyo-Kőrös-Maros vidéke

Györi medence

Hajdúság'

41. After Annex XI the following Annexes are added:

'*ANNEX XIA*

Seed aid ceilings in the new Member States referred to in Article 99(3)

(EUR million)

Calendar year	Czech Republic	Estonia	Cyprus	Latvia	Lithuania	Hungary	Malta	Poland	Slovenia	Slovakia
2005	0,87	0,04	0,03	0,10	0,10	0,78	0,03	0,56	0,08	0,04
2006	1,02	0,04	0,03	0,12	0,12	0,90	0,03	0,65	0,10	0,04
2007	1,17	0,05	0,04	0,14	0,14	1,03	0,04	0,74	0,11	0,05
2008	1,46	0,06	0,05	0,17	0,17	1,29	0,05	0,93	0,14	0,06
2009	1,75	0,07	0,06	0,21	0,21	1,55	0,06	1,11	0,17	0,07
2010	2,04	0,08	0,07	0,24	0,24	1,81	0,07	1,30	0,19	0,08
2011	2,33	0,10	0,08	0,28	0,28	2,07	0,08	1,48	0,22	0,09
2012	2,62	0,11	0,09	0,31	0,31	2,33	0,09	1,67	0,25	0,11
subsequent years	2,91	0,12	0,10	0,35	0,35	2,59	0,10	1,85	0,28	0,12

ANNEX XIB

National arable crops base areas and reference yields in the new Member States referred to in Articles 101 and 103

	Base area (hectares)	Reference yields (t/ha)
Czech Republic	2 253 598	4,20
Estonia	362 827	2,40
Cyprus	79 004	2,30
Latvia	443 580	2,50
Lithuania	1 146 633	2,70
Hungary	3 487 792	4,73
Malta	4 565	2,02
Poland	9 454 671	3,00
Slovenia	125 171	5,27
Slovakia	1 003 453	4,06'

Article 2

Article 5(2) of Regulation (EC) No 1786/2003 shall be replaced by the following:

'2. The maximum guaranteed quantity provided for in paragraph 1 shall be divided among the Member States as follows:

Guaranteed national quantities (tonnes)

Belgo-Luxembourg Economic Union (BLEU)	8 000
Czech Republic	27 942
Denmark	334 000
Germany	421 000
Greece	37 500
Spain	1 325 000
France	1 605 000
Ireland	5 000
Italy	685 000
Lithuania	650
Hungary	49 593
Netherlands	285 000
Austria	4 400
Poland	13 538
Portugal	30 000
Slovakia	13 100
Finland	3 000
Sweden	11 000
United Kingdom	102 000'

Article 3

In Article 33 of Regulation (EC) No 1257/1999 the following paragraph shall be added:

'The measure foreseen in the last indent of the second paragraph is not applicable for the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.'

Article 4

This Regulation shall enter into force on 1 May 2004 subject to the entry into force of the Treaty concerning the accession of the Czech Republic, the Republic of Estonia, the Republic of Cyprus, the Republic of Latvia, the Republic of Lithuania, the Republic of Hungary, the Republic of Malta, the Republic of Poland, the Republic of Slovenia and the Slovak Republic to the European Union.

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

Done at Brussels, 22 March 2004.

For the Council

The President

B. COWEN

COMMISSION REGULATION (EC) No 584/2004

of 29 March 2004

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 30 March 2004.

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

Done at Brussels, 29 March 2004.

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

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

ANNEX

to the Commission Regulation of 29 March 2004 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code (1)	Standard import value
0702 00 00	052	105,5
	204	41,2
	212	119,6
	624	124,8
	999	97,8
0707 00 05	052	114,0
	068	105,0
	096	80,6
	204	19,6
	220	135,1
	999	90,9
0709 90 70	052	113,8
	204	80,8
	999	97,3
0805 10 10, 0805 10 30, 0805 10 50	052	49,7
	204	44,5
	212	57,6
	220	45,4
	400	44,9
	624	61,4
	999	50,6
0805 50 10	052	47,5
	400	51,0
	999	49,3
0808 10 20, 0808 10 50, 0808 10 90	060	27,3
	388	84,4
	400	119,7
	404	99,5
	508	74,6
	512	78,0
	524	78,9
	528	78,1
	720	83,8
	804	144,6
	999	86,9
0808 20 50	388	72,5
	512	66,9
	528	66,6
	999	68,7

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

COMMISSION REGULATION (EC) No 585/2004

of 26 March 2004

amending Regulation (EC) No 282/2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/496/EEC of 15 July 1991 laying down the principles governing the organisation of veterinary checks on animals entering the Community from third countries and amending Directives 89/662/EEC, 90/425/EEC and 90/675/EEC [1], and in particular Article 3(2) and Article 7(2) thereof,

Whereas:

(1) The transitional provisions for the border inspection posts between the Member States and the new Member States which are due to be abolished on accession are not made sufficiently clear in Article 8 of Regulation (EC) No 282/2004 introducing a document for the declaration of, and veterinary checks on, animals from third countries entering the Community [2] and should be reworded to avoid any ambiguity.

(2) The common veterinary entry document (CVED) in Regulation (EC) No 282/2004 is imprecise as regards the declarations by the person responsible for the load in box 25 and the official veterinarian in box 42 and that document should be reworded.

(3) To clarify all these points, Regulation (EC) No 282/2004 should be amended accordingly.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 282/2004 is hereby amended as follows:

1. Article 8 is replaced by the following:

   '*Article 8*

   Until 1 May 2004 this Regulation shall not apply to the border inspection posts listed in Annex II which are due to be abolished upon the accession of the Czech Republic, Hungary, Poland, Slovenia and Slovakia.';

2. the model common veterinary entry document in Annex I is replaced by the model in the Annex hereto.

Article 2

This Regulation shall enter into force on 31 March 2004.

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

Done at Brussels, 26 March 2004.

For the Commission

David BYRNE

Member of the Commission

[1] OJ L 268, 24.9.1991, p. 56. Directive as last amended by Directive 96/43/EC (OJ L 162, 1.7.1996, p. 1).

[2] OJ L 49, 19.2.2004, p. 11.

ANNEX

EUROPEAN COMMUNITY **The common veterinary entry document, CVED animals**

Part 1: Details of consignment presented

1. Consignor / Exporter
Name
Address
Country + ISO code

2. CVED reference number

Border Inspection Post

Unit number

3. Consignee
Name
Address
Postal code
Country + ISO code

4. Person responsible for the consignment
Name
Address

5. Country of origin + ISO code

6. Region of origin Code

7. Importer
Name
Address
Postal code
Country + ISO code

8. Place of destination
Name
Approval number
Address
Postal code
Country + ISO code

9. Arrival at BIP (estimated date and time)
Date Time

10. Veterinary documents
Number
Date of issue
Accompanying document(s)
Number(s)

11. Means of transport:
Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐
Identification:
Documentary references:

12. Animal species, breed

13. Commodity code (CN code)

14. Number of animals

15. Number of packages

16. Animals certified as:
Breeding/production ☐ Fattening ☐ Slaughter ☐ Approved bodies ☐ Pets ☐ Other ☐
Quarantine ☐ Registered equidae ☐ Relaying ☐ Circus/exhibition ☐

17. Seal number and container numbers

18. For transhipment to ☐
BIP BIP unit no:
3rd country 3rd country ISO code:

19. For transit to 3rd country ☐
To 3rd country + ISO code
Exit BIP: BIP unit no:

20. For import or admission
Definitive import ☐
Horses re-entry ☐
Temporary admission horses ☐
Exit date
Exit point

21. Transiting Member States ☐
Member State + ISO code
Member State + ISO code
Member State + ISO code

22. Means of transport after border inspection post
Railway wagon ☐ Registered No
Aeroplane ☐ Flight No
Ship ☐ Name
Road vehicle ☐ Plate No
Other ☐

23. Transporter
Name Approval number
Address
Postal code
Country

24. Route plan
Yes ☐ No ☐

25. Declaration
I, the undersigned person responsible for the load detailed above, certify that to the best of my knowledge and belief the statements made in Part 1 of this document are true and complete and I agree to comply with the legal requirements of Directive 91/493/EEC, including payment for veterinary checks, as well as for redispatching consignments, for quarantine or isolation of animals, or costs of euthanasia and disposal if necessary.

Place and date of declaration
Name of signatory
Signature

EUROPEAN COMMUNITY

The common veterinary entry document, CVED animals

Part 2: Decision on consignment

26. Documentary check: ☐

EU standard — Satisfactory ☐ Not satisfactory ☐

Additional guarantees — Satisfactory ☐ Not satisfactory ☐

National requirements — Satisfactory ☐ Not satisfactory ☐

27. CVED Reference Number:

28. Identity check: Derogation ☐

Satisfactory ☐ Not satisfactory ☐

29. Physical check:

Derogation ☐ Total animals checked ☐

Satisfactory ☐ Not satisfactory ☐

30. Laboratory tests: No ☐ Yes ☐

Tested for:

Random ☐ Suspicion ☐

Results: Pending ☐ Satisfactory ☐ Not satisfactory ☐

31. Welfare check: Derogation ☐

upon arrival — Satisfactory ☐ Not satisfactory ☐

32. Impact of the transport on animals

Number of dead animals ☐ Estimation ☐

Number of unfit animals ☐ Estimation ☐

Number of birth or abortion ☐

33. ACCEPTABLE for Transhipment: ☐

BIP ☐ BIP unit no:

3rd country ☐ 3rd country ISO code:

34. ACCEPTABLE for Transit Procedure ☐

To 3rd country + ISO code

Exit BIP: BIP unit no:

35. ACCEPTABLE for definitive import ☐

For controlled destination

Slaughter ☐

Approved bodies ☐

Quarantine ☐

36. ACCEPTABLE for temporary admission ☐

Deadline

37. Reason for refusal

1. Absence/Invalid certificate ☐
2. Mismatch with documents ☐
3. Non-approved country ☐
4. Non-approved region ☐
5. Prohibited species ☐
6. Absence of additional guarantees ☐
7. Safeguard clause ☐
8. Diseased or suspect animals ☐
9. Non-satisfactory tests ☐
10. Unfit to travel ☐
11. Absence of national requirements ☐
12. Infringement of international transportation regulation ☐
13. Absence or non-legal identification ☐
14. Other ☐ ☐

38. NOT ACCEPTABLE ☐

1. Re-dispatching ☐
2. Slaughter ☐
3. Euthanasia ☐

39. Details of Controlled Destinations (35,36,38)

Approval no (where relevant):

Address:

Postal code

40. Consignment resealed

New seal no:

41. Full identification of border inspection post and official stamp

BIP Stamp

BIP unit no:

42. Official Veterinarian

I the undersigned official veterinarian for the BIP, certify that the veterinary checks on the consignment have been carried out in accordance with EU requirements and if needed in accordance with the national requirements of the Member States of destination

Name (in capitals):

Date: Signature:

43. Customs Document Reference:

Part 3: Control

44. Details on re-dispatching:

Means of transport no:

Railway wagon ☐ Aeroplane ☐ Ship ☐ Road vehicle ☐

Country of destination: + ISO code

Date:

45. Follow-up

Exit BIP: ☐ Final destination BIP ☐ Local Veterinary Unit ☐

Arrival of the consignment Yes ☐ No ☐ Correspondence of the consignement Yes ☐ No ☐

46. Official veterinarian

Name (in capitals):

Address: Unit number

Date: Stamp Signature:

COMMISSION REGULATION (EC) No 586/2004

of 29 March 2004

determining the extent to which applications lodged in March 2004 for import licences for certain poultrymeat sector products pursuant to Regulation (EC) No 2497/96 can be accepted

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 2497/96 of 18 December 1996 laying down rules for the application in the poultrymeat sector of the system provided for by the Association Agreement and the Interim Agreement between the European Community and the State of Israel [1], and in particular Article 4(5) thereof,

Whereas:

The applications for import licences lodged for the period 1 January to 30 April 2004 are greater than the quantities available and must therefore be reduced by a fixed percentage to ensure a fair distribution,

HAS ADOPTED THIS REGULATION:

Article 1

1. Applications for import licences for the period 1 January to 30 April 2004 submitted pursuant to Regulation (EC) No 2497/96 shall be met as referred to in Annex I.

2. During the first seven days of the period 1 May to 30 June 2004 applications may be lodged pursuant to Regulation (EC) No 2497/96 for import licences for the total quantities as referred to in Annex II.

Article 2

This Regulation shall enter into force on 30 March 2004.

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

Done at Brussels, 29 March 2004.

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

[1] OJ L 338, 28.12.1996, p. 48. Regulation as last amended by Regulation (EC) No 361/2004 (OJ L 63, 28.2.2004, p. 15).

ANNEX I

Group No	Percentage of acceptance of import licences submitted for the period 1 January to 30 April 2004
IL1	4,08
IL2	—

ANNEX II

(tonnes)

Group No	Available quantities
IL1	245,14
IL2	87,55

COMMISSION REGULATION (EC) No 587/2004

of 29 March 2004

fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [1], and in particular Article 5(2)(a) thereof,

Whereas:

Pursuant to Article 2(2) and Article 3 of abovementioned Regulation (EEC) No 4088/87, Community import and producer prices are fixed each fortnight for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses and apply for two-weekly periods. Pursuant to Article 1b of Commission Regulation (EEC) No 700/88 of 17 March 1988 laying down detailed rules for the application of the arrangements for the import into the Community of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip [2], those prices are determined for fortnightly periods on the basis of weighted prices provided by the Member States. Those prices should be fixed immediately so the customs duties applicable can be determined. To that end, provision should be made for this Regulation to enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

The Community producer and import prices for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses as referred to in Article 1b of Regulation (EEC) No 700/88 for a fortnightly period shall be as set out in the Annex.

Article 2

This Regulation shall enter into force on 30 March 2004.

It shall apply from 31 March to 13 April 2004.

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

Done at Brussels, 29 March 2004.

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

[1] OJ L 382, 31.12.1987, p. 22. Regulation as last amended by Regulation (EC) No 1300/97 (OJ L 177, 5.7.1997, p. 1).

[2] OJ L 72, 18.3.1988, p. 16. Regulation as last amended by Regulation (EC) No 2062/97 (OJ L 289, 22.10.1997, p. 1).

ANNEX

to the Commission Regulation of 29 March 2004 fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

(EUR/100 pieces)

Period: from 31 March to 13 April 2004

Community producer price	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
	12,44	11,99	28,13	14,41
Community import prices	**Uniflorous (bloom) carnations**	**Multiflorous (spray) carnations**	**Large-flowered roses**	**Small-flowered roses**
Israel	—	—	—	—
Morocco	—	—	—	—
Cyprus	—	—	—	—
Jordan	—	—	—	—
West Bank and Gaza Strip	7,97	—	—	—

COMMISSION DIRECTIVE 2004/33/EC

of 22 March 2004

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

(2) In order to prevent the transmission of diseases by blood and blood components and to ensure an equivalent level of quality and safety, Directive 2002/98/EC calls for the establishment of specific technical requirements.

(3) This Directive lays down those technical requirements, which take account of Council Recommendation 98/463/EC of 29 June 1998 on the suitability of blood and plasma donors and the screening of donated blood in the European Community [2], certain recommendations of the Council of Europe, the opinion of the Scientific Committee for Medicinal Products and Medical Devices, the monographs of the European Pharmacopoeia, particularly in respect of blood or blood components as a starting material for the manufacture of proprietary medicinal products and recommendations of the World Health Organisation (WHO), as well as international experience in this field.

(4) Blood and blood components imported from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood and human plasma, should meet the quality and safety requirements set out in this Directive.

(5) With regard to blood and blood components collected for the sole purpose of, and exclusive use in, autologous transfusion (autologous donation), specific technical requirements should be laid down, as required by Article 2(2) of Directive 2002/98/EC. Such donations should be clearly identified and kept separate from other donations to ensure that they are not used for transfusion to other patients.

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

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

For the purposes of this Directive, the definitions set out in Annex I shall apply.

Article 2

Provision of information to prospective donors

Member States shall ensure that blood establishments provide prospective donors of blood or blood components with the information set out in Part A of Annex II.

Article 3

Information required from donors

Member States shall ensure that upon agreement of willingness to commence the donation of blood or blood components, donors provide the information set out in Part B of Annex II to the blood establishment.

Article 4

Eligibility of donors

Blood establishments shall ensure that donors of whole blood and blood components comply with the eligibility criteria set out in Annex III.

Article 5

Storage, transport and distribution conditions for blood and blood components

Blood establishments shall ensure that the storage, transport and distribution conditions for blood and blood components comply with the requirements set out in Annex IV.

[1] OJ L 33, 8.2.2003, p. 30.
[2] OJ L 203, 21.7.1998, p. 14.

Article 6

Quality and safety requirements for blood and blood components

Blood establishments shall ensure that the quality and safety requirements for blood and blood components comply with the requirements set out in Annex V.

Article 7

Autologous donations

1. Blood establishments shall ensure that autologous donations comply with the requirements set out in Directive 2002/98/EC and the specific requirements set out in this Directive.

2. Autologous donations shall be clearly identified as such and shall be kept separate from allogeneic donations.

Article 8

Validation

Member States shall ensure that all testing and processes referred to in Annexes II to V are validated.

Article 9

Transposition

1. Without prejudice to Article 7 of Directive 2002/98/EC, Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 8 February 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 10

Entry into force

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

Article 11

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 22 March 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

DEFINITIONS

(as referred to in Article 1)

1. 'Autologous donation' means blood and blood components collected from an individual and intended solely for subsequent autologous transfusion or other human application to that same individual.

2. 'Allogeneic donation' means blood and blood components collected from an individual and intended for transfusion to another individual, for use in medical devices or as starting material/raw material for manufacturing into medicinal products.

3. 'Validation' means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled.

4. 'Whole blood' means a single blood donation.

5. 'Cryopreservation' means prolongation of the storage life of blood components by freezing.

6. 'Plasma' means the liquid portion of the blood in which the cells are suspended. Plasma may be separated from the cellular portion of a whole blood collection for therapeutic use as fresh-frozen plasma or further processed to cryoprecipitate and cryoprecipitate-depleted plasma for transfusion. It may be used for the manufacture of medicinal products derived from human blood and human plasma or used in the preparation of pooled platelets, or pooled, leucocyte-depleted platelets. It may also be used for re-suspension of red cell preparations for exchange transfusion or perinatal transfusion.

7. 'Cryoprecipitate' means a plasma component prepared from plasma, fresh-frozen, by freeze-thaw precipitation of proteins and subsequent concentration and re-suspension of the precipitated proteins in a small volume of the plasma.

8. 'Washed' means a process of removing plasma or storage medium from cellular products by centrifugation, decanting of the supernatant liquid from the cells and addition of an isotonic suspension fluid, which in turn is generally removed and replaced following further centrifugation of the suspension. The centrifugation, decanting, replacing process may be repeated several times.

9. 'Red cells' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed.

10. 'Red cells, buffy coat removed' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed.

11. 'Red cells, leucocyte-depleted' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed.

12. 'Red cells in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. A nutrient/preservative solution is added.

13. 'Additive solution' means a solution specifically formulated to maintain beneficial properties of cellular components during storage.

14. 'Red cells, buffy coat removed, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed. The buffy coat, containing a large proportion of the platelets and leucocytes in the donated unit, is removed. A nutrient/preservative solution is added.

15. 'Buffy coat' means a blood component prepared by centrifugation of a unit of whole blood, and which contains a considerable proportion of the leucocytes and platelets.

16. 'Red cells, leucocyte-depleted, in additive solution' means the red cells from a single whole blood donation, with a large proportion of the plasma from the donation removed, and from which leucocytes are removed. A nutrient/preservative solution is added.

17. 'Red cells, apheresis' means the red cells from an apheresis red cell donation.

18. 'Apheresis' means a method of obtaining one or more blood components by machine processing of whole blood in which the residual components of the blood are returned to the donor during or at the end of the process.

19. 'Platelets, apheresis' means a concentrated suspension of blood platelets obtained by apheresis.

20. 'Platelets, apheresis, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by apheresis, and from which leucocytes are removed.

21. 'Platelets, recovered, pooled' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation.

22. 'Platelets, recovered, pooled, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of whole blood units and pooling the platelets from the units during or after separation, and from which leucocytes are removed.

23. 'Platelets, recovered, single unit' means a concentrated suspension of blood platelets, obtained by processing of a single unit of whole blood.

24. 'Platelets, recovered, single unit, leucocyte-depleted' means a concentrated suspension of blood platelets, obtained by processing of a single whole blood unit from which leucocytes are removed.

25. 'Plasma, fresh-frozen' means the supernatant plasma separated from a whole blood donation or plasma collected by apheresis, frozen and stored.

26. 'Plasma, cryoprecipitate-depleted for transfusion' means a plasma component prepared from a unit of plasma, fresh-frozen. It comprises the residual portion after the cryoprecipitate has been removed.

27. 'Granulocytes, apheresis' means a concentrated suspension of granulocytes obtained by apheresis.

28. 'Statistical process control' means a method of quality control of a product or a process that relies on a system of analysis of an adequate sample size without the need to measure every product of the process.

ANNEX II

INFORMATION REQUIREMENTS

(as referred to in Articles 2 and 3)

PART A

Information to be provided to prospective donors of blood or blood components

1. Accurate educational materials, which are understandable for members of the general public, about the essential nature of blood, the blood donation procedure, the components derived from whole blood and apheresis donations, and the important benefits to patients.

2. For both allogeneic and autologous donations, the reasons for requiring an examination, health and medical history, and the testing of donations and the significance of 'informed consent'.

   For allogeneic donations, self-deferral, and temporary and permanent deferral, and the reasons why individuals are not to donate blood or blood components if there could be a risk for the recipient.

   For autologous donations, the possibility of deferral and the reasons why the donation procedure would not take place in the presence of a health risk to the individual whether as donor or recipient of the autologous blood or blood components.

3. Information on the protection of personal data: no unauthorised disclosure of the identity of the donor, of information concerning the donor's health, and of the results of the tests performed.

4. The reasons why individuals are not to make donations which may be detrimental to their health.

5. Specific information on the nature of the procedures involved either in the allogeneic or autologous donation process and their respective associated risks. For autologous donations, the possibility that the autologous blood and blood components may not suffice for the intended transfusion requirements.

6. Information on the option for donors to change their mind about donating prior to proceeding further, or the possibility of withdrawing or self-deferring at any time during the donation process, without any undue embarrassment or discomfort.

7. The reasons why it is important that donors inform the blood establishment of any subsequent event that may render any prior donation unsuitable for transfusion.

8. Information on the responsibility of the blood establishment to inform the donor, through an appropriate mechanism, if test results show any abnormality of significance to the donor's health.

9. Information why unused autologous blood and blood components will be discarded and not transfused to other patients.

10. Information that test results detecting markers for viruses, such as HIV, HBV, HCV or other relevant blood transmissible microbiologic agents, will result in donor deferral and destruction of the collected unit.

11. Information on the opportunity for donors to ask questions at any time.

PART B

Information to be obtained from donors by blood establishments at every donation

1. *Identification of the donor*

   Personal data uniquely, and without any risk of mistaken identity, distinguishing the donor, as well as contact details.

2. *Health and medical history of the donor*

   Health and medical history, provided on a questionnaire and through a personal interview performed by a qualified healthcare professional, that includes relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases, or health risks to themselves.

3. *Signature of the donor*

Signature of the donor, on the donor questionnaire, countersigned by the health care staff member responsible for obtaining the health history confirming that the donor has:

(a) read and understood the educational materials provided;

(b) had an opportunity to ask questions;

(c) been provided with satisfactory responses to any questions asked;

(d) given informed consent to proceed with the donation process;

(e) been informed, in the case of autologous donations, that the donated blood and blood components may not be sufficient for the intended transfusion requirements; and

(f) acknowledged that all the information provided by the donor is true to the best of his/her knowledge.

ANNEX III

ELIGIBILITY CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

(as referred to in Article 4)

1. ACCEPTANCE CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

Under exceptional circumstances, individual donations from donors who do not comply with the following criteria may be authorised by a qualified healthcare professional in the blood establishment. All such cases must be clearly documented and subject to the quality management provisions in Articles 11, 12, and 13 of Directive 2002/98/EC.

The following criteria do not apply to autologous donations.

1.1. **Age and body weight of donors**

Age	18 to 65 years	
	17 to 18 years	— unless classified as a minor by law, or with written consent of parent or legal guardian in accordance with law
	First time donors over 60 years	— at the discretion of the physician in the blood establishment
	Over 65 years	— with permission of the physician in the blood establishment, given annually
Body weight	≥ 50 kg for donors either of whole blood or apheresis blood components	

1.2. **Haemoglobin levels in donor's blood**

Haemoglobin	for females ≥ 125 g/l	for males ≥ 135 g/l	*Applicable to allogeneic donors of whole blood and cellular components*

1.3. **Protein levels in donor's blood**

Protein	≥ 60 g/l	*The protein analysis for apheresis plasma donations must be performed at least annually*

1.4. **Platelet levels in donor's blood**

Platelets	Platelet number greater than or equal to 150×10^9/l	*Level required for apheresis platelet donors*

2. DEFERRAL CRITERIA FOR DONORS OF WHOLE BLOOD AND BLOOD COMPONENTS

The tests and deferral periods indicated by an asterisk (*) are not required when the donation is used exclusively for plasma for fractionation.

2.1. **Permanent deferral criteria for donors of allogeneic donations**

Cardiovascular disease	Prospective donors with active or past serious cardiovascular disease, except congenital abnormalities with complete cure
Central nervous system disease	A history of serious CNS disease
Abnormal bleeding tendency	Prospective donors who give a history of a coagulopathy

Repeated episodes of syncope, or a history of convulsions	Other than childhood convulsions or where at least three years have elapsed since the date the donor last took anticonvulsant medication without any recurrence of convulsions
Gastrointestinal, genitourinary, haematological, immunological, metabolic, renal, or respiratory system diseases	Prospective donors with serious active, chronic, or relapsing disease
Diabetes	If being treated with insulin
Infectious diseases	Hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune
	Hepatitis C
	HIV-1/2
	HTLV I/II
	Babesiosis (*)
	Kala Azar (visceral leishmaniasis) (*)
	Trypanosomiasis cruzi (Chagas' disease) (*)
Malignant diseases	Except *in situ* cancer with complete recovery
Transmissible spongiform encephalopathies (TSEs), (e.g. Creutzfeldt Jakob Disease, variant Creutzfeldt Jakob Disease)	Persons who have a family history which places them at risk of developing a TSE, or persons who have received a corneal or dura mater graft, or who have been treated in the past with medicines made from human pituitary glands. For variant Creutzfeldt Jacob disease, further precautionary measures may be recommended.
Intravenous (IV) or intramuscular (IM) drug use	Any history of non-prescribed IV or IM drug use, including body-building steroids or hormones
Xenotransplant recipients	
Sexual behaviour	Persons whose sexual behaviour puts them at high risk of acquiring severe infectious diseases that can be transmitted by blood

2.2. **Temporary deferral criteria for donors of allogeneic donations**

2.2.1. *Infections*

Duration of deferral period

After an infectious illness, prospective donors shall be deferred for at least two weeks following the date of full clinical recovery.

However, the following deferral periods shall apply for the infections listed in the table:

Brucellosis (*)	**2** years following the date of full recovery
Osteomyelitis	**2** years after confirmed cured
Q fever (*)	**2** years following the date of confirmed cured
Syphilis (*)	**1** year following the date of confirmed cured
Toxoplasmosis (*)	**6** months following the date of clinical recovery
Tuberculosis	**2** years following the date of confirmed cured

Rheumatic fever	**2** years following the date of cessation of symptoms, unless evidence of chronic heart disease
Fever > °C	**2** weeks following the date of cessation of symptoms
Flu-like illness	**2** weeks after cessation of symptoms
Malaria (*)	
— individuals who have lived in a malarial area within the first five years of life	**3** years following return from last visit to any endemic area, provided person remains symptom free; may be reduced to 4 months if an immunologic or molecular genomic test is negative at each donation
— individuals with a history of malaria	**3** years following cessation of treatment *and* absence of symptoms. Accept thereafter only if an immunologic or molecular genomic test is negative
— asymptomatic visitors to endemic areas	**6** months after leaving the endemic area unless an immunologic or molecular genomic test is negative
— individuals with a history of undiagnosed febrile illness during or within six months of a visit to an endemic area	**3** years following resolution of symptoms; may be reduced to 4 months if an immunologic or molecular test is negative
West Nile Virus (WNV) (*)	**28** days after leaving an area with ongoing transmission of WNV to humans

2.2.2. *Exposure to risk of acquiring a transfusion-transmissible infection*

— Endoscopic examination using flexible instruments, — mucosal splash with blood or needlestick injury, — transfusion of blood components, — tissue or cell transplant of human origin, — major surgery, — tattoo or body piercing, — acupuncture unless performed by a qualified practitioner and with sterile single-use needles, — persons at risk due to close household contact with persons with hepatitis B.	Defer for **6** months, or for **4** months provided a NAT test for hepatitis C is negative
Persons whose behaviour or activity places them at risk of acquiring infectious diseases that may be transmitted by blood.	Defer after cessation of risk behaviour for a period determined by the disease in question, and by the availability of appropriate tests

2.2.3. *Vaccination*

Attenuated viruses or bacteria	**4** weeks
Inactivated/killed viruses, bacteria or rickettsiae	No deferral if well
Toxoids	No deferral if well
Hepatitis A or hepatitis B vaccines	No deferral if well and if no exposure
Rabies	No deferral if well and if no exposure If vaccination is given following exposure defer for one year
Tick-borne encephalitis vaccines	No deferral if well and if no exposure

2.2.4. *Other temporary deferrals*

Pregnancy	**6** months after delivery or termination, except in exceptional circumstances and at the discretion of a physician
Minor surgery	**1** week
Dental treatment	Minor treatment by dentist or dental hygienist — defer until next day (NB: Tooth extraction, root-filling and similar treatment is considered as minor surgery)
Medication	Based on the nature of the prescribed medicine, its mode of action and the disease being treated

2.3. **Deferral for particular epidemiological situations**

Particular epidemiological situations (e.g. disease outbreaks)	Deferral consistent with the epidemiological situation (These deferrals should be notified by the competent authority to the European Commission with a view to Community action)

2.4. **Deferral criteria for donors of autologous donations**

Serious cardiac disease	Depending on the clinical setting of the blood collection
Persons with or with a history of — hepatitis B, except for HBsAg-negative persons who are demonstrated to be immune — hepatitis C — HIV-1/2 — HTLV I/II	Member States may, however, establish specific provisions for autologous donations by such persons
Active bacterial infection	

ANNEX IV

STORAGE, TRANSPORT AND DISTRIBUTION CONDITIONS FOR BLOOD AND BLOOD COMPONENTS

(as referred to in Article 5)

1. STORAGE

1.1. **Liquid storage**

Component	Temperature of storage	Maximum storage time
Red cell preparations and whole blood (if used for transfusion as whole blood)	+ 2 to + 6 °C	**28** to **49** days according to the processes used for collection, processing and storage
Platelet preparations	+ 20 to + 24 °C	**5** days; may be stored for **7** days in conjunction with detection or reduction of bacterial contamination
Granulocytes	+ 20 to + 24 °C	**24** hours

1.2. **Cryopreservation**

Component	Storage conditions and duration
Red blood cells	Up to **30** years according to processes used for collection, processing and storage
Platelets	Up to **24** months according to processes used for collection, processing and storage
Plasma and cryoprecipitate	Up to **36** months according to processes used for collection, processing and storage
Cryopreserved red blood cells and platelets must be formulated in a suitable medium after thawing. The allowable storage period after thawing to depend on the method used.	

2. TRANSPORT AND DISTRIBUTION

Transport and distribution of blood and blood components at all stages of the transfusion chain must be under conditions that maintain the integrity of the product.

3. ADDITIONAL REQUIREMENTS FOR AUTOLOGOUS DONATIONS

3.1. Autologous blood and blood components must be clearly identified as such and stored, transported and distributed separately from allogeneic blood and blood components.

3.2. Autologous blood and blood components must be labelled as required by Directive 2002/98/EC and in addition the label must include the identification of the donor and the warning 'FOR AUTOLOGOUS TRANSFUSION ONLY'.

ANNEX V

QUALITY AND SAFETY REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

(as referred to in Article 6)

1. THE BLOOD COMPONENTS

1. **Red cell preparations**	The components listed in points 1.1 to 1.8 may be further processed within blood establishments and must be labelled accordingly
1.1	Red cells
1.2	Red cells, buffy coat removed
1.3	Red cells, leucocyte-depleted
1.4	Red cells, in additive solution
1.5	Red cells, buffy coat removed, in additive solution
1.6	Red cells, leucocyte-depleted, in additive solution
1.7	Red cells, apheresis
1.8	Whole blood
2. **Platelet preparations**	The components listed in points 2.1 to 2.6 may be further processed within blood establishments and must be labelled accordingly
2.1	Platelets, apheresis
2.2	Platelets, apheresis, leucocyte-depleted
2.3	Platelets, recovered, pooled
2.4	Platelets, recovered, pooled, leucocyte-depleted
2.5	Platelets, recovered, single unit
2.6	Platelets, recovered, single unit, leucocyte-depleted
3. **Plasma preparations**	The components listed in 3.1 to 3.3 may be further processed within blood establishments and must be labelled accordingly.
3.1	Fresh-frozen plasma
3.2	Fresh-frozen plasma, cryoprecipitate-depleted
3.3	Cryoprecipitate
4.	Granulocytes, apheresis
5. **New components**	Quality and safety requirements for new blood components must be regulated by the competent national authority. Such new components must be notified to the European Commission with a view to Community action

2. QUALITY CONTROL REQUIREMENTS FOR BLOOD AND BLOOD COMPONENTS

2.1. Blood and blood components must comply with the following technical quality measurements and meet the acceptable results.

2.2. Appropriate bacteriological control of the collection and manufacturing process must be performed.

2.3. Member States must take all necessary measures to ensure that all imports of blood and blood components from third countries, including those used as starting material/raw material for the manufacture of medicinal products derived from human blood or human plasma, shall meet equivalent standards of quality and safety to the ones laid down in this Directive.

2.4. For autologous donations, the measures marked with an asterisk (*) are recommendations only.

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	**Acceptable results for quality measurements**
Red cells	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, buffy coat removed, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 43 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Red cells, leucocyte-depleted, in additive solution	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Leucocyte content	Less than 1×10^6 per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	Acceptable results for quality measurements
Red cells, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis
	Haemoglobin (*)	Not less than 40 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Whole blood	Volume	Valid for storage characteristics to maintain product within specifications for haemoglobin and haemolysis 450 ml +/- 50ml For paediatric autologous whole blood collections — not to exceed 10,5 ml per kg body weight
	Haemoglobin (*)	Not less than 45 g per unit
	Haemolysis	Less than 0,8 % of red cell mass at the end of the shelf life
Platelets, apheresis	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, apheresis, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single donation are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per unit
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, pooled	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than $0,2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0,05 \times 10^9$ per single unit (buffy coat method)
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life

Component	**Quality measurements required** *The required frequency of sampling for all measurements shall be determined using statistical process control*	Acceptable results for quality measurements
Platelets, recovered, pooled, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per pool are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than 1×10^6 per pool
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, single unit	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leucocyte content	Less than $0{,}2 \times 10^9$ per single unit (platelet-rich plasma method) Less than $0{,}05 \times 10^9$ per single unit (buffy coat method)
	pH	6,4 – 7,4 corrected for 22 °C, at the end of the shelf life
Platelets, recovered, single unit, leucocyte-depleted	Volume	Valid for storage characteristics to maintain product within specifications for pH
	Platelet content	Variations in platelet content per single unit are permitted within limits that comply with validated preparation and preservation conditions
	Leukocyte content	Less than 1×10^6 per unit
	pH	6, 4 — 7,4 corrected for 22 °C, at the end of the shelf life
Plasma, fresh-frozen	Volume	Stated volume +/- 10 %
	Factor VIIIc (*)	Average (after freezing and thawing): 70 % or more of the value of the freshly collected plasma unit
	Total protein (*)	Not less than 50 g/l
	Residual cellular content (*)	Red cells: less than $6{,}0 \times 10^9$/l Leucocytes: less than $0{,}1 \times 10^9$/l Platelets: less than 50×10^9/l
Plasma, fresh-frozen, cryoprecipitate-depleted	Volume	Stated volume: +/- 10 %
	Residual cellular content (*)	Red cells: less than $6{,}0 \times 10^9$/l Leucocytes: less than $0{,}1 \times 10^9$/l Platelets: less than 50 × 109/l
Cryoprecipitate	Fibrinogen content (*)	Greater than or equal to 140 mg per unit
	Factor VIIIc content (*)	Greater than or equal to 70 international units per unit
Granulocytes, apheresis	Volume	Less than 500 ml
	Granulocyte content	Greater than 1×10^{10} granulocytes per unit

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 19 June 2002

pursuant to Article 14 of Council Regulation (EEC) No 4064/89 imposing fines on an undertaking for supplying incorrect and misleading information in a notification in merger control proceedings

(Case No COMP/M.2624 — BP/Erdölchemie)

(notified under document number C(2002) 2208)

(Only the English text is authentic)

(Text with EEA relevance)

(2004/285/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,

Having regard to Council Regulation (EEC) No 4064/89 of 21 December 1989 on the control of concentrations between undertakings [1], as last amended by Regulation (EC) No 1310/97 [2], and in particular Article 14(1)(b) thereof,

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 [3],

Having regard to the final report of the Hearing Officer in this case [3],

Whereas:

I. THE PARTIES AND THE TRANSACTION

(1) On 23 February 2001 the Commission received a notification pursuant to Article 4 of Regulation (EEC) No 4064/89 (the Merger Regulation) from Deutsche BP AG (Deutsche BP) of a proposed concentration in the chemicals industry (case COMP/M.2345-BP/Erdölchemie), by which it acquires within the meaning of Article 3(1)(b) of the Merger Regulation sole control of the undertaking Erdölchemie GmbH (EC) [4].

(2) Deutsche BP is a German subsidiary of BP plc (BP), the holding company of a multinational oil exploration, petroleum and petrochemical group. EC is a manufacturer and seller of petrochemicals with manufacturing facilities at Cologne in Germany, which was initially established as a joint venture jointly controlled by Bayer AG and BP via Deutsche BP. The transaction therefore consisted of a change from joint to sole control.

II. PROCEDURE

(3) One of the chemical products where according to the notification the horizontal overlaps between the parties would lead to an affected market was acrylonitrile (ACN). The notification was declared incomplete on 21 March 2001, due to lacking information on ACN technology licensing, ACN catalyst and the ACN supply/demand situation and trade flows world-wide. After the parties had provided additional information regarding Form CO sections 4, 7 and 8 for ACN technology and catalyst and the requested information on the

[1] OJ L 395, 30.12.1989, p. 1; corrected version in OJ L 257, 21.9.1990, p. 13.
[2] OJ L 180, 9.7.1997, p. 1.
[3] OJ C 79, 30.3.2004.
[4] OJ C 71, 3.3.2001, p. 22.

ACN market, the notification was declared complete on 22 March 2001. On 26 April 2001, the Commission declared the concentration compatible with the common market and the functioning of the EEA agreement pursuant to Article 6(1)(b) of the Merger Regulation ([1]).

(4) It became apparent that the notification made by Deutsche BP contained misleading and incorrect information as regards three issues related to the product ACN: (i) BP's agreements with ACN competitors […] (*), (ii) BP's activities in ACN technology licensing, and (iii) BP's activities in ACN catalyst. In its Statement of Objections of 23 November 2001, the Commission communicated its preliminary view that Deutsche BP negligently supplied incorrect and misleading information in a notification pursuant to Article 4 of the Merger Regulation, and that a fine should be imposed on Deutsche BP in accordance with Article 14(1)(b) and Article 14(3) of the Merger Regulation. Deutsche BP submitted its comments on the Statement of Objections on 7 March 2002.

III. **RELEVANT FACTS**

1. **Information on BP's cooperation agreements with […]* competitors**

(a) *The information given in the notification*

(5) Under the heading 'Cooperative agreements', the Form CO, which specifies the information to be provided in a merger notification pursuant to Article 3(1) of Commission Regulation (EC) No 447/98 of 1 March 1998 on the notifications, time limits and hearings provided for in Council Regulation (EEC) No 4064/89 on the control of concentrations between undertakings ([2]), in section 8.11 asks the following question: 'To what extent do cooperative agreements (horizontal or vertical) exist in the affected markets?'. The answer submitted in the parties notification (page 51) with regard to ACN reads as follows:

'The Parties are not aware of any significant cooperative arrangements as regards acrylonitrile in the EEA. However, at the horizontal level, various producers sometimes exchange material geographically so as to reduce distribution costs (for example, Erdölchemie currently exchanges c.[…]* kt (kilotonnes) of acrylonitrile p.a. with BP within the EEA). The only significant vertical arrangements are the captive propylene positions and forward integration outlined in section 7.8, above.'

(6) In section 8.12 the Form CO asks for the following information: 'Give details of the most important cooperative agreements engaged in by the parties to the concentration in the affected markets, such as research and development, licensing, joint production, specialisation, distribution, long-term supply and exchange of information agreements'. The parties submitted the following answer with regard to ACN in their notification (p. 52):

'Not applicable.'

(7) The parties provided no information on cooperation agreements with competitors as regards ACN in other sections in the Form CO. In section 6 concerning the relevant geographical market definition (p. 19), they stated: 'The parties consider the appropriate geographical market definition for acrylonitrile to be worldwide …'.

(b) *Result of the investigation*

(8) In reply to the general question in a letter under Article 11 of the Merger Regulation ('Article 11 letter') asking for 'the impact of the operation on the market', a competitor informed the Commission that BP and Sterling Chemicals Inc. (Sterling), another major US producer (BP's ACN plants are located in the United States of America) have an ACN export joint venture, called Anexco. On 8 March (17.49 h) the Commission thereupon sent an e-mail to the lawyers representing BP and Deutsche BP (BP's lawyers) stating: 'We understand that BP has a joint acrylonitrile export company (Anexco) in partnership with Sterling, another major US producer. This is, to my understanding, not mentioned in the Form CO. Please supply all relevant information as to this company, the impact of Sterling on the market and all other elements that may have an influence on the Commission's assessment as to the consequences of the merger.'

(9) The existence of that joint venture with Sterling was confirmed by BP's lawyers in a fax dated 12 March 2001. It was specified that this joint venture sells BP and Sterling ACN in regions outside North America and Europe and therefore is not active in Europe. However, it was stated that BP also has a non-exclusive distribution agreement with Sterling, by which BP sells up to […]* kt per annum of ACN to Europe and Turkey. In its submission, BP's lawyers referred to the fact that this had been previously brought to the Commission's attention. The agreements with Sterling had been notified to the Commission under the antitrust-provisions according to Form A/B in April 1998 (case IV/E-2/37.035-BP-Sterling). The Commission issued a negative clearance type comfort letter on 1 June 1999.

([1]) OJ C 174, 19.6.2001, p. 5.
(*) Parts of this text have been edited to ensure that confidential information is not disclosed; those parts are enclosed in square brackets and marked with an asterisk.
([2]) OJ L 61, 2.3.1998, p. 1.

(10) In a telephone conference on 15 March, the Commission asked BP's lawyers to provide information on any links with other […]* suppliers. In their written reply to that question of March 16, BP's lawyers indicated (p. 6) that BP:

'has no joint venture and/or distribution agreements with any [other producer]*, with exception of the links with Sterling set out in BP's fax of March 12. […] However, BP does [have an arrangement with another producer affecting exports to Europe]*'

(11) By telephone and e-mail (16.56 h) on 19 March, the Commission requested further information about the quantities involved and the duration of the arrangement with […]*. In the reply to those questions dated 19 March, BP's lawyers indicated that [details of the arrangement which limit the producer's ability to independently export ACN to Europe]*

(12) According to the [arrangement, …]*.

(13) The potential of […]* producers to supply ACN to Europe was an important element for the assessment of BP's competitive position on the market for ACN. The USA is the main exporting region for ACN due to significant excess capacity in relation to local demand. BP's sales of ACN in Europe are entirely based on imports from its production sites in the USA. [Sterling is one of the largest merchant sellers in the US following the market leader BP with a market share of around 20 % (BP: 35 %). It is therefore an important potential competitor of BP for ACN sales into Europe. The agreement significantly limits its potential to actively compete with BP in Europe. All its material sold into Western Europe went through the agreement, i.e. was marketed by BP, except for some marginal sales below 5 kt which Sterling marketed directly]*. The [arrangement with …]* gives BP a large measure of control over […]* exports to Europe. […]*

(14) In conclusion, there were two important cooperation [arrangements]* for ACN between BP and [ACN producers]*. No reference was made to these [arrangements]* in the Form CO.

2. **Information on BP's activities as regards ACN technology licensing**

(a) *Information given in the notification*

(15) Section 6.1 of the Form CO requires the parties to identify each affected market, and in Sections 7 and 8 detailed information has to be provided with regard to these markets. Section 6III(b) defines vertically affected markets as relevant product markets where 'one or more of the parties to the concentration are engaged in business activities in a product market, which is upstream or downstream of a product market in which any other party to the concentration is engaged, and any of their individual or combined market shares is 25 % or more […]'.

(16) Section 8.9 of the Form CO requires the parties to describe the various factors influencing market entry. In point (d) of that section, particular information is requested on 'the extent to which each of the parties to the concentration are licensees or licensors of patents, know-how and other rights in the relevant markets.'

(17) BP's position in the licensing of ACN production technology, which has to be considered as being upstream of ACN production activities, is not explained in the notification, neither as an affected market nor in section 8.9 nor elsewhere. In Deutsche BP's submission under section 8.9, technology is mentioned as one of the relevant entry factors and it is indicated that:

'the necessary technology can be readily purchased via license from various ACN producers (e.g. Asahi, BP, Solutia, DuPont, various Chinese licensors and others). These licensors carry on active licensing programs and availability of technology and intellectual property rights do not constrain entry into ACN production.'

(b) *Result of the investigation*

(18) In reply to an Article 11 letter, a competitor informed the Commission that BP was the most important seller of technology for the production of ACN. After this issue was raised with BP's lawyers in a telephone conference on 13 March 2001, they submitted a memo in that regard dated 14 March 2001, stating that:

'of total installed ACN capacity today, 85 to 90 % of the underlying technology was originally licensed by BP.'

(19) Further submissions by BP's lawyers, including additional Form CO sections 4, 7 and 8 as regards ACN technology licensing, and the Commission's investigation revealed that until 1994, BP had a monopoly in the licensing of ACN technology. After that date, three world-scale ACN production plants have been built by Solutia, Tae Kwang and Formosa Plastic. Formosa obtained its technology licence from BP. Solutia developed its own production technology and built its plant on its own technology without the need for third party licences. The Tae Kwang plant is based on Solutia's technology and the licence was obtained in 1995 from Solutia. [BP did not

offer its technology to Tae Kwang]* In addition, an earlier BP licence to Formosa granted on 10 June 1987 […]* BP's licence to the South African producer Sasol gave BP a first option to buy their exports, and BP actually marketed Sasol's exports of […]* until production at the Sasol plant was stopped.

(20) With regard to the licensing activities of the other companies mentioned by Deutsche BP as source of ACN technology licences, the investigation revealed the following: At the time of the investigation, DuPont was not active in third party licensing, and considered any information on that issue submitted to the Commission in reply to an Article 11 letter as business secrets. Asahi had so far only licensed out its technology to its joint ventures or subsidiaries and to Sinopec (China) for three small-scale plants, of which only one is in operation today. In addition, Asahi's licences in China were part of a cooperation agreement between BP and Asahi for the joint licensing of acrylonitrile technology in China. The 'Chinese licensors' mentioned in the Form CO relates to Sinopec that offers its ACN technology on its website, but had not licensed a single plant. Sinopec is also a joint-venture partner of BP with regard to a possible licence for a new plant in China and has taken licences from Asahi for three small-scale plants.

(21) Thus, the notification omitted relevant information and did not accurately describe BP's position as regards ACN technology licensing.

3. **Information on BP's activities as regards ACN catalyst**

(22) A catalyst is an essential processing input in ACN production as it ensures that the propylene and ammonia feedstock materials produce ACN. Catalysts are sold on the market and constitute a separate product market.

(a) *Information given in the notification*

(23) ACN catalyst was not identified as a (vertically) affected market within the meaning of section 6 III (b) of the Form CO. BP's activities in ACN catalyst are not mentioned at all in the Form CO. The only mention to ACN catalysts in the notification is in Section 8.10 (concerning the importance of research and development) where it is stated that:

'R & D is not critical to entry into, or continued operation on acrylonitrile markets. In particular, there are many suppliers of catalyst technology (eg. Nitto, Asahi, DuPont, Solutia, etc)...'.

(b) *Result of the investigation*

(24) Again, in reply to a general question in an Article 11 letter, a competitor informed the Commission that BP is a leading catalyst seller. After this issue was raised with BP's lawyers in a telephone conference on 13 March 2001, BP's lawyers submitted in a paper dated 14 March 2001, that:

'… catalyst for new ACN plants will typically initially be bought from the technology licensor …. BP estimates that at present only [55 to 65 %]* of all ACN units worldwide … still use BP catalysts.'

(25) In their complementary sections 4, 7 and 8 of Form CO on ACN catalyst which were submitted after the Commission had declared the notification incomplete, the parties indicate that BP accounted for [65 to 75 %]* of the worldwide merchant market for ACN catalyst in 1997 and they estimate BP's share to be [70 to 80 %]* in 2001. These figures had been largely confirmed by the Commission's market investigation. As regards BP's competitors, the investigation revealed the following: DuPont does not offer its own type of catalyst, but is only active in regenerating used catalysts. In the view of customers, regenerated catalyst does not allow for the same plant performance as new catalyst. Solutia's catalyst is radioactive and according to market participants only operates with its own technology. Asahi only entered the merchant business at the beginning of 2001. Until 31 December 2000, BP had the exclusive right to sell Asahi catalyst worldwide (except for Asahi technology licensees and sales in Japan, Taiwan, Korea and China, which required Asahi's approval). BP had rights to all information disclosed by Asahi on catalysts during the term of the agreement, including developments on Asahi's new catalyst that it is now marketing alone. In addition, BP and Asahi have an ongoing cooperation agreement for catalyst sales in China. Sinopec has so far sold its catalyst only in China. BP's most important competitor is Mitsubishi (formerly called Nitto). […]*. Only Mitsubishi and Asahi catalysts are fully compatible with BP's technology, i.e. they can be used as a [change out/replacement]* catalyst even if the plant initially was installed and run based on BP catalyst.

(26) Thus, the notification did not mention BP's position in the catalyst market, and did not describe the market situation properly.

IV. ASSESSMENT UNDER ARTICLE 14 OF THE MERGER REGULATION

(27) Under Article 14(1)(b) of the Merger Regulation the Commission may by decision impose fines from EUR 1 000 to 50 000 where, intentionally or negligently, an undertaking supplies incorrect or misleading information in a notification pursuant to Article 4.

1. Incorrectness of the information on cooperation agreements

(28) The possibility for competitors to export material is a major element for the Commission to assess the geographical scope of the relevant markets as well as the competitive impact of the transaction in the common market. Deutsche BP submitted in the Form CO that there were no cooperation agreements as regards ACN. This proved to be incorrect, as BP had entered into agreements as described in recitals 8 to 13 with […]*, which affected their ability to export ACN to Europe and other destinations, and to compete there with BP. In particular as Deutsche BP argued that the relevant geographical market for ACN was worldwide, agreements in all parts of the world […]* had to be disclosed in the notification. It therefore has to be concluded that the information on ACN cooperation agreements provided in the Form CO was incorrect.

2. Incorrect or at least misleading character of the information provided on ACN licensing

(29) The possible control of upstream markets like the ACN process technology market is an important aspect in assessing a party's position on a relevant market. BP's strong position in ACN licensing was not mentioned at all in the Form CO. The parties omitted to identify ACN technology licensing as a vertically affected market, and to provide the respective information required in the Form CO. The (little) information on ACN licensing gave a distorted picture of the true facts, as it gave the impression that BP was active with a market share below 25 % among several other competitors well established and highly active (in section 8.9 BP refers to 'active licensing programs') in the licensing market. This proved to be incorrect or at least misleading. BP was and still is the world-leader in ACN licensing. DuPont was not active in ACN technology licensing. Deutsche BP submits that it had good reason to believe that DuPont was an active licensor, as according to an article in an industry publication (Chemicals Week) of June 1998, a DuPont manager announced the opening up of DuPont's 25 speciality chemicals businesses to licensing including, *inter alia*, the ACN process. From this article, no conclusions can be drawn as regards the actual status of DuPont's ACN licensing business at the time of the notification. An article published two and a half years before the notification, and in which only the ambitions and business plans of a company are reported, cannot support the statement in the notification that the technology was readily available from DuPont. Furthermore, there were not 'various Chinese licensors' as submitted in the notification, but only one theoretically (Sinopec), which at the time had not granted any licence. The failure to mention the limitation of Asahi's activities to own plants and China and the fact that it has a cooperation agreement with BP for China has to be considered as at least misleading, as it gives the impression that Asahi is active without any geographic restrictions and completely independently from BP. It therefore has to be concluded that the information provided in the Form CO on ACN technology was incorrect or at least misleading.

3. Incorrect or at least misleading character of the information provided on ACN catalyst

(30) The catalyst market has to be considered as a market upstream of BP's ACN production activities which is important for the assessment of their position on that latter market. It was not mentioned at all in the notification that BP is active in ACN catalyst. Again, the parties omitted to identify a vertically affected market. The limited information given on ACN catalyst gave the impression that BP was not active and that there were several other competitors well established and independently active on the catalyst market. This proved to be incorrect or at least misleading. BP was and still is the world-leader in ACN catalyst sales with over 70 % market share. DuPont was not active on the market for new catalyst. In not mentioning the former and ongoing links between BP and Asahi, Deutsche BP omitted important information for the assessment of Asahi's potential as BP's competitor. The same applies to BP's relation to Mitsubishi. In conclusion, the information submitted in the notification on ACN catalyst has to be considered as incorrect or at least misleading.

4. **Negligence**

(31) In its reply to the Commission's Statement of Objections, Deutsche BP takes the view that the failure to supply the relevant information has not been negligent, or at least that there was only a very low degree of negligence. Deutsche BP explains the omissions in the notification as follows: The omissions are mainly a result of internal communication and coordination problems and are related to the participation of several individuals from different BP units and from outside BP at the preparation and the drafting of the notification. The central unit which started the drafting of the notification requested the information according to the Form CO from the relevant business unit, which was located in the USA. This was done apparently without explaining to the necessary extent the different notions and technical terms in the Form CO, and the relevance of certain business relations for a competition assessment under the Merger Regulation.

(32) Consequently, according to Deutsche BP, the agreement with the US producer Sterling and […]* were not mentioned because initially the parties intended to propose a Europe-wide market definition for ACN, and relations with […]* producers [in other geographical regions]* therefore had not been considered relevant. When it was decided to shift to a worldwide market definition, the section of the Form CO on agreements was not amended accordingly.

(33) As regards ACN technology and catalyst, Deutsche BP submits that the product experts preparing the Form CO did not consider these activities as 'products up- or downstream' of ACN in the sense of the Form CO. Business people tend to interpret this term as input raw materials (such as propylene and ammonia in the case of ACN), rather than technology. According to Deutsche BP, these initial misunderstandings remained undiscovered during the whole drafting process.

(34) Deutsche BP finally submits that the organisation put in place by BP (i.e. gathering information by sending the precise wording of the relevant sections of the Form CO to the respective business units in good time, appointing specialist external counsel and making every effort to follow the Commission/ECLF Best Practice Guidelines ([1])) was reasonable and generally should have been sufficient to avoid any shortcomings in the preparation of the notification. Deutsche BP thus takes the view that the incompleteness is not due to an organisational negligence, but to an exceptional set of unfortunate circumstances in an isolated case.

(35) There are no indications that Deutsche BP acted intentionally. However, the Commission takes the view that the provision of the incorrect and misleading information was committed negligently. As regards the cooperation agreements, the questions in the Form CO are clear and precise. Deutsche BP must have been aware that these agreements form an important element in the assessment of the parties' position and the independence of their competitors. The availability of imports and the ability of outside competitors to put products on the market in Europe independently is an important element of the assessment, which must have been evident for Deutsche BP. The relevance of the missing information is independent of the geographical market definition finally applied. The relevant questions in section 8 of the Form CO do not contain any geographical limitation, and answers to this section should cover all parts of the world, in particular if the parties defend a world-wide market definition. Links between competitors are a relevant element of the competitive analysis on a Europe-wide as well as on an worldwide market. Therefore, Deutsche BP's argument that the omission resulted from the fact that in the course of preparing the notification, they changed their market definition for ACN from Europe-wide to worldwide, but accidentally failed to adjust section 8 of Form CO accordingly, is not such as to eliminate the negligent character of the omission.

(36) The fact that the agreement with Sterling had been notified to the Commission previously under Article 81 of the Treaty according to Form A/B supports the Commission's conclusion that Deutsche BP had no intention to hide any information from the Commission. However, it does not establish that there was no negligence. The Form CO requires the parties to submit a complete and comprehensive set of information including all aspects relevant for the assessment of the concentration. The fact that some information might have been brought to the attention of the Commission in another procedure or framework does not reduce the obligation of the parties to complete all chapters of the Form CO in full. Moreover, the parties did not even include a reference to the former procedure in the notification.

(37) As regards ACN technology and catalyst, the definition of a vertically affected market is clearly laid out in section 6 III (b) of the Form CO. The submission of the parties that their business units involved did not consider technology licensing and catalyst as a 'product market' in the sense of section 6 of the Form CO, but only considered chemicals up- or downstream of ACN, is only of limited relevance and does not establish that there was no negligence. It is well established in the Commission's case law that technology licensing can constitute a distinct product market. In particular, in the Dow Chemical/Union Carbide case ([2]), the Commission extensively considered the market for polyethylene technology licensing. BP was an active participant in the Commission's investigation in that case. Although the case concerned a different product (polyethylene), it did not contain any indications that the approach as regards technology licensing had to be limited to this specific product and was not applicable to other chemicals.

([1]) http://europa.eu.int/comm/competition/mergers/others/best_practice_gl.html

([2]) Commission Decision 2001/684/EC in Case No. Comp/M.1671, OJ L 245, 14.9.2001, p.1, at recitals 74-95.

(38) The argument is even less acceptable as regards ACN catalyst, as this is a distinct chemical product, which is necessary as an additive for the ACN production process. The fact that Deutsche BP was aware of the relevance of technology licensing and catalyst for the competitive assessment is also shown by the fact that it was mentioned in the Form CO under the headings entry barriers and relevance of R&D, although in an incorrect or at least misleading way. Furthermore, Deutsche BP could not have been unaware of BP's very strong position with regard to these two markets. Finally, it has to be mentioned that Deutsche BP is part of a multinational company with a large record of notifications to the Commission including in the chemicals sector, and therefore has an extensive experience in merger review procedures and the interpretation of the Form CO.

(39) Finally, the Commission cannot accept Deutsche BP's argument that there was no negligence due to the sound process and organisation of BP with regard to the preparation of merger notifications and the unfortunate and exceptional character of the present case. The Commission acknowledges that so far the members of the BP group have a satisfactory record of merger notifications. However, the present case showed that the procedures applied by BP and Deutsche BP in the present case, which according to BP and Deutsche BP deviated from their usual procedures in merger notifications, failed to ensure a complete and satisfactory notification. A complete Form CO with comprehensive information is of crucial importance for the Commission's merger control procedure, *inter alia* due to the tight legal deadlines the Commission is required to meet in these procedures, and the notifying parties must be aware of this importance. The internal provisions set up within the notifying party for the preparation of the Form CO have to reflect this high importance of a complete notification. Consequently, the party has to organise its internal procedures with the highest care to ensure that the legal duties and requirements under the Merger Regulation are communicated to all relevant units, and that all relevant information is identified and supplied in the Form CO. The fact that in the present case information was missing in three different areas revealed imperfections in the procedures applied by BP and Deutsche BP in this instance, which led to submission of an incomplete Form CO.

(40) These omissions go beyond minor errors which might be unavoidable in view of the complexity of large multinational undertakings. The explanation provided by Deutsche BP also does not establish any extraordinary circumstances which, despite all reasonable efforts, made it impossible to provide the missing information. There were three distinct aspects which have not been properly dealt with in the Form CO, and which were all of an evident relevance and importance for the competition assessment. This is also reflected in the fact that the missing issues were brought to the Commission's attention immediately by third parties at a very early stage of the investigation.

(41) In terms of the degree of negligence, it has, however, to be taken into account that ACN was not the sole focus of the case. The Commission acknowledges that the present transaction affected a large number of different chemicals which had to be discussed in the notification, ACN being only one of them.

(42) Against this background, it has to be concluded that Deutsche BP acted negligently in submitting the incorrect and misleading information, and that the negligence was of a considerable degree.

5. **Nature and gravity of the infringement**

(43) Under Article 14(3) of the Merger Regulation, in setting the amount of the fine, the Commission has to take account of the nature and the gravity of the infringement.

(a) *Nature*

(44) The infringement committed by Deutsche BP took the form of negligent failure to disclose important cooperation [arrangements with Sterling and …]* and to identify ACN technology and catalysts as affected markets, as well as of providing misleading information on the competitive situation on the technology and catalyst markets and BP's position on these markets.

(b) *Gravity*

1. Deutsche BP's arguments

(45) Deutsche BP submits that the following elements should be considered as mitigating factors: First, Deutsche BP stresses that there was no intention to mislead, and that at no point did Deutsche BP intentionally withhold any information from the Commission. Deutsche BP further submits that the omission of the information arose as a result of a very unfortunate combination of circumstances, rather than as a consequence of negligent behaviour.

(46) Second, Deutsche BP underlines the limited competitive impact of the omitted information. Deutsche BP argues that in neither case did the omitted information, once fully investigated by the Commission, prove to be significant enough to merit a remedy. In that respect, Deutsche BP refers to the previous cases where a fine was imposed by the Commission for lacking information in a notification. Deutsche BP takes the view that in all these cases the information was either withheld intentionally or there was a significant link between the omitted information and the decision on the substance of the case, in the sense that a remedy was required or the Commission based its competition concerns on the information.

(47) Third, Deutsche BP considers it as a mitigating factor that it does not dispute the incompleteness of the Form CO as submitted. It further argues that it was fully and immediately cooperative as soon as the Commission indicated that the information was missing. With regard to the information on [the other arrangement]* and the way full details emerged, Deutsche BP refers again to the limited impact of [it]* on the competitive assessment.

2. Evaluation

(48) The Commission takes the view that the infringement is of considerable gravity. The notification is the basis and the starting point of the Commission's investigation of a merger case. It determines to a large extent the approach of the Commission towards the case and the areas and focal points of its investigation. Incorrect and misleading information creates the risk that important aspects relevant for the competitive assessment of the transaction are neither investigated nor analysed by the Commission, and its final decision consequently is based on incorrect information. In assessing mergers, the Commission is subject to extremely tight deadlines. In this framework it is essential for the Commission's work that it can focus its investigation on the relevant issues from the very beginning of the procedure, based on comprehensive and correct information provided in the notification.

(49) The notification in the present case was incorrect and misleading on three separate occasions. Two of the aspects were not brought to the Commission's attention at all in the notification: no reference was made to the cooperation agreements, and there was no mention at all that BP was active in ACN catalyst. The infringements concern three important elements in the assessment of the case which prima facie could have led to serious competition problems. The incorrect and misleading information in the Form CO with regard to the ACN market resulted in a misdirected and incomplete first investigation by the Commission, which failed to include these important issues. The relevant information only came to the attention of the Commission as part of information volunteered by third parties in the course of the investigation conducted by the Commission, which otherwise would not have considered these points at all. After the notification had been declared incomplete, the Commission had to re-launch an extensive investigation to verify and assess the new facts subsequently disclosed by BP, Deutsche BP and other market participants.

(50) As regards Deutsche BP's points, the Commission's views are as follows: The absence of intention and the degree of negligence has already been dealt with in the relevant section above, which has to be taken into account in adjusting the amount of a fine. The Commission agrees that there was no intention on Deutsche BP's side, but takes the view that Deutsche BP acted negligently in a considerable degree.

(51) The fact that the omitted information did not form the basis for competition concerns which resulted in a need for remedies cannot be taken into account as a mitigating factor. The information requirements set out in the Form CO, which Article 14(1)(b) of the Merger Regulation serves to protect and enforce, do not differentiate according to the likely outcome of the competition analysis. In the present context it is only relevant that the information omitted was of importance for the proper investigation and assessment of BP's competitive position on the ACN market. It has to be recalled that, *inter alia*, two clearly affected markets had not been identified. The fact that at the end of the Commission's assessment, taking into account the information that initially was missing, the transaction did not lead to competition concerns, does not reduce the gravity of the omission. This gravity depends on the relevance of the information for the investigation and assessment, but not on the final outcome of this assessment.

(52) Accordingly, the reference to the absence of competition concerns in the Commission's final decision cannot be taken into account as regards the way the information on [the other arrangement]* was provided.

(53) As explained in recitals 8 to 11, even after the Commission raised the agreement with Sterling with Deutsche BP for the first time, Deutsche BP did not disclose [the other arrangement]* immediately. And even after the Commission asked for further information […]*, Deutsche BP did not provide immediately the full information on [the other arrangement]*. Another request for further information was necessary to discover [the full scope of the restrictive content of this arrangement]*. In the light of the fact that it was only after several requests and after a total delay of 11 days (8 March to 19 March) the full information was provided, there is no basis for taking into account Deutsche BP's cooperation as a mitigating factor.

(54) As an attenuating circumstance it has to be taken into account that Deutsche BP did not dispute the facts discovered by the Commission and agreed that the relevant information should have been included in the Form CO.

6. **Amount of the fine**

(55) Accordingly, taking account of the circumstances in the case, the Commission considers it appropriate to impose a fine of EUR 35 000 on Deutsche BP, pursuant to Article 14(1)(b) of the Merger Regulation. In the event of late payment, the interests should be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this decision is adopted, which for June is 3,5 % as published in the *Official Journal of the European Communities* C 132 of 4 June 2002, plus 3,5 percentage points,

HAS ADOPTED THIS DECISION:

Article 1

A fine of EUR 35 000 is hereby imposed on Deutsche BP AG pursuant to Article 14(1)(b) of Regulation (EEC) No 4064/89 for having supplied incorrect and misleading information in the notification submitted to the Commission under that Regulation on 23 February 2001.

Article 2

The fine imposed in Article 1 shall be paid, within three months of the date of notification of this Decision to the following bank account of the European Commission:

Account No 642-0029000-95
European Commission
Banco Bilbao Vizcaya Argentaria (BBVA)
Code Swift: BBVABEBB — Code IBAN: BE 76 6420 0290 0095
Avenue des Arts, 43
B-1040 Brussels.

After expiry of that period, interest shall automatically be payable at the interest rate applied by the European Central Bank to its main refinancing operations on the first day of the month in which this Decision is adopted, plus 3,5 percentage points, that is to say 6,75 %.

Article 3

This Decision is addressed to:

Deutsche BP AG
Max-Born-Strasse 2
D-22761 Hamburg.

Done at Brussels, 19 June 2002.

For the Commission
Mario MONTI
Member of the Commission

COMMISSION DECISION

of 23 July 2003

on research and development aid in the aviation field which Spain is planning to implement for Gamesa

(notified under document number C(2003) 2518)

(Only the Spanish text is authentic)

(Text with EEA relevance)

(2004/286/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Having regard to Council Regulation (EC) No 659/1999 laying down detailed rules for the application of Article 93 of the EC Treaty ([1]), and in particular Article 7 thereof,

Having called on interested parties to submit their comments pursuant to the abovementioned Article,

Whereas:

1. PROCEDURE

(1) By letter dated 28 June 2001, registered as received on 2 July 2001, the Spanish Permanent Representation notified the proposed R&D aid measure in the aviation field for Gamesa in accordance with Article 88(3) of the EC Treaty. Further information was provided by letters dated 3 October 2001, registered as received on 5 October 2001, and 11 January 2002, registered as received on 15 January 2002.

(2) The Commission had the file analysed by an independent scientific expert. The analysis gave rise to a contract signed on 14 December 2001.

(3) By letter dated 12 March 2002, the Commission informed Spain that it had decided to initiate the procedure provided for in Article 88(2) of the EC Treaty in respect of the proposed aid.

(4) By letter dated 26 April 2002 ([2]), registered as received on 29 April 2002, the Spanish authorities sent the Commission their comments.

(5) The Commission's decision to initiate the procedure (referred to below as the decision of 12 March 2002 or decision to initiate the formal examination procedure) was published in the *Official Journal of the European Communities* on 27 April 2002. The Commission called on interested parties to submit their comments on the aid. No interested parties submitted comments within the period set by the Commission.

(6) By letter dated 24 February 2003, the Commission asked the Spanish authorities for additional information. The Spanish authorities provided the information by letter dated 25 March 2003, registered as received on 26 March 2003.

2. DESCRIPTION

(7) The recipient is Gamesa, which manufactures and supplies high-tech goods, equipment and services in the fields of aviation and renewable energy. The number of Gamesa's employees and its turnover exceed the thresholds provided for in Annex I to Commission Regulation (EC) No 70/2001 of 12 January 2001 on the application of Articles 87 and 88 of the EC Treaty to State aid to small and medium-sized enterprises ([3]) below which an enterprise is deemed to be an SME.

(8) Gamesa is currently taking part in a development project for two new regional aeroplanes: the ERJ-170 and the ERJ-190. The project was launched by the Brazilian company Embraer. Gamesa was tasked with supplying the rear fuselage, stabilisers and the tail fin of the two aircraft.

(9) Accordingly, Gamesa set up an R&D project in the Basque Country with a view to acquiring the technologies necessary for developing rear sections for commercial aircraft, which will apply to the ERJ-170/190 project and to other future programmes as well. The project is scheduled to last four years, from 2000 to 2003.

(10) The total cost of the project is […] (*), or […].

(11) The Basque Government (regional administration) plans to support the project by granting aid consisting of an interest-free loan amounting to ESP 4 621 000 000, or EUR 27 772 769,34.

([1]) OJ L 83, 27.3.1999, p. 1.
([2]) OJ C 153, 27.6.2002, p. 14.
([3]) OJ L 10, 13.1.2001, p. 33.
(*) Parts of the text of this decision have been edited to ensure that confidential information is not enclosed; those parts are enclosed in square brackets and marked with an asterisk.

(12) According to the Spanish authorities, the project's work programme comprises the following activities:

(a) *Feasibility studies*

These include the technical study on the project and an analysis of its technical and economic viability.

(b) *Industrial research*

The aim is to acquire the technologies necessary to develop the project:

— overall mechanical technologies
  — leading edges: optimal design, metal/composite, bird impact, icing, simulations, tests,
  — pressure bulkheads: stability, compression of semi-mounted thin rings, composite bulkheads,
  — interchangeability of stabilisers: special equipment, local milling,
  — lightning impact,
  — installation of systems (antennae) on stabilisers,
  — zonal analysis: installation of actuators,
  — drainage systems;
— materials, processes and production technologies
  — composite and plastic materials: qualification of new materials, plastic injection technology, qualification of components, production of leading edges,
  — mechanical materials: use of precipitation-hardenable steels, influence of heat treatment,
  — large forged rings, production techniques,
  — peen-forming,
  — qualification of special cutting technologies;
— inspection, maintenance and repair technologies
  — structural reliability techniques,
  — corrosion prevention: galvanic corrosion, new compound inhibitors, portable anodising,
  — composite repair,
  — repair of bearing housings,
  — advanced inspection methods;
— project technologies
— information technologies
  — simulation and modelling,
  — diagonal voltage,
  — electronic control system (fly-by-wire),
  — calculation methodologies;

(c) *Precompetitive development activities*

This concerns the technical activities necessary for the delivery design, development, integration, testing, certification and operational support for the vertical and horizontal stabilisers and rear fuselage of the ERJ-170/190 aircraft.

In particular, this includes work on:

— basic geometry: basic structural outline,
— definition of standards: production processes must be approved,
— costs: calculation of internal and external costs in order to avoid gaps,
— design: definition, determination of product structure, detailed structural design, system installation design, digital models, test documents for structural interfaces and systems, definition and design of ground support equipment, etc.,
— structures engineering: calculations and structural analysis (static, fatigue, damage tolerance), etc.,
— systems engineering: systems integration support, analysis of distribution of ice masses, analysis of lightning protection, zonal analysis (engine turbine failure, bird impact), etc.,
— certification tests: development of tests with a view to obtaining certification from the relevant authorities,
— maintenance studies: development of maintenance programmes (general accessibility, use of standard components, interchangeability, design techniques for preventing and isolating cracks, etc.),
— development and design of equipment: development of specific assembly tools, design of calibration tools,
— definition of production methods.

3. GROUNDS FOR INITIATING THE PROCEDURE

(13) In its decision of 12 March 2002, the Commission expressed a series of doubts on the following aspects of the proposed aid:

— the classification of work in accordance with the stages of research defined in Annex I to the Community framework for State aid for research and development [1] (the R&D framework) and, in particular, the R&D nature of the certification work and maintenance studies,

[1] OJ C 45, 17.2.1996, p. 5.

— the incentive effect of the aid within the meaning of point 6 of the R&D framework, since the data submitted by the Spanish authorities, pointing to an increase in the company's R&D staff and budget, were difficult to interpret as having an incentive effect. In addition, the Spanish authorities did not mention the costs associated with cross-border cooperation or submit any data which pointed clearly to a market failure. Lastly, the aircraft mainly concerned by the project's results, the ERJ-170/190, had already achieved a very significant degree of maturity, since they were rolled out on 29 October 2001, their maiden flight being scheduled to take place early in 2002 and their first delivery by the end of 2002, which seemed to rule out the existence of significant risks making funding by a non-governmental source impossible.

4. **COMMENTS FROM SPAIN**

(14) The Spanish authorities consider, firstly, that the aid intensity is well within the limits allowed under the R&D framework, even assuming that all the activities involved in the project had to be classified as precompetitive development activities. The initial calculations, carried out in April 2001, were based on the initial timetable, which provided for payments to be made to Gamesa in 2000, 2001, 2002 and 2003 and for repayments to be made by it between 2007 and 2013.

(15) Secondly, as regards the selective nature and the comparative advantage conferred by the aid, the Spanish authorities point out that the aid falls within the framework of a general industrial policy set out in the Interinstitutional Plan for the Economic Promotion of the Basque Country. In particular, the aid for Gamesa was granted as part of a programme of strategic projects. Furthermore, the Spanish authorities argue, there is no selectivity in so far as the two aerospace groups operating in the Basque Country (Gamesa and ITP), although operating in different subsectors, have received equivalent aid proposals under the programme of strategic projects. In addition, it is generally accepted that the average level of government support for R&D activities in the aerospace sector in Europe is below 50 %. The proposed aid for Gamesa, it was argued, is thus in line with, and indeed below, the instruments which other European companies have at their disposal for the development of R&D activities, and not granting the aid would put the company in an unequal position.

(16) As far as the incentive effect of the aid is concerned, the Spanish authorities point out that, in its framework programme 2002-2006 for research, technological development and demonstration activities (the sixth framework programme) aimed at contributing to the creation of the European Research Area, the Commission sets out to promote support for research at international level in key priority areas of exceptional usefulness and added value for Europe, one such area being aerospace. More specifically, the sixth framework programme includes amongst its research priorities that of reinforcing the competitiveness of the fuselage manufacturing industry, by reducing aircraft development costs and aircraft operating costs, and by concentrating on integrated design systems and processes, smarter production technologies, aircraft configuration, aerodynamics, materials and structures, mechanical, electrical and hydraulic systems, etc. According to the Spanish authorities, the Gamesa project is an example of adjusting to these guidelines.

(17) The Spanish authorities take the view that support for this type of activity is necessary and that the incentive effect is clear in the case of Gamesa, given the technological and financial risks involved, the size of the company and the circumstances surrounding the project. In this respect, they argue, account should be taken of the fact that the aerospace industry is closely tied to research and development, which, in this type of enterprise, is markedly cyclical in character due to product life, being especially intensive during the preliminary development stages. Consequently, maintaining a stable research structure is feasible only for large firms, whereas, in the case of medium-sized enterprises such as Gamesa, the objective can only be a medium-term one.

(18) The Spanish authorities point to the considerable increase in research activity anticipated as a result of the project, both in terms of expenditure and staff. As a direct result of the project, thanks to the know-how, technologies and capacities acquired by the firm, it is at present able to present itself as a candidate for equivalent projects carried out by other American manufacturers, under more realistic risk conditions.

(19) With regard to the Commission's doubts as to the unduly large fluctuation in the research budget, the Spanish authorities explain that, in 1999, before the start of the project, research staff consisted of 109 persons, and average expenditure was ESP 2 490 million. Following the start of the project, it is hoped that expenditure will amount to some ESP 4 000 or 4 500 million, with research staff stabilising at around 300 persons. As pointed out by the Spanish authorities, R&D expenditure in aerospace is cyclical, being very substantial during the preliminary product development stages and falling rapidly thereafter. In the case in point, Gamesa anticipates investing […] in four years, with more than half of this being spent in the first year. The firm's objective is to try to maintain a stable R&D structure at the levels attained at the end of the project by incorporating other projects in future that would be pursued at the same time as it, thus allowing the firm to maintain the human capital and technological development capacity achieved.

(20) Furthermore, the ERJ 170/190 project, it is argued, also involves a very substantial need for cross-border cooperation during the development stage. The percentage which cross-border cooperation represents in relation to the total costs for staff directly involved in the research could be put at between 30 % and 50 % as regards cooperation within the European Union, and between 10 % and 20 % outside the European Union, depending on results and how the project develops.

(21) As far as market failure is concerned, the Spanish authorities also point to the cyclical nature of the aerospace market, as may be seen from the figures published by the leading world manufacturers (Airbus, Boeing, Bombardier and Embraer) on deliveries and orders year on year. This trend is normally in line with the trend of world GDP. However, airlines usually react immediately to changes in the trend, by increasing or reducing their orders, thus creating market failures in the aerospace industry throughout the subcontracting chain. This context, which means that the possible profitability of the investments may be compromised, reinforces the role of aid as an incentive instrument in the face of market failures.

(22) Furthermore, according to the Spanish authorities, it is an established fact that development cycles in aerospace programmes have become much shorter, requiring greater investment intensity and resulting in an increase in risks, particularly in the case of research projects whose development allows subsequent participation in other aerospace programmes. Thus, the development cycle has fallen in recent years from 10 to five years: 12 months for the conceptual design of the aircraft, eight months for the preliminary design, 17 months for the detailed design, 11 months to the maiden flight and 12 months to certification of the aircraft. In view of the competitiveness of the sector, the conceptual, preliminary and detailed design stages have speeded up considerably, thus increasing the inherent risks and the investment required.

(23) The Spanish authorities thus consider that aid designed to offset this situation has a very significant incentive effect.

(24) As regards the question of the apparent degree of maturity of the project, the Spanish authorities point out that the fact that the aircraft had been rolled out and the maiden flight had taken place was due more to a question of product marketing than to the finalisation of the product's development. Furthermore, the project was not aimed solely at developing a product, but also at developing the technologies that would provide the capacity for developing an aircraft structure applicable to different models. According to the Spanish authorities, the timing of a maiden flight was important in the process of developing an aircraft, particularly in order to determine the real aerodynamic characteristics of the aircraft and identify certification tasks. But it was also very important in commercial terms, since it influenced the sales campaign, which gets under way well before the product is ready to be manufactured. At this stage, a large number of technical problems remain to be solved, such as weight optimisation, emergency handling of the aircraft, etc. The Spanish authorities also point out that, when the decision was taken to initiate proceedings, the ERJ 190 model had not yet carried out its maiden flight and that it carries 108 passengers as opposed to the 70 carried by the ERJ 170, which means a 50 % increase in the aircraft's maximum take-off weight and requires a major redesign of the aircraft's internal structure.

(25) With regard to the Commission's doubts as to the R&D nature of the certification work and maintenance studies, the Spanish authorities reiterate that all the tests included in the project are directly linked to the development of the product and that the project does not include any certification test that is linked to the marketing or indeed the manufacture of products. The Spanish authorities stress that the costs and time involved in developing aerospace projects mean that any stage that may affect the viability of the project should be tackled early. This is the case with development tests, since they anticipate and preclude any risk in future certification tests and underpin the development of the product itself. Such development tests serve to validate the technologies developed by Gamesa. Such studies may therefore be considered to form part of the same R&D stage as the development of this technology itself (industrial research). Of course, the tests must be performed on similar models in terms of materials and structural characteristics as those whose technology is to be validated, but not necessarily on versions of the product that are sufficiently close to the version that is to be marketed.

(26) The Spanish authorities state that they share the Commission's view that it is not possible to classify as R&D activities within the meaning of the R&D guidelines certification activities carried out on an already approved prototype with a view to providing legal backing for the marketing of the prototype. However, according to the Spanish authorities, the development of any product involves a large number of tests, trials and certifications which affect materials, specifications and designs and which, depending on the results, affect the project or require modifications to the product. The Spanish authorities consider that these types of tests form part of the development of a new product and are customary in R&D projects in any sector.

(27) According to the Spanish authorities, the same applies to maintenance studies, which must begin during the initial design stages, since they affect the direct operational cost (DOC) resulting from the project and hence its very viability. The DOC is the total of the various costs involved in flight and maintenance, which include essentially ownership costs (amortisation and

interest on capital invested), insurance, flight costs (crew, fuel and oil, takeoff and landing charges) and maintenance costs. The total cost of maintenance is the sum of the engine, the structure and the maintenance margins, and the design of structures has a major influence on questions such as the selection of materials and standardised processes for the aircraft, tools, accessibility, reliability, intervals between inspections, the life of the various components, scope for replacement components, etc. All of this means that, during the initial stages of design, work must be carried out specifically on these tasks so as to keep maintenance costs as low as possible, such costs being an essential parameter in the development of aerospace products.

(28) The Spanish authorities also state that the Commission itself, in the sixth framework programme, included amongst research priorities in the aerospace sector those linked to reducing aircraft development costs. The Spanish authorities believe it would be difficult to explain how the same type of activity could be considered a priority for research guidelines in Europe at general level and at the same time called into question in this specific case.

(29) As regards the Commission's doubts as to the classification of work in accordance with the stages of research defined in Annex I to the R&D framework, the Spanish authorities consider that the definitions of these stages are sufficiently general for their application to a specific and complex project to be able to give rise to different points of view. The Spanish authorities believe that they have already explained their reasons for including the various costs in each of the stages. In their view, it would be difficult at all events to take the view that a project on such a scale could take place without an industrial research stage, particularly for a firm dealing for the first time with the technologies required for complex structures such as those being developed in this project.

(30) In the case in point, it was considered that […] (*) out of a total of […] could correspond to this category of costs, taking into account the costs incurred in acquiring new know-how to enable Gamesa to develop structures that it had never developed before. Specifically, the new know-how relates to the following technologies: mechanical technologies (leading edges, pressure hulls, action and control systems, electrical cabling, rudders, fins/stabilisers, rear fuselage interface), manufacturing technologies (composite material, cutting technologies, joining technologies), inspection, maintenance and repair technologies (non-destructive inspections, servicing plans, corrosion, repair technologies) and drafting and certification technologies (informational, analytical and simulation technologies, test technology).

(*) 24 % of the eligible costs notified by the Spanish authorities

(31) All the other research activities more directly linked to development of the product were included in the category precompetitive research. At all events, this was, according to the Spanish authorities, a purely indicative classification, since, in the aid proposal notified to the Commission, the whole of the project was treated as precompetitive development activities.

5. **ASSESSMENT**

(32) The measures planned by the Spanish authorities confer an advantage on the recipient firm by relieving it of some of the costs incurred through the research activities which it should in principle bear itself. This advantage is also selective with respect to other Community firms which might wish to carry out such research projects. It could also affect intra-Community trade, since Gamesa competes with European firms such as GKN (United Kingdom), Hurel-Dubois (France and the United Kingdom) and Latecoère (France). Lastly, the interest-free loans are granted direct by the Basque Government, and consequently the advantages must be deemed to have been conferred by means of State resources. The measures in question therefore constitute State aid within the meaning of Article 87(1) of the EC Treaty.

(33) As stated in paragraph (13) of this Decision, the Commission has expressed doubts on this project. The questions arising will be examined below.

With regard to the classification of certain activities under the stage of research within the meaning of Annex I to the R&D framework

(34) The Commission notes firstly that the Spanish authorities have not provided any new information to justify why certain activities in the research programme are classified as industrial research within the meaning of Annex I to the R&D framework. The Commission therefore considers that its doubts on this matter stand and that it must accordingly regard all of the work as being at most as close to the market as precompetitive development activities.

(35) As far as the classification of the certification work is concerned, the Commission notes that the Spanish authorities seem to draw a distinction between some certification work that is more directly involved in the commercial version of the product and other certification work that is reported to be merely preliminary testing. The Spanish authorities share the Commission's analysis that the certification activities do not involve R&D within the meaning of the R&D framework as regards the first of these categories, but not as regards the second. The Commission recognises that,

during the aircraft development process, some tests are technological (but preliminary) in nature, whereas others relate to product certification. The Commission notes, however, that the Spanish authorities have not provided any additional details on the specifics of the work to which the Commission's doubts relate and on the proportion of such work that might not be strictly certification work, but rather preliminary testing work.

(36) In the absence of further details, the Commission therefore considers that the certification activities covered by the programme do not constitute research and development activities within the meaning of the R&D framework and that the costs associated with these activities cannot therefore be included in the costs eligible for aid under the R&D framework. Their total amount, i.e. […], must therefore be withdrawn from the total amount of eligible costs notified by the Spanish authorities.

(37) With regard to the classification of maintenance studies, the Spanish authorities stated that such activities were carried out concurrently with the conceptual design of the aircraft. They also noted that they contributed to reducing the development costs of the aircraft and that research into the reduction of such costs was one of the points in the sixth framework programme, which meant that such activities did indeed come under the heading of R&D. The Commission considers that the fact that some activities are carried out partly in parallel to development of the aircraft and use the results of such development as input data only allows the conclusion to be drawn that they relate to that aircraft in particular and does not allow the conclusion to be drawn that they form part of the research process. At all events, the Commission notes that the activities in question are ones which by definition relate to the final marketed state of the product. Lastly, the Commission notes that the fact that the sixth framework programme includes the reduction of aircraft development costs as one of its objectives does not in any way allow the conclusion to be drawn that any activity aimed at reducing such costs constitutes research. Reducing costs is one of the objectives naturally pursued by any company in a competitive situation. There can be no question of research being involved in this area unless the reduction in costs draws on new processes or new technological concepts, and the Spanish authorities have not provided any precise demonstration of this in the case in point. The Commission therefore considers that its doubts as to the R&D nature of the certification work under the R&D framework still stand.

(38) The Commission therefore considers that the maintenance studies do not constitute research and development activities within the meaning of the R&D framework and that the costs associated with such activities cannot therefore be included in the costs eligible for aid under the R&D framework. The relevant amount, […], must therefore be withdrawn from the total amount of eligible costs notified by the Spanish authorities.

(39) In view of the above considerations, the total amount of eligible costs must therefore be reduced to ESP 8 206 000 000, i.e. EUR 49 319 053,29.

With regard to the incentive effect of the aid

(40) The Commission takes note firstly of the additional information provided by the Spanish authorities regarding the scope of the quantitative data in respect of the incentive effect of the aid. The Commission considers that this information allows it to withdraw its doubts as to the possibility of taking these data into account in assessing the incentive effect of the aid.

(41) Furthermore, from the qualitative point of view, the Commission also takes note of the fact that some of the aspects which it had considered in expressing its doubts as to the degree of maturity of the project did not reflect its real degree of maturity. This is the case in particular with the roll out of the aircraft, which the Commission notes was more in the nature of a statement to customers than a technical stage of the project.

(42) Lastly, the Commission notes that the request for aid was made by the company to the local authorities before the programme was launched.

(43) In view of the above considerations, the Commission takes the view that, in this case, it can regard the aid as having an incentive effect within the meaning of section 6 of the R&D framework.

Conclusion

(44) In view of the above considerations, the Commission takes the view that most of the activities notified by the Spanish authorities can receive aid that is compatible with the conditions set out in the R&D framework. This covers eligible costs amounting to ESP 8 206 000 000, i.e. EUR 49 319 053,29, relating to precompetitive development activities within the meaning of Annex I to the R&D framework.

(45) The maximum admissible intensity of the aid is 25 %, pursuant to point 5.5 of the R&D framework, to which an extra five percentage points may be added pursuant to the second paragraph of point 5.10.2 of the R&D framework, the work being carried out in an area eligible for regional aid under Article 87(3)(c) of the EC Treaty.

(46) The Commission therefore considers that the aid may be authorised under the R&D framework, provided that its gross grant equivalent does not exceed 30 % of EUR 49 319 053,29, i.e. EUR 14 795 715,99.

(47) The Commission notes in this respect that the gross grant equivalent of the aid must be calculated using the reference and discount rate published by it, plus a premium of 400 basis points, since the loan granted by the State does not have any security [1]. For the calculation of the gross grant equivalent of the aid, the Spanish authorities may refer to section 3 of Annex I to the guidelines on national regional aid [2],

HAS ADOPTED THIS DECISION:

Article 1

The State aid which Spain is planning to implement for Gamesa, consisting of an interest-free loan amounting to a total of EUR 27 772 769,34, is compatible with the common market within the meaning of Article 87(3)(c) of the EC Treaty, provided that the gross grant equivalent of the aid does not exceed EUR 14 795 715,99.

The gross grant equivalent of the aid shall be calculated using the reference and discount rate published by the Commission, plus a premium of 400 basis points.

Article 2

Spain shall inform the Commission, within two months of notification of this Decision, of the measures taken to comply with Article 1 above.

Article 3

This Decision is addressed to the Kingdom of Spain.

Done at Brussels, 23 July 2003.

For the Commission

Mario MONTI

Member of the Commission

[1] OJ C 273, 9.9.1997, p. 3.
[2] OJ C 74, 10.3.1998, p. 7.

COMMISSION DECISION

of 24 March 2004

providing for the temporary marketing of certain seed of the species *Vicia faba* and *Glycine max* not satisfying the requirements of Council Directives 66/401/EEC or 2002/57/EC respectively

(notified under document number C(2004) 884)

(Text with EEA relevance)

(2004/287/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed [1], and in particular Article 17(1) thereof,

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants [2], and in particular Article 21(1) thereof,

Whereas:

(1) In France the quantity of available seed of field bean (*Vicia faba*) and of soya bean (*Glycine max*) suitable to the national climatic conditions and which satisfies the germination capacity requirements of Directives 66/401/EEC or 2002/57/EC respectively is insufficient and is therefore not adequate to meet the needs of that Member State.

(2) It is not possible to meet the demand for seed of these species satisfactorily with seed from other Member States or from third countries which satisfies all the requirements laid down in Directives 66/401/EEC or 2002/57/EC respectively.

(3) Accordingly, France should be authorised to permit the marketing of seed of these species subject to less stringent requirements for a period expiring on 30 April 2004.

(4) In addition, other Member States irrespective of whether the seed was harvested in a Member State or in a third country covered by Council Decision 2003/17/EC of 16 December 2002 on the equivalence of field inspections carried out in third countries on seed-producing crops and the equivalence of seed produced in third countries [3] which are in a position to supply France with seed of that species, should be authorised to permit the marketing of such seed.

(5) It is appropriate that France act as coordinator in order to ensure that the total amount of seed authorised pursuant to this Decision does not exceed the maximum quantity covered by this Decision.

(6) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry,

HAS ADOPTED THIS DECISION

Article 1

The marketing in the Community of seed of field bean (*Vicia faba*) which does not satisfy the minimum germination capacity requirements laid down in Directive 66/401/EEC shall be permitted, for a period expiring on 30 April 2004, in accordance with the terms set out in the Annex to this Decision and subject to the following conditions:

(a) the germination capacity must be at least that set out in the Annex to this Decision;

(b) the official label must state the germination ascertained in the official examination carried out pursuant to Article 2(1)(C)(d) of Directive 66/401/EEC;

(c) the seed must have been first placed on the market in accordance with Article 3 of this Decision.

Article 2

The marketing in the Community of seed of soya bean (*Glycine max)* which does not satisfy the minimum germination capacity requirements laid down in Directive 2002/57/EC shall be permitted, for a period expiring on 30 April 2004, in accordance with the terms set out in the Annex to this Decision and subject to the following conditions:

(a) the germination capacity must be at least that set out in the Annex to this Decision;

(b) the official label must state the germination ascertained in the official examination carried out pursuant to Article 2(1)(f) and (g) of Directive 2002/57/EC;

(c) the seed must have been first placed on the market in accordance with Article 3 of this Decision.

[1] OJ 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2003/61/EC (OJ L 165, 3.7.2003, p. 23).
[2] OJ L 193, 20.7.2002, p. 74. Directive as last amended by Directive 2003/61/EC.
[3] OJ L 8, 14.1.2003, p. 10. Decision as amended by Decision 2003/403/EC (OJ L 141 7.6.2003, p. 23).

Article 3

Any seed supplier wishing to place on the market the seeds referred to in Articles 1 and 2 shall apply for authorisation to the Member State in which he is established or importing.

The Member State concerned shall authorise the supplier to place that seed on the market, unless:

(a) there is sufficient evidence to doubt as to whether the supplier is able to place on the market the amount of seed for which he has applied for authorisation; or

(b) the total quantity authorised to be marketed pursuant to the derogation concerned would exceed the maximum quantity specified in the Annex.

Article 4

The Member States shall assist each other administratively in the application of this Decision.

France shall act as coordinating Member State in respect of Articles 1 and 2 in order to ensure that the total amount authorised does not exceed the maximum quantity specified in the Annex.

Any Member State receiving an application under Article 3 shall immediately notify the coordinating Member State of the amount covered by the application. The coordinating Member State shall immediately inform the notifying Member State as to whether authorisation would result in the maximum quantity being exceeded.

Article 5

Member States shall immediately notify the Commission and the other Member States of the quantities in respect of which they have granted marketing authorisation pursuant to this Decision.

Article 6

This Decision is addressed to the Member States.

Done at Brussels, 24 March 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

Species	Type of variety	Maximum quantity (tonnes)	Minimum germination (% of pure seed)
Glycine max	(maturity class: medium late) Dekabig, Zen, Sapporo, Fukui, Safrana, Nikko, Celior, Giulietta, Paoki	2 500	75
	(maturity class: medium late to late) Imari, Mariana	700	
Vicia faba	Divine, Gloria, Maya, Melodie, Victoria	3 980	80

COMMISSION DECISION

of 26 March 2004

granting Australia and New Zealand temporary access to the Community reserves of foot-and-mouth disease virus antigens

(notified under document number C(2004) 967)

(Text with EEA relevance)

(2004/288/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 2003/85/EC of 29 September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decision 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC [1], and in particular Article 83(3) thereof,

Whereas:

(1) In accordance with Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines [2], stocks of antigens for the express formulation into vaccines against foot-and-mouth disease have been established.

(2) Pending the completion of their own arrangements for reserves of foot-and-mouth disease virus antigens, Australia and New Zealand have requested temporary assistance from the Community in case emergency vaccination would be introduced to control a possible foot-and-mouth disease outbreak.

(3) The competent authorities of Australia and New Zealand have provided information on their risk assessment and estimates of the quantities and subtypes of antigens required within the framework of their contingency plans.

(4) Following the assessment of the request made by the authorities of Australia and New Zealand and taking into account the capacity and availability of the quantities and subtypes of antigens stored in the Community antigen reserves, it appears that the requested assistance could be provided without unnecessarily compromising the Community contingency arrangements.

(5) Australia and New Zealand should be granted temporary access to the Community antigen reserves subject to certain conditions.

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

HAS ADOPTED THIS DECISION:

Article 1

Australia and New Zealand are granted temporary access to the Community reserves of antigens for the formulation of vaccines against foot-and-mouth disease under the following conditions:

1. access shall be granted until 31 December 2004, in the form of drawing rights for each of the two countries concerned for a maximum of 500 000 vaccine equivalent cattle doses and in any case for both countries together not more than 50 % of the existing stocks of each of the antigens in the Community reserves;

2. depending on the specification in the written request by the competent authorities of Australia or New Zealand, the Commission shall immediately arrange for the urgent or immediate formulation of the appropriate antigens and the production, bottling, labelling and delivery of the vaccines under the terms of existing contracts concluded between itself and the manufacturer;

3. the Commission shall make arrangements so as to ensure that in the event referred to in paragraph 2 the costs for the following actions are born in appropriate proportions by the competent authorities of Australia or New Zealand, whoever has requested the formulation into vaccines of antigens stored in the Community reserves:

   (a) the transfer of antigens from the place of storage to the establishment of the manufacturer;

   (b) the formulation and production of vaccines, including any additional testing that might prove necessary;

   (c) the bottling and labelling of the vaccines and their transport to the indicated place of delivery;

   (d) the replacement without delay of any used quantity of antigen by antigens of at least the same quality and origin.

[1] OJ L 306, 22.11.2003, p. 1.
[2] OJ L 368, 31.12.1991, p. 21. Decision as last amended by Regulation (EC) No 807/2003 (OJ L 122, 16.5.2003, p. 36).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 26 March 2004.

For the Commission
David BYRNE
Member of the Commission

CORRIGENDA

Corrigendum to Council Decision 2004/161/EC of 10 February 2004 extending the period of application of Decision 2000/185/EC authorising Member States to apply a reduced rate of VAT to certain labour-intensive services in accordance with the procedure provided for in Article 28(6) of Directive 77/388/EEC

(Official Journal of the European Union L 52 of 21 February 2004)

In the title of the Decision, both on the cover and on page 62:

for: 'Council Decision 2004/161/EC …'

read: 'Council Decision 2004/189/EC …'.