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Legislation

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(Acts whose publication is obligatory)

COMMISSION REGULATION (EEC) No 120/87

of 16 January 1987

fixing the import levies on cereals and on wheat or rye flour, groats and meal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular Article 13 (5) thereof,

Having regard to Council Regulation (EEC) No 1676/85 of 11 June 1985 on the value of the unit of account and the exchange rates to be applied for the purposes of the common agricultural policy (3), and in particular Article 3 thereof,

Having regard to the opinion of the Monetary Committee,

Whereas the import levies on cereals, wheat and rye flour, and wheat groats and meal were fixed by Commission Regulation (EEC) No 2010/86 (4) and subsequent amending Regulations;

Whereas, if the levy system is to operate normally, levies should be calculated on the following basis:

— in the case of currencies which are maintained in relation to each other at any given moment within a band of 2,25 %, a rate of exchange based on their central rate, multiplied by the corrective factor provided for in the last paragraph of Article 3 (1) of Regulation (EEC) No 1676/85,

— for other currencies, an exchange rate based on the arithmetic mean of the spot market rates of each of these currencies recorded for a given period in relation to the Community currencies referred to in the previous indent, and the aforesaid coefficient;

Whereas these exchange rates being those recorded on 15 January 1987;

Whereas the aforesaid corrective factor affects the entire calculation basis for the levies, including the equivalence coefficients;

Whereas it follows from applying the detailed rules contained in Regulation (EEC) No 2010/86 to today's offer prices and quotations known to the Commission that the levies at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies to be charged on products listed in Article 1 (a), (b) and (c) of Regulation (EEC) No 2727/75 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 17 January 1987.

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 139, 24. 5. 1986, p. 29.
(3) OJ No L 164, 24. 6. 1985, p. 1.
(4) OJ No L 173, 1. 7. 1986, p. 1.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

ANNEX

to the Commission Regulation of 16 January 1987 fixing the import levies on cereals and on wheat or rye flour, groats and meal

(ECU/tonne)

CCT heading No	Description	Levies	
		Portugal	Third country
10.01 B I	Common wheat, and meslin	3,65	197,62
10.01 B II	Durum wheat	37,10	250,61 (1) (5)
10.02	Rye	33,36	173,13 (6)
10.03	Barley	31,61	185,95
10.04	Oats	90,74	155,29
10.05 B	Maize, other than hybrid maize for sowing	—	179,38 (2) (3) (8)
10.07 A	Buckwheat	22,15	22,15
10.07 B	Millet	31,61	134,90 (4)
10.07 C II	Grain sorghum, other than hybrid sorghum for sowing	17,35	181,06 (4) (8)
10.07 D I	Triticale	(7)	(7)
10.07 D II	Canary seed ; other cereals	31,61	60,04 (5)
11.01 A	Wheat or meslin flour	19,73	291,28
11.01 B	Rye flour	61,32	257,00
11.02 A I a)	Durum wheat groats and meal	71,00	401,94
11.02 A I b)	Common wheat groats and meal	19,53	312,81

(1) Where durum wheat originating in Morocco is transported directly from that country to the Community, the levy is reduced by 0,60 ECU/tonne.

(2) In accordance with Regulation (EEC) No 486/85 the levies are not applied to imports into the French overseas departments of products originating in the African, Caribbean and Pacific States or in the 'overseas countries and territories'.

(3) Where maize originating in the ACP or OCT is imported into the Community the levy is reduced by 1,81 ECU/tonne.

(4) Where millet and sorghum originating in the ACP or OCT is imported into the Community the levy is reduced by 50 %.

(5) Where durum wheat and canary seed produced in Turkey are transported directly from that country to the Community, the levy is reduced by 0,60 ECU/tonne.

(6) The import levy charged on rye produced in Turkey and transported directly from that country to the Community is laid down in Council Regulation (EEC) No 1180/77 and Commission Regulation (EEC) No 2622/71.

(7) The levy applicable to rye shall be charged on imports of the product falling within subheading 10.07 D I (triticale).

(8) The levy referred to in Article 1 of Council Regulation (EEC) No 2913/86 shall be fixed on the basis of an invitation to tender in accordance with Commission Regulation (EEC) No 3140/86.

COMMISSION REGULATION (EEC) No 121/87

of 16 January 1987

fixing the premiums to be added to the import levies on cereals, flour and malt

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular Article 15 (6) thereof,

Having regard to Council Regulation (EEC) No 1676/85 of 11 June 1985 on the value of the unit of account and the exchange rates to be applied for the purposes of the common agricultural policy (3), and in particular Article 3 thereof,

Having regard to the opinion of the Monetary Committee,

Whereas the premiums to be added to the levies on cereals and malt were fixed by Commission Regulation (EEC) No 2011/86 (4) and subsequent amending Regulations ;

Whereas, if the levy system is to operate normally, levies should be calculated on the following basis :

— in the case of currencies which are maintained in relation to each other at any given moment within a band of 2,25 %, a rate of exchange based on their central rate, multiplied by the corrective factor provided for in the last paragraph of Article 3 (1) of Regulation (EEC) No 1676/85,

— for other currencies, an exchange rate based on the arithmetic mean of the spot market rates of each of these currencies recorded for a given period in relation to the Community currencies referred to in the previous indent, and the aforesaid coefficient ;

Whereas these exchange rates being those recorded on 15 January 1987 ;

Whereas, on the basis of today's cif prices and cif forward delivery prices, the premiums at present in force, which are to be added to the levies, should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION :

Article 1

1. The premiums referred to in Article 15 of Regulation (EEC) No 2727/75 to be added to the import levies fixed in advance in respect of cereals and malt originating in Portugal shall be zero.

2. The premiums referred to in Article 15 of Regulation (EEC) No 2727/75 to be added to the import levies fixed in advance in respect of cereals and malt originating in third countries shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 139, 24. 5. 1986, p. 29.
(3) OJ No L 164, 24. 6. 1985, p. 1.
(4) OJ No L 173, 1. 7. 1986, p. 4.

ANNEX

to the Commission Regulation of 16 January 1987 fixing the premiums to be added to the import levies on cereals, flour and malt from third countries

A. Cereals and flour

(ECU/tonne)

CCT heading No	Description	Current	1st period	2nd period	3rd period
		1	2	3	4
10.01 B I	Common wheat, and meslin	0	0	0	0
10.01 B II	Durum wheat	0	0	0	0
10.02	Rye	0	0	0	0
10.03	Barley	0	4,04	4,04	4,04
10.04	Oats	0	0	0	0
10.05 B	Maize, other than hybrid maize for sowing	0	0	0	0
10.07 A	Buckwheat	0	95,57	95,57	95,57
10.07 B	Millet	0	8,76	8,76	8,76
10.07 C II	Grain sorghum, other than hybrid sorghum for sowing	0	0	0	0
10.07 D	Other cereals	0	0	0	0
11.01 A	Wheat or meslin flour	0	0	0	0

B. Malt

(ECU/tonne)

CCT heading No	Description	Current	1st period	2nd period	3rd period	4th period
		1	2	3	4	5
11.07 A I a)	Unroasted malt, obtained from wheat, in the form of flour	0	0	0	0	0
11.07 A I b)	Unroasted malt, obtained from wheat, other than in the form of flour	0	0	0	0	0
11.07 A II a)	Unroasted malt, other than that obtained from wheat, in the form of flour	0	7,19	7,19	7,19	7,19
11.07 A II b)	Unroasted malt, other than that obtained from wheat, other than in the form of flour	0	5,37	5,37	5,37	5,37
11.07 B	Roasted malt	0	6,26	6,26	6,26	6,26

COMMISSION REGULATION (EEC) No 122/87
of 16 January 1987
fixing the import levies on rice and broken rice

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 1418/76 of 21 June 1976 on the common organization of the market in rice (1), as last amended by Regulation (EEC) No 1449/86 (2), and in particular Article 11 (2) thereof,

Whereas the import levies on rice and broken rice were fixed by Commission Regulation (EEC) No 2683/86 (3), as last amended by Regulation (EEC) No 93/87 (4);

Whereas, if the levy system is to operate normally, levies should be calculated on the following basis:

— in the case of currencies which are maintained in relation to each other at any given moment within a band of 2,25 %, a rate of exchange based on their central rate, multiplied by the corrective factor provided for in the last paragraph of Article 3 (1) of Council Regulation (EEC) No 1676/85 (5),

— for other currencies, an exchange rate based on the arithmetic mean of the spot market rates of each of these currencies recorded over a given period in relation to the Community currencies referred to in the previous indent, and the aforesaid coefficient;

Whereas it follows from applying the detailed rules contained in Regulation (EEC) No 2683/86 to today's offer prices and quotations known to the Commission that the levies at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies to be charged on the products listed in Article 1 (1) (a) and (b) of Regulation (EEC) No 1418/76 shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 19 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission
Frans ANDRIESSEN
Vice-President

(1) OJ No L 166, 25. 6. 1976, p. 1.
(2) OJ No L 133, 21. 5. 1986, p. 1.
(3) OJ No L 246, 30. 8. 1986, p. 5.
(4) OJ No L 13, 15. 1. 1987, p. 16.
(5) OJ No L 164, 24. 6. 1985, p. 1.

ANNEX

to the Commission Regulation of 16 January 1987 fixing the import levies on rice and broken rice

(ECU / tonne)

CCT heading No	Description	Portugal	Third countries (3)	ACP or OCT (1) (2) (3)
ex 10.06	Rice :			
	B. Other :			
	I. Paddy rice ; husked rice :			
	a) Paddy rice :			
	1. Round grain	—	322,48	157,64
	2. Long grain	—	361,73	177,26
	b) Husked rice :			
	1. Round grain	—	403,10	197,95
	2. Long grain	—	452,16	222,48
	II. Semi-milled or wholly milled rice :			
	a) Semi-milled rice :			
	1. Round grain	13,05	525,73	250,94
	2. Long grain	12,97	650,89	313,56
	b) Wholly milled rice :			
	1. Round grain	13,90	559,91	267,60
	2. Long grain	13,90	697,76	336,53
	III. Broken rice	80,06	218,40	106,20

N.B. The levies are to be converted into national currencies using the specific agricultural conversion rates fixed in Regulation (EEC) No 3294/86.

(1) Subject to the application of the provisions of Articles 10 and 11 of Regulation (EEC) No 486/85 and of Regulation No 551/85.

(2) In accordance with Regulation (EEC) No 486/85, the levies are not applied to imports into the overseas department of Réunion of products originating in the African, Caribbean and Pacific States or in the 'overseas countries and territories'.

(3) The import levy on rice entering the overseas department of Réunion is specified in Article 11a of Regulation (EEC) No 1418/76.

COMMISSION REGULATION (EEC) No 123/87

of 16 January 1987

fixing the premiums to be added to the import levies on rice and broken rice

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 1418/76 of 21 June 1976 on the common organization of the market in rice (1), as last amended by Regulation (EEC) No 1449/86 (2), and in particular Article 13 (6) thereof,

Whereas the premiums to be added to the levies on rice and broken rice were fixed by Commission Regulation (EEC) No 2684/86 (3), as last amended by Regulation (EEC) No 94/87 (4);

Whereas, if the levy system is to operate normally, levies should be calculated on the following basis:

— in the case of currencies which are maintained in relation to each other at any given moment within a band of 2,25 %, a rate of exchange based on their central rate, multiplied by the corrective factor provided for in the last paragraph of Article 3 (1) of Council Regulation (EEC) No 1676/85 (5),

— for other currencies, an exchange rate based on the arithmetic mean of the spot market rates of each of these currencies recorded over a given period in relation to the Community currencies referred to in the previous indent, and the aforesaid coefficient;

Whereas, on the basis of today's cif prices and cif forward delivery prices, the premiums at present in force, which are to be added to the levies, should be altered to the amounts shown in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

1. The premiums to be added to the import levies fixed in advance in respect of rice and broken rice originating in Portugal shall be zero.

2. The premiums to be added to the import levies fixed in advance in respect of rice and broken rice originating in third countries shall be as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 19 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 166, 25. 6. 1976, p. 1.
(2) OJ No L 133, 21. 5. 1986, p. 1.
(3) OJ No L 246, 30. 8. 1986, p. 8.
(4) OJ No L 13, 15. 1. 1987, p. 18.
(5) OJ No L 164, 24. 6. 1985, p. 1.

ANNEX

to the Commission Regulation of 16 January 1987 fixing the premiums to be added to the import levies on rice and broken rice

(ECU / tonne)

CCT heading No	Description	Current	1st period	2nd period	3rd period
		1	2	3	4
ex 10.06	Rice :				
	B. Other :				
	I. Paddy rice ; husked rice :				
	a) Paddy rice :				
	1. Round grain	0	0	0	—
	2. Long grain	0	0	0	—
	b) Husked rice :				
	1. Round grain	0	0	0	—
	2. Long grain	0	0	0	—
	II. Semi-milled or wholly milled rice :				
	a) Semi-milled rice :				
	1. Round grain	0	0	0	—
	2. Long grain	0	0	0	—
	b) Wholly milled rice :				
	1. Round grain	0	0	0	—
	2. Long grain	0	0	0	—
	III. Broken rice	0	0	0	0

COMMISSION REGULATION (EEC) No 124/87

of 16 January 1987

amending Commission Regulation (EEC) No 1836/82 laying down the procedure and conditions for the disposal of cereals held by intervention agencies

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular Articles 7 (5) and 8 thereof,

Having regard to Council Regulation (EEC) No 1677/85 of 11 June 1985 on monetary compensatory amounts in agriculture (3), as last amended by Regulation (EEC) No 2502/86 (4), and in particular Article 9 thereof,

Whereas, in view of the quantities of stocks of cereals in intervention in the Community and in order to ensure sound management of the market, the disposal of the abovementioned stocks on the internal market and on that of third countries, should be decided according to the Management Committee procedure;

Whereas, in accordance with the provisions of Article 3 (1) of Council Regulation (EEC) No 1581/86 of 23 May 1986 laying down general rules for intervention on the market in cereals (5), cereals are to be put up for sale on the internal market at prices enabling disturbance of the market to be avoided; whereas that aim may be achieved if the selling price reflects the real situation on the market but is not less than the intervention price; whereas special situations exist during the changeover from one marketing year to the next when the market continues to be supplied with cereals from the old harvest; whereas that should consequently be taken into account when conditions of sale are being fixed; whereas special measures should also be considered to resell stocks purchased in previous years;

Whereas certain technical adjustments are required following amendments to the rules with effect from the 1986/87 marketing year; whereas Commission Regulation (EEC) No 1836/82 (6), as last amended by Regulation (EEC) No 3447/85 (7) should therefore be amended;

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 139, 24. 5. 1986, p. 29.
(3) OJ No L 164, 24. 6. 1985, p. 6.
(4) OJ No L 219, 6. 8. 1986, p. 8.
(5) OJ No L 139, 24. 5. 1986, p. 36.
(6) OJ No L 202, 9. 7. 1982, p. 23.
(7) OJ No L 328, 7. 12. 1985, p. 17.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 1836/82 is hereby amended as follows:

1. Article 2 is replaced by the following:

'*Article 2*

1. The decision to issue an invitation to tender shall be taken in accordance with the procedure laid down in Article 26 of Regulation (EEC) No 2727/75. The decision shall specify in particular:

(a) the quantities to be put up for tender;

(b) the closing date for the submission of tenders in the case of a specific invitation to tender and the first and final closing dates for the submission of tenders in the case of a standing invitation to tender.

The decision provided for in the first subparagraph shall be brought to the attention of all interested parties by its publication in the *Official Journal of the European Communities.*

A period of at least eight days must elapse between the date of such publication and the first closing date for the submission of tenders.

2. The provisions of paragraph 1 shall not apply to invitations to tender relating to quantities of less than 1 000 tonnes.'

2. Article 3 is replaced by the following:

'*Article 3*

1. Intervention agencies shall draw up notices of invitation to tender in accordance with the provisions of Article 12 and shall publicize them, in particular by displaying them at their head offices. In the case of a standing invitation to tender they shall specify therein the closing dates for the submission of tenders for each partial invitation to tender.

2. Notices of invitation to tender shall specify the minimum quantities to which tenders may relate.'

3. Article 4 is replaced by the following:

'*Article 4*

The invitations to tender referred to in Article 2 may be restricted to specified uses and/or destinations.'.

4. Article 5 is replaced by the following :

'Article 5

1. For resale other than as referred to in paragraph 3, successful tenders must offer a price at least equal to the price recorded, for an equivalent quality and for a representative quantity, on the market for the place of storage or, failing this, on the nearest market, account being taken of transport costs. The tender price may not in any circumstances be lower than the intervention price applicable on the closing date for the submission of tenders, adjusted where appropriate :

— in accordance with Article 4 (6) of Regulation (EEC) No 1570/77 [1], in the case of certain varieties of durum wheat,

— by the special increase provided for in the third indent of Article 3 (1) of Regulation (EEC) No 2727/75, in the case of rye of breadmaking quality or common wheat of superior breadmaking quality,

— by the reduction provided for in the first subparagraph of Article 4a (1) of Regulation (EEC) No 1570/77 ; however, in the case of common wheat offered for intervention before 1 July 1986 and held in storage by the intervention agencies after that date, the abovementioned reduction shall not apply :

— to quantities purchased under the special intervention measures for common wheat of breadmaking quality,

— to quantities of common wheat purchased at the intervention price but not tested for the technological and physical characteristics referred to in Article 4a (1) of Regulation (EEC) No 1570/77.

2. For the purposes of paragraph 1, the intervention prices to be taken into consideration during the 11th and 12th months of the marketing year shall be those in force for the 10th month to which one and two monthly price increases respectively have been added.

3. In the case of resale during the first three months of the marketing year for maize and sorghum and during the first two months of the marketing year for common wheat, durum wheat, rye and barley, successful tenders must offer a price at least equal to the intervention price in force for the 10th month of the preceding marketing year, plus two monthly increases fixed for that year and adjusted, where appropriate, in accordance with paragraph 1.

4. If, during a marketing year, there are disruptions in the operation of the common organization of the market on account in particular of difficulty in selling cereals at prices which comply with paragraph 1, special price conditions may be fixed in accordance with the procedure laid down in Article 26 of Regulation (EEC) No 2727/75.'

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

'(c) where the price tendered adjusted where appropriate in accordance with Article 5 (1) is less than the intervention price, they are accompanied by a written undertaking by the tenderer, endorsed by a credit institution, to the effect that, not later than two working days after receipt of the statement of award of contract referred to in Article 15, the tenderer will provide a security covering the difference between the two prices adjusted by the amount of any increases or reductions applied pursuant to Article 7 (5) of Regulation (EEC) No 2727/75, excluding the specific adjustments referred to in Article 5 (1), first and third indent of this Regulation.'

6. In Article 10, the words 'the refund and monetary compensatory amount fixed in advance' are deleted.

7. Article 12 is amended as follows :

— in the second indent of the first paragraph, the second sentence is deleted,

— the last paragraph is replaced by the following :

'Such notice and any amendments thereto shall be forwarded to the Commission before the first closing date for the submission of tenders.'

8. Article 13 is amended as follows :

— in the second subparagraph of paragraph 1 the words 'Articles 7 (5) and 8 (4)' are replaced by 'Article 7 (5)',

— paragraph 2 is replaed by the following :

'2. In the case of sales for export, tenders shall be drawn up by reference to the actual quality of the lot to which the tender relates.'

9. In the second paragraph of Article 16, the last sentence is deleted.

10. Article 17 (1) is replaced by the following :

'1. The securities referred to in this Regulation shall be provided in accordance with the provisions of Title III of Commission Regulation (EEC) No 2220/85 [1].

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[1] OJ No L 205, 3. 8. 1985 , p. 5.'

11. In Article 17 (2) and (4), the term 'Article 13 (2)' is replaced by 'Article 13 (4).'

Article 2

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

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

COMMISSION REGULATION (EEC) No 125/87

of 16 January 1987

on offers tendered in respect of the eighth invitation to tender issued under the standing invitation to tender referred to in Regulation (EEC) No 1812/86

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 805/68 of 27 June 1968 on the common organization of the market in beef and veal (1), as last amended by Regulation (EEC) No 3768/85 (2), and in particular Article 7 (3) thereof,

Whereas, pursuant to Commission Regulation (EEC) No 1812/86 of 11 June 1986 on the sale by tender, for export, of beef held by certain intervention agencies (3), as amended by Regulation (EEC) No 2388/86 (4), intervention agencies have issued a standing invitation to tender in respect of certain quantities of beef which they hold;

Whereas no offers were received in respect of the eighth individual invitation to tender;

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

HAS ADOPTED THIS REGULATION:

Article 1

For the eighth individual invitation to tender pursuant to Regulation (EEC) No 1812/86 in respect of which the time limit for the submission of tenders expired on 14 January 1987, no award shall be made.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 148, 28. 6. 1968, p. 24.
(2) OJ No L 362, 31. 12. 1985, p. 8.
(3) OJ No L 157, 12. 6. 1986, p. 43.
(4) OJ No L 206, 30. 7. 1986, p. 23.

COMMISSION REGULATION (EEC) No 126/87

of 16 January 1987

fixing the minimum selling prices for unboned beef put up for sale by tender in accordance with Regulation (EEC) No 3905/86

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 805/68 of 27 June 1968 on the common organization of the market in beef and veal (1), as last amended by Regulation (EEC) No 3768/85 (2), and in particular Article 7 (3) thereof,

Whereas, tenders have been invited for certain quantities of unboned beef and veal fixed by Commission Regulation (EEC) No 3905/86 (3);

Whereas, pursuant to Article 9 of Commission Regulation (EEC) No 2173/79 (4), the minimum selling prices for meat put up for sale by tender should be fixed, taking into account tenders submitted;

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

HAS ADOPTED THIS REGULATION:

Article 1

The minimum selling prices for unboned beef for the first specific invitation to tender held in accordance with Regulation (EEC) No 3905/86 for which the time limit for the submission of tenders was 14 January 1987 shall be as set out in the Annex hereto.

Article 2

The Regulation shall enter force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 148, 28. 6. 1968, p. 24.
(2) OJ No L 362, 31. 12. 1985, p. 8.
(3) OJ No L 364, 23. 12. 1986, p. 17.
(4) OJ No L 251, 5. 10. 1979, p. 12.

ANEXO — BILAG — ANHANG — ΠΑΡΑΡΤΗΜΑ — ANNEX — ANNEXE — ALLEGATO — BIJLAGE — ANEXO

Categoría	A :	Canales de jóvenes animales machos no castrados de menos de 2 años,
Categoría	C :	Canales de animales machos castrados.
Kategori	A :	Slagtekroppe af unge ikke-kastrerede handyr på under to år,
Kategori	C :	Slagtekroppe af kastrerede handyr.
Kategorie	A :	Schlachtkörper von jungen männlichen, nicht kastrierten Tieren von weniger als 2 Jahren,
Kategorie	C :	Schlachtkörper von männlichen kastrierten Tieren.
Κατηγορία	A:	Σφάγια νεαρών μη ευνουχισμένων αρρένων ζώων κάτω των 2 ετών,
Κατηγορία	C:	Σφάγια ευνουχισμένων αρρένων ζώων.
Category	A :	Carcases of uncastrated young male animals of less than two years of age,
Category	C :	Carcases of castrated male animals.
Catégorie	A :	Carcasses de jeunes animaux mâles non castrés de moins de 2 ans,
Catégorie	C :	Carcasses d'animaux mâles castrés.
Categoria	A :	Carcasse di giovani animali maschi non castrati di età inferiore a 2 anni,
Categoria	C :	Carcasse di animali maschi castrati.
Categorie	A :	Geslachte niet-gecastreerde jonge mannelijke dieren minder dan 2 jaar oud,
Categorie	C :	Geslachte gecastreerde mannelijke dieren.
Categoria	A :	Carcaças de animais jovens machos, não castrados, de menos de dois anos,
Categoria	C :	Carcaças de animais machos castrados.

Precios de venta mínimos (ECUS/tonelada) — Mindstesalgspriser (ECU/ton) — Mindesverkaufspreise (ECU/Tonne) — Ελάχιστες τιμές πωλήσεως (ECU/τόνο) — Minimum selling prices (ECU/tonne) — Prix de vente minimaux (Écus/t) — Prezzi minimi di vendita (ECU/t) — Minimumverkoopprijzen (Ecu/ton) — Preço mínimo de venda (ECUs/tonelada)

ITALIA

— *Quarti anteriori, taglio a 5 costole, il pancettone fa parte del quarto anteriore, provenienti dai :*	
Vitelloni 1 / Vitelloni 2 / Categoria A, classi U, R e O	701
— *Quarti posteriori, taglio a 8 costole, detto pistola, provenienti dai :*	
Vitelloni 1 / Vitelloni 2 / Categoria A, classi U, R e O	701
— *Quarti anteriori, taglio a 8 costole, il pancettone fa parte del quarto anteriore, provenienti dai :*	
Vitelloni 1 / Vitelloni 2 / Categoria A, classi U, R e O	701
— *Quarti posteriori, taglio a 5 costole, detto pistola, provenienti dai :*	
Vitelloni 1 / Vitelloni 2 / Categoria A, classi U, R e O	701

COMMISSION REGULATION (EEC) No 127/87

of 16 January 1987

amending Regulation (EEC) No 4079/86 fixing the rates of the refunds applicable to certain cereal and rice products exported in the form of goods not covered by Annex II to the Treaty

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular the first sentence of the fourth subparagraph of Article 16 (2) thereof,

Having regard to Council Regulation (EEC) No 1418/76 of 21 June 1976 on the common organization of the market in rice (3), as last amended by Regulation (EEC) No 1449/86 (4), and in particular the first sentence of the fourth subparagraph of Article 17 (2) thereof,

Whereas the rates of the refunds applicable from 1 January 1987 to certain cereal and rice products exported in the form of goods not covered by Annex II to the Treaty were fixed by Commission Regulation (EEC) No 4079/86 (5);

Whereas it has been found that certain of these rates are erroneous; whereas they must therefore be corrected and the relevant Regulation must be amended;

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

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Regulation (EEC) No 4079/86 is hereby replaced by the Annex to this Regulation.

Article 2

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

However, on application via the party concerned, it shall apply to operations completed from 1 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 139, 24. 5. 1986, p. 29.
(3) OJ No L 166, 25. 6. 1976, p. 1.
(4) OJ No L 133, 21. 5. 1986, p. 1.
(5) OJ No L 371, 31. 12. 1986, p. 42.

ANNEX

(ECU/100 kg)

CCT heading No	Description	Rate of refund
10.01 B I	Common wheat, and meslin (mixed wheat and rye):	
	— For the manufacture of starch	13,544 (1)
	— Other than for the manufacture of starch	13,544
10.01 B II	Durum wheat	18,715 (2)
10.02	Rye	12,029
10.03	Barley	15,099
10.04	Oats	12,088
10.05 B	Maize, other than hybrid maize for sowing:	
	— For the manufacture of starch	14,395 (1)
	— Other than for the manufacture of starch	14,395
10.06 B I b) 1	Round grain husked rice	38,673
10.06 B I b) 2	Long grain husked rice	43,572
10.06 B II b) 1	Round grain wholly milled rice	49,901
10.06 B II b) 2	Long grain wholly milled rice	63,148
10.06 B III	Broken rice:	
	— For the manufacture of starch	21,053 (1)
	— Other than for the manufacture of starch	21,053
10.07 C II	Grain sorghum	15,392
11.01 A	Wheat or meslin flour	16,026
11.01 B	Rye flour	21,589
11.02 A I a)	Durum wheat groats and meal	29,088 (2)
11.02 A I b)	Common wheat groats and meal	16,026

(1) On exportation of goods covered by the Annex to Regulation (EEC) No 1009/86, this amount must be reduced by the amount of the production refund applicable for the goods in question, in accordance with Regulations (EEC) No 2742/75 and (EEC) No 1009/86 and their implementing provisions.

On exportation of other goods, this amount must be reduced by the amount of the production refund applicable for the goods in question at the time of export.

(2) With the exception of the quantities referred to in the Commission's Decision of 19 March 1986.

COMMISSION REGULATION (EEC) No 128/87

of 16 January 1987

amending the monetary coefficients applicable on imports of dried grapes

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 426/86 of 24 February 1986 on the common organization of the market in products processed from fruit and vegetables (1), as amended by Regulation (EEC) No 1838/86 (2), and in particular Article 9 (6) thereof,

Having regard to Council Regulation (EEC) No 1676/85 of 11 June 1985 on the value of the unit of account and the conversion rates to be applied for the purposes of the common agricultural policy (3), and in particular Article 2 (4) thereof,

Whereas the monetary coefficients applicable on imports of dried grapes from 5 January until 1 March 1987 have been fixed in Commission Regulation (EEC) No 5/87 (4); whereas with effect from 12 January 1987 the central rates have been adjusted; whereas as a consequence thereof the real monetary gap as referred to in Articles 5 (2) and 6 of Council Regulation (EEC) No 1677/85 (5), as last amended by Regulation (EEC) No 90/87 (6), has changed for most of the currencies of the Member States; whereas as a consequence thereof the monetary coefficients laid down in Regulation (EEC) No 5/87 should be amended;

Whereas the measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Products Processed from Fruit and Vegetables,

HAS ADOPTED THIS REGULATION:

Article 1

After having converted the minimum import prices and the import prices as set out in Annexes I and II of Commission Regulation (EEC) No 2382/86 (7) into one of the following national currencies by applying the agricultural conversion rate, the resulting amount shall be multiplied by the following coefficient:

— for the German mark:	0,972
— for the Dutch guilder:	0,972
— for the Greek drachma:	1,438
— for the pound sterling:	1,317
— for the Portuguese escudo:	1,163
— for the Spanish peseta:	1,093
— for the French franc:	1,095
— for the Irish pound:	1,105
— for the Danish kroner:	1,035
— for the Italian lira:	1,059

Article 2

This Regulation shall enter into force on 19 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 49, 27. 2. 1986, p. 1.
(2) OJ No L 159, 14. 6. 1986, p. 1.
(3) OJ No L 164, 24. 6. 1985, p. 1.
(4) OJ No L 1, 3. 1. 1987, p. 10.
(5) OJ No L 164, 24. 6. 1985, p. 6.
(6) OJ No L 13, 15. 1. 1987, p. 12.
(7) OJ No L 206, 30. 7. 1986, p. 18.

COMMISSION REGULATION (EEC) No 129/87

of 16 January 1987

altering the export refunds on cereals and on wheat or rye flour, groats and meal

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular the fifth subparagraph of Article 16 (2) thereof,

Whereas the export refunds on cereals and on wheat or rye flour, groats and meal were fixed by Regulation (EEC) No 118/87 (3);

Whereas it follows from applying the detailed rules contained in Regulation (EEC) No 118/87 to the information known to the Commission that the export refunds at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The export refunds on the products listed in Article 1 (a), (b) and (c) of Regulation (EEC) No 2727/75, exported in the natural state, as fixed in the Annex to Regulation (EEC) No 118/87 are hereby altered as shown in the Annex to this Regulation in respect of the products set out therein.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 118, 7. 5. 1986, p. 1.
(3) OJ No L 14, 16. 1. 1987, p. 46.

ANNEX

to the Commission Regulation of 16 January 1987 altering the export refunds on cereals and on wheat or rye flour, groats and meal

(ECU / tonne)

CCT heading No	Description	Refund
10.01 B I	Common wheat and meslin	
	for exports to :	
	— Switzerland, Austria, Liechtenstein, Ceuta and Melilla	122,00
	— zone II b)	128,00
	— other third countries	15,00
10.01 B II	Durum wheat	
	for exports to :	
	— Switzerland, Austria and Liechtenstein	5,00 (3)
	— zone I and zone II a)	196,00 (3)
	— other third countries	10,00 (3)
10.02	Rye	
	for exports to :	
	— Switzerland, Austria and Liechtenstein	5,00
	— other third countries	10,00
10.03	Barley	
	for exports to :	
	— Switzerland, Austria, Liechtenstein, Ceuta and Melilla	125,00
	— zone II b)	129,00
	— Cyprus, Israel and Tunisia	25,00
	— other third countries	20,00
10.04	Oats	
	for exports to :	
	— Switzerland, Austria and Liechtenstein	—
	— zone I	95,00
	— other third countries	—
10.05 B	Maize, other than hybrid maize for sowing	
	for exports to :	
	— Switzerland, Austria and Liechtenstein	10,00
	— zone I, zone V, the German Democratic Republic and the Canary Islands	20,00
	— other third countries	—
10.07 B	Millet	—
10.07 C II	Grain sorghum, other than hybrid sorghum for sowing	—
ex 11.01 A	Wheat flour :	
	— of an ash content of 0 to 520	193,00
	— of an ash content of 521 to 600	193,00
	— of an ash content of 601 to 900	170,00
	— of an ash content of 901 to 1 100	157,00
	— of an ash content of 1 101 to 1 650	146,00
	— of an ash content of 1 651 to 1 900	130,00

(ECU / tonne)

CCT heading No	Description	Refund
ex 11.01 B	Rye flour :	
	— of an ash content of 0 to 700	193,00
	— of an ash content of 701 to 1 150	193,00
	— of an ash content of 1 151 to 1 600	193,00
	— of an ash content of 1 601 to 2 000	193,00
11.02 A I a)	Durum wheat groats and meal :	
	— of an ash content of 0 to 1 300 (1)	312,00 (3)
	— of an ash content of 0 to 1 300 (2)	295,00 (3)
	— of an ash content of 0 to 1 300	263,00 (3)
	— of an ash content of more than 1 300	248,00 (3)
11.02 A I b)	Common wheat groats and meal :	
	— of an ash content of 0 to 520	193,00

(1) Meal of which less than 10 % by weight is capable of passing through a sieve of 0,250 mm mesh.

(2) Meal of which less than 10 % by weight is capable of passing through a sieve of 0,160 mm mesh.

(3) With the exception of the quantities referred to in the Commission's Decision of 19 March 1986.

N.B. The zones are those defined in Regulation (EEC) No 1124/77 (OJ No L 134, 28. 5. 1977), as last amended by Regulation (EEC) No 3817/85 (OJ No L 368, 31. 12. 1985).

COMMISSION REGULATION (EEC) No 130/87
of 16 January 1987
fixing the amount of the subsidy on oil seeds

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation No 136/66/EEC of 22 September 1966 on the establishment of a common organization of the market in oils and fats (1), as last amended by Regulation (EEC) No 1454/86 (2), and in particular Article 27 (4),

Having regard to Council Regulation (EEC) No 1678/85 of 11 June 1985 fixing the conversion rates to be applied in agriculture (3), as last amended by Regulation (EEC) No 2332/86 (4),

Having regard to Council Regulation (EEC) No 1569/72 of 20 July 1972 laying down special measures for colza, rape and sunflower seed (5), as last amended by Regulation (EEC) No 1474/84 (6), and in particular Article 2 (3) thereof,

Having regard to the opinion of the Monetary Committee,

Whereas the amount of the subsidy referred to in Article 27 of Regulation No 136/66/EEC was fixed by Commission Regulation (EEC) No 3776/86 (7), as last amended by Regulation (EEC) No 95/87 (8);

Whereas the target price and the monthly increments in the target price for colza, rape and sunflower seed for the 1986/87 marketing year have been fixed in Council Regulations (EEC) No 1457/86 (9) and (EEC) No 1458/86 (10);

Whereas it follows from applying the detailed rules contained in Regulation (EEC) No 3776/86 to the information known to the Commission that the amount of the subsidy at present in force should be altered to the amount set out in the Annexes hereto,

HAS ADOPTED THIS REGULATION:

Article 1

1. The amounts of the subsidy and the exchange rates referred to in Article 33 (2) and (3) of Commission Regulation (EEC) No 2681/83 (11) shall be as set out in the Annexes hereto.

2. The amount of the compensatory aid referred to in Article 14 of Council Regulation (EEC) No 475/86 (12) and Article 12 of Council Regulation (EEC) No 476/86 (13) shall be as shown in Annex III to this Regulation for sunflower seed harvested in Spain and Portugal.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No 172, 30. 9. 1966, p. 3025/66.
(2) OJ No L 133, 21. 5. 1986, p. 8.
(3) OJ No L 164, 24. 6. 1985, p. 11.
(4) OJ No L 204, 28. 7. 1986, p. 1.
(5) OJ No L 167, 25. 7. 1972, p. 9.
(6) OJ No L 143, 30. 5. 1984, p. 4.
(7) OJ No L 349, 11. 12. 1986, p. 34.
(8) OJ No L 13, 15. 1. 1987, p. 20.
(9) OJ No L 133, 21. 5. 1986, p. 12.
(10) OJ No L 133, 21. 5. 1986, p. 14.
(11) OJ No L 266, 28. 9. 1983, p. 1.
(12) OJ No L 53, 1. 3. 1986, p. 47.
(13) OJ No L 53, 1. 3. 1986, p. 51.

ANNEX I

Aids to colza and rape seed other than 'double zero'

(amounts per 100 kilograms)

	Current month	2nd month	3rd month	4th month	5th month	6th month
1. Gross aids (ECU):						
— Spain	0,610	0,610	0,610	0,610	0,610	0,610
— Portugal	0,000	0,000	0,000	0,000	0,000	0,000
— Other Member States	34,593	34,889	35,222	35,455	35,211	35,048
2. Final aids:						
(a) Seed harvested and processed in:						
— Federal Republic of Germany (DM)	83,48	84,20	85,02	85,69	85,12	85,04
— Netherlands (Fl)	94,06	94,87	95,78	96,53	95,89	95,76
— BLEU (Bfrs/Lfrs)	1 614,85	1 628,63	1 644,16	1 654,37	1 642,81	1 630,55
— France (FF)	235,99	237,96	239,98	241,03	239,12	238,49
— Denmark (Dkr)	291,18	293,65	296,44	298,35	296,20	294,43
— Ireland (£ Irl)	25,888	26,104	26,348	26,358	26,144	25,912
— United Kingdom (£)	18,844	18,990	19,167	19,260	19,059	18,806
— Italy (Lit)	51 705	52 137	52 513	52 964	52 562	52 058
— Greece (Dr)	3 305,58	3 308,35	3 312,82	3 312,32	3 270,37	3 179,60
(b) Seed harvested in Spain and processed:						
— in Spain (Pta)	88,94	88,94	88,94	88,94	88,94	88,94
— in another Member State (Pta)	4 045,22	4 085,67	4 132,01	4 134,13	4 094,79	4 063,69
(c) Seed harvested in Portugal and processed:						
— in Portugal (Esc)	0,00	0,00	0,00	0,00	0,00	0,00
— in another Member State (Esc)	4 891,73	4 926,83	4 941,52	4 959,42	4 915,46	4 842,77

ANNEX II

Aids to colza and rape seed 'double zero'

(amounts per 100 kilograms)

	Current month	2nd month	3rd month	4th month	5th month	6th month
1. Gross aids (ECU):						
— Spain	1,860	1,860	1,860	1,860	1,860	1,860
— Portugal	1,250	1,250	1,250	1,250	1,250	1,250
— Other Member States	35,843	36,139	36,472	36,705	36,461	36,298
2. Final aids:						
(a) Seed harvested and processed in:						
— Federal Republic of Germany (DM)	86,47	87,19	88,00	88,67	88,11	88,03
— Netherlands (Fl)	97,43	98,24	99,15	99,89	99,26	99,13
— BLEU (Bfrs/Lfrs)	1 673,44	1 687,22	1 702,76	1 712,97	1 701,41	1 689,15
— France (FF)	244,87	246,84	248,86	249,90	248,00	247,37
— Denmark (Dkr)	301,86	304,33	307,12	309,04	306,88	305,11
— Ireland (£ Irl)	26,867	27,082	27,327	27,336	27,123	26,891
— United Kingdom (£)	19,629	19,775	19,951	20,045	19,843	19,590
— Italy (Lit)	53 629	54 061	54 437	54 888	54 487	53 982
— Greece (Dr)	3 451,42	3 454,19	3 458,67	3 458,16	3 416,22	3 325,45
(b) Seed harvested in Spain and processed:						
— in Spain (Pta)	271,19	271,19	271,19	271,19	271,19	271,19
— in another Member State (Pta)	4 227,47	4 267,92	4 314,26	4 316,38	4 277,04	4 245,94
(c) Seed harvested in Portugal and processed:						
— in Portugal (Esc)	189,77	189,77	189,77	189,77	189,77	189,77
— in another Member State (Esc)	5 081,50	5 116,60	5 131,29	5 149,19	5 105,23	5 032,54

ANNEX III

Aids to sunflower seed

(amounts per 100 kilograms)

	Current month	2nd month	3rd month	4th month	5th month
1. Gross aids (ECU):					
— Spain	1,720	1,720	1,720	1,720	1,720
— Portugal	0,000	0,000	0,000	0,000	0,000
— Other Member States	42,086	42,604	43,063	41,664	41,664
2. Final aids:					
(a) Seed harvested and processed in (1):					
— Federal Republic of Germany (DM)	101,45	102,69	103,81	100,67	100,67
— Netherlands (Fl)	114,31	115,71	116,95	113,41	113,41
— BLEU (Bfrs/Lfrs)	1 965,40	1 989,65	2 011,10	1 944,20	1 944,20
— France (FF)	288,24	291,87	294,79	283,39	283,39
— Denmark (Dkr)	354,75	359,15	363,04	350,67	350,67
— Ireland (£ Irl)	31,635	32,034	32,380	30,994	30,994
— United Kingdom (£)	23,261	23,572	23,833	22,678	22,678
— Italy (Lit)	63 085	63 872	64 435	62 263	62 263
— Greece (Dr)	4 107,61	4 140,86	4 159,46	3 904,67	3 904,67
(b) Seed harvested in Spain and processed:					
— in Spain (Pta)	250,77	250,77	250,77	250,77	250,77
— in another Member State (Pta)	4 086,01	4 160,55	4 225,68	3 969,96	3 969,96
(c) Seed harvested in Portugal and processed:					
— in Portugal (Esc)	0,00	0,00	0,00	0,00	0,00
— in Spain (Esc)	6 652,55	6 726,53	6 759,48	6 487,75	6 487,75
— in another Member State (Esc)	6 436,68	6 508,25	6 540,14	6 277,22	6 277,22
3. Compensatory aids:					
— in Spain (Pta)	4 030,50	4 106,83	4 172,41	3 919,81	3 919,81
— in Portugal (Esc)	6 402,39	6 475,07	6 507,23	6 246,25	6 246,25

(1) For seed harvested in the Community as constituted at 31 December 1985 and processed in Spain, the amounts shown in 2 (a) to be multiplied by 1,037269.

ANNEX IV

Exchange rate of the ECU to be used for converting final aids into the currency of the processing country when the latter is a country other than the country of production

(value of 1 ECU)

	Current month	2nd month	3rd month	4th month	5th month	6th month
DM	2,060500	2,054700	2,049460	2,044470	2,044470	2,029920
Fl	2,337650	2,333750	2,329520	2,325190	2,325190	2,314210
Bfrs/Lfrs	42,895000	42,980300	42,970100	42,953000	42,953000	42,952800
FF	6,873280	6,878390	6,892110	6,906860	6,906860	6,931610
Dkr	7,846410	7,867740	7,879270	7,891680	7,891680	7,939980
£ Irl	0,770743	0,774624	0,777406	0,780372	0,780372	0,787844
£	0,736598	0,738475	0,740528	0,742405	0,742405	0,749294
Lit	1 472,50	1 477,11	1 480,47	1 483,76	1 483,76	1 495,35
Dr	149,09200	151,35700	153,60700	155,55300	155,55300	161,54500
Esc	158,48900	159,97500	160,90200	161,80000	161,80000	164,61700
Pta	142,21600	143,12100	143,68900	144,31300	144,31300	146,04800

COMMISSION REGULATION (EEC) No 131/87

of 16 January 1987

fixing the import levies on white sugar and raw sugar

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal,

Having regard to Council Regulation (EEC) No 1785/81 of 30 June 1981 on the common organization of the markets in the sugar sector (1), as last amended by Regulation (EEC) No 3666/86 (2), and in particular Article 16 (8) thereof,

Whereas the import levies on white sugar and raw sugar were fixed by Commission Regulation (EEC) No 2051/86 (3), as last amended by Regulation (EEC) No 114/87 (4);

Whereas it follows from applying the detailed rules contained in Regulation (EEC) No 2051/86 to the information known to the Commission that the levies at present in force should be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies referred to in Article 16 (1) of Regulation (EEC) No 1785/81 shall be, in respect of white sugar and standard quality raw sugar, as set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 177, 1. 7. 1981, p. 4.
(2) OJ No L 339, 2. 12. 1986, p. 10.
(3) OJ No L 173 1. 7. 1986, p. 91.
(4) OJ No L 14, 16. 1. 1987, p. 38.

ANNEX

to the Commission Regulation of 16 January 1987 fixing the import levies on white sugar and raw sugar

(ECU/100 kg)

CCT heading No	Description	Levy
17.01	Beet sugar and cane sugar, in solid form:	
	A. White sugar: flavoured or coloured sugar	51,35
	B. Raw sugar	44,29 (1)

(1) Applicable to raw sugar with a yield of 92 %; if the yield is other than 92 %, the levy applicable is calculated in accordance with the provisions of Article 2 of Regulation (EEC) No 837/68.

COMMISSION REGULATION (EEC) No 132/87

of 16 January 1987

altering the import levies on products processed from cereals and rice

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to the Act of Accession of Spain and Portugal.

Having regard to Council Regulation (EEC) No 2727/75 of 29 October 1975 on the common organization of the market in cereals (1), as last amended by Regulation (EEC) No 1579/86 (2), and in particular Article 14 (4) thereof,

Having regard to Council Regulation (EEC) No 1418/76 of 21 June 1976 on the common organization of the market in rice (3), as last amended by Regulation (EEC) No 1449/86 (4) and in particular Article 12 (4) thereof,

Having regard to Council Regulation No 1676/85 of 11 June 1985 on the value of the unit of account and the exchange rates to be applied for the purposes of the common agricultural policy (5) and in particular Article 3 thereof,

Having regard to the advice of the Monetary Committee,

Whereas the import levies on products processed from cereals and rice were fixed by Commission Regulation (EEC) No 4071/86 (6), as last amended by Regulation (EEC) No 100/87 (7);

Whereas Council Regulation (EEC) No 1588/86 (8) as amended by Council Regulation (EEC) No 2744/75 (9) as regards products falling within subheading 23.02 A of the Common Customs Tariff;

Whereas, if the levy system is to operate normally, levies should be calculated on the following basis:

— in the case of currencies which are maintained in relation to each other at any given moment within a band of 2,25 %, a rate of exchange based on their central rate, multiplied by the corrective factor provided for in the last paragraph of Article 3 (1) of Regulation (EEC) No 1676/85,

— for other currencies, an exchange rate based on the arithmetic mean of the spot market rates of each of these currencies recorded over a given period in relation to the Community currencies referred to in the previous indent, and the aforesaid coefficient;

Whereas these exchange rates being those recorded on 15 January 1987;

Whereas the aforesaid corrective factor affects the entire calculation basis for the levies, including the equivalence coefficients;

Whereas the levy on the basic product as last fixed differs from the average levy by more than 3,02 ECU per tonne of basic product; whereas, pursuant to Article 1 of Commission Regulation (EEC) No 1579/74 (10) the levies at present in force must therefore be altered to the amounts set out in the Annex hereto,

HAS ADOPTED THIS REGULATION:

Article 1

The import levies to be charged on products processed from cereals and rice covered by Regulation (EEC) No 2744/75, as last amended by Regulation (EEC) No 1588/86, as fixed in the Annex to amended Regulation (EEC) No 4071/86 are hereby altered to the amounts set out in the Annex hereto.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission

Frans ANDRIESSEN

Vice-President

(1) OJ No L 281, 1. 11. 1975, p. 1.
(2) OJ No L 139, 24. 5. 1986, p. 29.
(3) OJ No L 166, 25. 6. 1976, p. 1.
(4) OJ No L 133, 21. 5. 1986, p. 1.
(5) OJ No L 164, 24. 6. 1985, p. 1.
(6) OJ No L 371, 31. 12. 1986, p. 19.
(7) OJ No L 13, 15. 1. 1987, p. 30.
(8) OJ No L 139, 24. 5. 1986, p. 47.
(9) OJ No L 281, 1. 11. 1975, p. 65.
(10) OJ No L 168, 25. 6. 1974, p. 7.

ANNEX

to the Commission Regulation of 16 January 1987 altering the import levies on products processed from cereals and rice

(ECU/tonne)

CCT heading No	Import levies	
	Third countries (other than ACP or OCT)	ACP or OCT
07.06 A I	185,95 (1)	184,14 (1) (5)
07.06 A II	188,97 (1)	184,14 (1) (5)
11.01 C (2)	340,75	334,71
11.02 A III (2)	340,75	334,71
11.02 B I a) 1 (2)	300,54	297,52
11.02 B I b) 1 (2)	300,54	297,52
11.02 C III (2)	470,92	464,88
11.02 D III (2)	192,69	189,67
11.02 E I a) 1 (2)	192,69	189,67
11.02 E I b) 1 (2)	377,94	371,90
11.02 F III (2)	340,75	334,71
11.04 C I	188,97	182,32 (5)
11.07 A II a)	341,87 (4)	330,99
11.07 A II b)	258,19	247,31
11.07 B	299,10 (4)	288,22

(1) This levy is limited to 6 % of the value for customs purposes, subject to certain conditions.

(2) For the purpose of distinguishing between products falling within heading Nos 11.01 and 11.02 and those falling within subheading 23.02 A, products falling within heading Nos 11.01 and 11.02 shall be those meeting the following specifications :

— a starch content (determined by the modified Ewers polarimetric method), referred to dry matter, exceeding 45 % by weight,

— an ash content by weight, referred to dry matter (after deduction of any added minerals), not exceeding 1,6 % for rice, 2,5 % for wheat, 3 % for barley, 4 % for buckwheat, 5 % for oats and 2 % for other cereals.

Germ of cereals, whole, rolled, flaked or ground, falls in all cases within heading No 11.02.

(4) In accordance with Regulation (EEC) No 1180/77 this levy is reduced by 5,44 ECU/tonne for products originating in Turkey.

(5) In accordance with Regulation (EEC) No 486/85 the levy shall not be charged on the following products originating in the African, Caribbean and Pacific States and in the overseas countries and territories :

— arrowroot falling within subheading ex 07.06 A,

— flours and meal of arrowroot falling within subheading 11.04 C,

— arrowroot starch falling within subheading ex 11.08 A V.

COMMISSION REGULATION (EEC) No 133/87
of 16 January 1987
suspending advance fixing of the additional aid for dried fodder

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community,

Having regard to Council Regulation (EEC) No 1117/78 of 22 May 1978 on the common organization of the market in dried fodder [1], as last amended by Regulation (EEC) No 1985/86 [2],

Having regard to Council Regulation (EEC) No 1417/78 of 14 June 1978 on the aid system for dried fodder [3], as last amended by Regulation (EEC) No 2026/82 [4], and in particular the second subparagraph of Article 12 (2),

Whereas, pursant to Article 12 of Regulation (EEC) No 1417/78, the application of the provisions concerning advance fixing may be suspended if the volume of applications for advance fixing of the subsidy does not appear to be related to normal outlets for dried fodder harvested in the Community and if the certificate applied for has not yet ben issued;

Whereas the above situation requires that application of the provisions concerning advance fixing of subsidies for the products concerned be temporarily suspended and that, in accordance with Article 9 of Regulation (EEC) No 1528/78 [5], as last amended by Regulation (EEC) No 2341/86 [6], certificates, for which the application is pending, should not be issued,

HAS ADOPTED THIS REGULATION:

Article 1

Advance fixing of the additional aid for dried fodder is hereby suspended between 17 and 21 January 1987.

Article 2

This Regulation shall enter into force on 17 January 1987.

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

Done at Brussels, 16 January 1987.

For the Commission
Frans ANDRIESSEN
Vice-President

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[1] OJ No L 142, 30. 5. 1978, p. 1.
[2] OJ No L 171, 28. 6. 1986, p. 4.
[3] OJ No L 171, 28. 6. 1978, p. 1.
[4] OJ No L 218, 27. 7. 1982, p. 2.
[5] OJ No L 179, 1. 7. 1978, p. 10.
[6] OJ No L 203, 26. 7. 1986, p. 17.

II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DIRECTIVE

of 18 December 1986

on the harmonization of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances

(87/18/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

Having regard to the proposal from the Commission,

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

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

Whereas Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances (3), as last amended by Directive 84/449/EEC (4), requires tests to be carried out on chemical substances in order to enable their potential risk to man and the environment to be determined;

Whereas Directive 75/318/EEC (5) as amended by Directive 87/19/EEC (6), and Directive 81/852/EEC (7) as amended by Directive 87/20/EEC (8) lay down that non-clinical tests on pharmaceutical products shall be carried out in accordance with the principles of good laboratory practice in force in the Community for chemical substances;

Whereas when the active substances in pesticides undergo tests they shall do so in accordance with the protocols provided for by Directive 67/548/EEC, and hence in accordance with good laboratory practice for chemical substances;

Whereas the methods to be used for these tests are laid down in Annex V to Directive 67/548/EEC;

Whereas it is necessary to comply with the principles of good laboratory practice in carrying out the tests laid down by Directive 67/548/EEC so as to ensure that the results are comparable and of high quality;

Whereas the Commission intends shortly to submit a proposal to the Council for a Directive aiming at verifying compliance with the principles of good laboratory practice;

Whereas the resources devoted to the tests must not be wasted by having to repeat tests owing to differences in laboratory practice from one Member State to another;

Whereas the Council of the Organization for Economic Cooperation and Development (OECD) took a Decision on 12 May 1981 on the mutual acceptance of data for the evaluation of chemical products; whereas it issued a recommendation on 26 July 1983 concerning the mutual recognition of compliance with good laboratory practice;

Whereas animal protection requires that the number of experiments conducted on animals be restricted; whereas mutual recognition of the results of tests obtained using standard and recognized methods is an essential condition for reducing the number of experiments in this area;

(1) OJ No C 120, 20. 5. 1986, p. 177.
(2) OJ No C 354, 31. 12. 1985, p. 5.
(3) OJ No 196, 16. 8. 1967, p. 1.
(4) OJ No L 251, 19. 9. 1984, p. 1.
(5) OJ No L 147, 9. 6. 1975, p. 1.
(6) See page 31 of this Official Journal.
(7) OJ No L 317, 6. 11. 1981, p. 16.
(8) See page 34 of this Official Journal.

Whereas it is necessary to set up a procedure allowing rapid adaptation of the principles of good laboratory practice,

HAS ADOPTED THIS DIRECTIVE:

Article 1

1. Member States shall take all measures necessary to ensure that laboratories carrying out tests on chemical products, in accordance with Directive 67/548/EEC, comply with the principles of good laboratory practice specified in Annex 2 to the Decision of 12 May 1981 of the Council of the OECD on the mutual acceptance of data for the evaluation of chemical products.

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

Article 2

When submitting results, the laboratories referred to in Article 1 must certify that the tests have been carried out in conformity with the principles of good laboratory practice referred to in that Article.

Article 3

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

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

Article 4

Adaptations to the principles of good laboratory practice mentioned in Article 1 may be adopted in accordance with the procedure laid down in Article 21 of Directive 67/548/EEC.

Article 5

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

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

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

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

Article 6

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive not later than 30 June 1988. They shall forthwith inform the Commission thereof.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 18 December 1986.

For the Council

The President

M. JOPLING

COUNCIL DIRECTIVE

of 22 December 1986

amending Directive 75/318/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products

(87/19/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the testing of proprietary medicinal products must regularly be adapted to scientific and technical progress in order to ensure optimum protection of public health in the Community;

Whereas, in order to achieve such optimum protection of health, the resources allocated to pharmaceutical research must not be squandered on obsolete or repetitive tests resulting from divergences between the Member States in assessing the state of the art in science and technology;

Whereas, for ethical reasons, it is necessary to replace existing methods as soon as scientific and technical advances so allow by methods involving as few laboratory animals as possible;

Whereas, it is therefore necessary to introduce a rapid procedure for adapting to technical progress the requirements regarding the testing of proprietary medicinal products listed in the Annex to Directive 75/318/EEC (4), as amended by Directive 83/570/EEC (5), whilst ensuring close cooperation between the Commission and the Member States within a 'Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medical Products Sector';

Whereas the requirements relating to the testing of medicinal products must also be capable of rapid revision by the same procedure, having regard to the evolution of test methods and of good laboratory practices recognized by the Community or in international trade in proprietary medicinal products,

(1) OJ No C 293, 5. 11. 1984, p. 4.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 147, 9. 6. 1975, p. 1.
(5) OJ No L 332, 28. 11. 1983, p. 1.

HAS ADOPTED THIS DECISION:

Article 1

Directive 75/318/EEC is hereby amended as follows:

1. The following Articles 2a, 2b and 2c shall be inserted:

'Article 2a

Any changes which are necessary in order to adapt the Annex to take account of technical progress shall be adopted in accordance with the procedure laid down in Article 2c.

If appropriate, the Commission shall propose to the Council that the procedure in Article 2c be reviewed in connection with the detailed rules set for the exercise of the powers of implementation granted to the Commission.

Article 2b

1. A Committee on the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Proprietary Medicinal Products Sector, hereinafter called "the Committee", is hereby set up; it shall consist of representatives of the Member States with a representative of the Commission as chairman.

2. The Committee shall adopt its own rules of procedure.

Article 2c

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the chairman either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the chairman, having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The chairman shall not vote.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.' ;

2. Part 1 of the Annex, 'Physico-Chemical, Biological or Microbiological Tests of Proprietary Medicinal Products', shall be amended as follows :

(a) In (A), the following section shall be inserted :

'4. An explanation should be provided with regard to the choice of composition, constituents and container, supported by scientific data on development pharmaceutics. The overage, with justification thereof, should be stated.' ;

(b) In (B) the following fifth indent shall be inserted :

'— experimental studies validating the manufacturing process, where a non-standard method of manufacture is used or where it is critical for the product.' ;

(c) In (C) (2), subparagraph (b) shall be replaced by the following :

'(b) the description of the substance, set down in a form similar to that used in a descriptive item in the European Pharmacopoeia, shall be accompanied by any necessary explanatory evidence, especially concerning the molecular structure where appropriate ; it must be accompanied by an appropriate description of the method of synthetic preparation. Where substances can only be described by their method of preparation, the description should be sufficiently detailed to characterize a substance which is constant both in its composition and in its effects ;'

3. Part 2 of the Annex, 'Toxicological and Pharmacological Tests', is hereby amended as follows :

(a) The following paragraph shall be inserted after the introductory paragraph :

'Member States shall ensure that the safety tests are executed in conformity with the principles of good laboratory practice recognized by Community law in the field of tests on dangerous substances, or in the absence thereof, with those recommended by the Organization for Economic Cooperation and Development.' ;

(b) In Chapter 1 (B), the text of paragraph 1 shall be replaced by the following :

'1. **Single dose toxicity**

An acute test infers a qualitative and quantitative study of the toxic reactions which may result from a single administration of the active substance or substances contained in the proprietary medicinal product, in the proportions and physico-chemical state in which they are present in the actual product.

The acute toxicity test must be carried out in two or more mammalian species of known strain unless a single species can be justified. At least two different routes of administration shall normally be used, one being identical with or similar to that proposed for use in human beings and the other ensuring systemic absorption of the substance.

This study will cover the signs observed, including local reactions. The period during which the test animals are observed shall be fixed by the investigator as being adequate to reveal tissue or organ damage or recovery, usually for a period of 14 days but not less than seven days, but without exposing the animals to prolonged suffering. Animals dying during the observation period should be subject to autopsy as also should all animals surviving to the end of the observation period. Histopathological examinations should be considered on any organ showing macroscopic changes at autopsy. The maximum amount of information should be obtained from the animals used in the study. The single dose toxicity tests should be conducted in such a way that signs of acute toxicity are revealed and the mode of death assessed as far as reasonably possible. In suitable species a quantitative evaluation of the approximate lethal dose and information on the dose effect relationship should be obtained, but a high level of precision is not required.

These studies may give some indication of the likely effects of acute overdosage in man and may be useful for the design of toxicity studies requiring repeated dosing on the suitable animal species.

In the case of active substances in combination, the study must be carried out in such a way as to check whether or not there is enhancement of toxicity or if novel toxic effects occur.'

Article 2

Member States shall take the measures necessary in order to comply with this Directive no later than 1 July 1987. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1986.

For the Council

The President

G. SHAW

COUNCIL DIRECTIVE

of 22 December 1986

amending Directive 81/852/EEC on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of veterinary medicinal products

(87/20/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas, the testing of veterinary medicinal products must regularly be adapted to scientific and technical progress in order to safeguard the health of consumers of livestock products and to ensure optimum protection of animal health in the Community;

Whereas, in order to achieve this optimum protection of public health, the resources allocated to pharmaceutical research must not be squandered on obsolete or repetitive tests resulting from divergences between the Member States in assessing the state of the art in science and technology;

Whereas, for ethical reasons, it is necessary to replace the existing methods as soon as scientific and technical advances so allow by methods involving as few laboratory animals as possible;

Whereas, it is therefore necessary to introduce a rapid procedure for adapting to technical progress the requirements regarding the testing of the veterinary medicinal products listed in the Annex to Directive 81/852/EEC (4), whilst ensuring close cooperation between the Member States and the Commission within a 'Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector';

Whereas the requirements relating to the testing of veterinary medicinal products must also be capable of rapid revision by the same procedure, having regard to the evolution of test methods and of good laboratory practices recognized by the Community or in international trade in veterinary medicinal products,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 81/852/EEC is hereby amended as follows:

1. The following Articles 2a, 2b and 2c shall be inserted:

'Article 2a

Any changes which are necessary in order to adapt the Annex to take account of technical progress shall be adopted in accordance with the procedure laid down in Article 2c.

If appropriate, the Commission shall propose to the Council that the procedure in Article 2c be reviewed in connection with the detailed rules set for the exercise of the powers of implementation granted to the Commission.

Article 2b

1. A Committee for the Adaptation to Technical Progress of the Directives on the Removal of Technical Barriers to Trade in the Veterinary Medicinal Products Sector, hereinafter called "the Committee", is hereby set up; it shall consist of representatives of the Member States with a representative of the Commission as Chairman.

2. The Committee shall adopt its own rules of procedure.

Article 2c

1. Where the procedure laid down in this Article is to be followed, matters shall be referred to the Committee by the Chairman, either on his own initiative or at the request of the representative of a Member State.

2. The representative of the Commission shall submit to the Committee a draft of the measures to be adopted. The Committee shall deliver its opinion on the draft within a time limit set by the Chairman having regard to the urgency of the matter. It shall act by a qualified majority, the votes of the Member States being weighted as provided in Article 148 (2) of the Treaty. The Chairman shall not vote.

(1) OJ No C 293, 5. 11. 1984, p. 6.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 317, 6. 11. 1981, p. 16.

3. (a) The Commission shall adopt the measures envisaged where they are in accordance with the opinion of the Committee.

(b) Where the measures envisaged are not in accordance with the opinion of the Committee, or if no opinion is adopted, the Commission shall without delay propose to the Council the measures to be adopted. The Council shall act by a qualified majority.

(c) If, within three months of the proposal being submitted to it, the Council has not acted, the proposed measures shall be adopted by the Commission.' ;

2. Part 1 of the Annex, 'Analytical (Physico-Chemical, Biological or Microbiological) Tests of Veterinary Medicinal Products', shall be amended as follows :

(a) in (A), the following section shall be inserted :

'4. An explanation should be provided with regard to the choice of composition, constituents and container, supported by data on development pharmaceutics. The overage, with justification thereof, should be stated.'

(b) in (B) the following fifth indent shall be inserted :

'— experimental studies validating the manufacturing process, where a non-standard method of manufacture is used or where it is critical for the product.' ;

(c) in (C) (2), subparagraph (b) shall be replaced by the following :

'(b) the description of the substance, set down in a form similar to that used in a descriptive item in the European Pharmacopoeia, shall be accompanied by any necessary explanatory evidence, especially concerning the molecular structure where appropriate ; it must be accompanied by an appropriate description of the method of synthetic preparation. Where substances can only be described by their method of preparation, the description should be sufficiently detailed to characterize a substance which is constant both in its composition, and in its effects ;'

3. Part 2 of the Annex, 'Toxicological and Pharmacological Tests' is hereby amended as follows :

(a) The following paragraph shall be inserted after the two introductory paragraphs :

'The Member States shall ensure that the laboratory tests are executed in conformity with the principles of good laboratory practice recognized by Community law in the field of tests on dangerous substances or, in the absence thereof, with those recommended by the Organization for Economic Cooperation and Development.'

(b) In Chapter I (B) (1) the fourth subparagraph shall be replaced by the following :

'This study will cover the signs observed, including local reactions. The period during which the test animals are observed shall be fixed by the investigator as being adequate to reveal tissue or organ damage or recovery, usually for a period of 14 days but not less than seven days, but without exposing the animals to prolonged suffering. Animals dying during the observation period should be subject to autopsy as also should all animals surviving to the end of the observation period. Histopathological examination should be considered on any organ showing macroscopic changes at autopsy. The maximum amount of information should be obtained from the animals used in the study. The single dose toxicity tests should be conducted in such a way that signs of acute toxicity are revealed and the mode of death assessed as far as reasonably possible. In suitable species a quantitative evaluation of the approximate lethal dose and information on the dose effect relationship should be obtained, but a high level of precision is not required.'

Article 2

Member States shall take the measures necessary to comply with this Directive no later than 1 July 1987. They shall forthwith inform the Commission thereof.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1986.

For the Council

The President

G. SHAW

COUNCIL DIRECTIVE

of 22 December 1986

amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

(87/21/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas point 8 of the second paragraph of Article 4 of Council Directive 65/65/EEC (4), as last amended by Directive 83/570/EEC (5), provides that various types of proof of the safety and efficacy of a proprietary medicinal product may be put forward in an application for marketing authorization depending upon the objective situation of the proprietary medicinal product in question;

Whereas experience has shown that it is advisable to stipulate more precisely the cases in which the results of pharmacological and toxicological tests or clinical trials do not have to be provided with a view to obtaining authorization for a proprietary medicinal product which is essentially similar to an authorized product, while ensuring that innovative firms are not placed at a disadvantage;

Whereas additional details were provided in respect of the application of the abovementioned provision by Council Directive 75/318/EEC of 20 May 1975 on the approximation of the laws of the Member States relating to analytical, pharmaco-toxicological and clinical standards and protocols in respect of the testing of proprietary medicinal products (6), as last amended by Directive 87/19/EEC (7);

Whereas, however, there are reasons of public policy for not conducting repetitive tests on humans or animals without over-riding cause;

Whereas it is also advisable to make the packaging of certain proprietary medicinal products, particularly sought after by drug addicts, less distinctive by removing the obligation to place a special mark on the outer packaging and the container of proprietary medicinal products classified as narcotics;

(1) OJ No C 293, 5. 11. 1984, p. 8.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No 22, 9. 2. 1965, p. 369/65.
(5) OJ No L 332, 28. 11. 1983, p. 1.
(6) OJ No L 147, 9. 6. 1975, p. 1.
(7) See page 31 of this Official Journal.

Whereas the Hellenic Republic, the Kingdom of Spain and the Portuguese Republic should have additional time to transpose this Directive so that they may as a priority complete the review of old proprietary medicinal products as provided for in Article 39 of the Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (8) as last amended by Directive 83/570/EEC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 65/65/EEC is hereby amended as follows:

1. Point 8 of the second paragraph of Article 4 shall be replaced by the following text:

'8. Results of:

— physico-chemical, biological or microbiological tests,
— pharmacological and toxicological tests,
— clinical trials.

However, and without prejudice to the law relating to the protection of industrial and commercial property:

(a) The applicant shall not be required to provide the results of pharmacological and toxicological tests or the results of clinical trials if he can demonstrate:

(i) either that the proprietary medicinal product is essentially similar to a product authorized in the country concerned by the application and that the person responsible for the marketing of the original proprietary medicinal product has consented to the pharmacological, toxicological or clinical references contained in the file on the original proprietary medicinal product being used for the purpose of examining the application in question;

(ii) or by detailed references to published scientific literature presented in accordance with the second paragraph of Article 1 of Directive 75/318/EEC that the constituent or constituents of the proprietary medicinal product have a well established medicinal use, with recognized efficacy and an acceptable level of safety;

(8) OJ No L 147, 9. 6. 1975, p. 13.

(iii) or that the proprietary medicinal product is essentially similar to a product which has been authorized within the Community, in accordance with Community provisions in force, for not less than six years and is marketed in the Member State for which the application is made; this period shall be extended to 10 years in the case of high-technology medicinal products within the meaning of Part A in the Annex to Directive 87/22/EEC (1) or of a medicinal product within the meaning of Part B in the Annex to that Directive for which the procedure laid down in Article 2 thereof has been followed; furthermore, a Member State may also extend this period to 10 years by a single Decision covering all the products marketed on its territory where it considers this necessary in the interest of public health. Member States are at liberty not to apply the abovementioned six-year period beyond the date of expiry of a patent protecting the original product.

However, where the proprietary medicinal product is intended for a different therapeutic use from that of the other proprietary medicinal products marketed or is to be administered by different routes or in different doses, the results of appropriate pharmacological and toxicological tests and/or of appropriate clinical trials must be provided.

(b) In the case of new proprietary medicinal products containing known constituents not hitherto used in combination for therapeutic purposes, the results of pharmacological and toxicological tests and of clinical trials relating to that combination must be provided, but it shall not be necessary to provide references relating to each individual constituent.

(1) OJ No L 15, 17. 1. 1987, p. 38.';

2. Article 16 is hereby repealed.

Article 2

Member States shall take the measures necessary to comply with this Directive no later than 1 July 1987. They shall forthwith inform the Commission thereof.

However, with regard to the Hellenic Republic, the Kingdom of Spain and the Portuguese Republic, the date referred to in the first paragraph shall be replaced by 1 January 1992.

Article 3

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1986.

For the Council

The President

G. SHAW

COUNCIL DIRECTIVE

of 22 December 1986

on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology

(87/22/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 100 thereof,

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

Having regard to the opinion of the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas the essential aim of any rules governing the production and distribution of medicinal products must be to safeguard public health ;

Whereas high-technology medicinal products requiring lengthy periods of costly research will continue to be developed in Europe only if they benefit from a favourable regulatory environment, particularly identical conditions governing their placing on the market throughout the Community ;

Whereas Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products (4), as last amended by Directive 83/570/EEC (5), makes provision for certain procedures for coordinating national decisions relating to the placing on the market of proprietary medicinal products for human use ; whereas pharmaceutical undertakings may, according to these provisions, request a Member State to take due account of an authorization already issued by another Member State ;

Whereas Council Directive 81/851/EEC of 28 September 1981 on the approximation of the laws of the Member States relating to veterinary medicinal products (6) makes provision for a procedure for coordinating national decisions relating to veterinary medicinal products ;

Whereas, however, these procedures are not sufficient to open up to high-technology medicinal products the large Community-wide single market they require ;

Whereas, in this technically advanced sector, the scientific expertise available to each of the national authorities is not always sufficient to resolve problems posed by high-technology medicinal products ;

Whereas it is consequently important to provide for a Community mechanism for concertation, prior to any national decision relating to a high-technology medicinal product, with a view to arriving at uniform decisions throughout the Community ;

Whereas it is desirable to extend this Community concertation to immunological products and substitutes for blood constituents developed by means of new biotechnological processes, and to new products based on radioisotopes, the development of which in Europe can only take place if a sufficiently large and homogeneous market exists ;

Whereas the need for the adoption of new technical rules applying to high-technology medicinal products or for the amendment of existing rules must be examined during a preliminary concertation between the Member States and the Commission within the competent Committees so as not to endanger the advance of pharmaceutical research whilst at the same time ensuring optimum protection of public health within the Community,

HAS ADOPTED THIS DIRECTIVE :

Article 1

Before taking a decision on a marketing authorization or on the withdrawal or, subject to Article 4 (2), suspension of a marketing authorization in respect of the medicinal products listed in the Annex, Member States' authorities shall, in accordance with Articles 2, 3 and 4, refer the matter for an opinion to the Committees referred to in Article 8 of Directive 75/319/EEC and Article 16 of Directive 81/851/EEC.

Article 2

1. As soon as they receive an application for marketing authorization relating to a medicinal product referred to in the Annex (Lists A and B), the competent authorities shall, at the request of the person responsible for placing the product on the market, bring the matter before either

(1) OJ No C 293, 5. 11. 1984, p. 1.
(2) OJ No C 36, 17. 2. 1986, p. 152.
(3) OJ No C 160, 1. 7. 1985, p. 18.
(4) OJ No L 147, 9. 6. 1975, p. 13.
(5) OJ No L 332, 28. 11. 1983, p. 1.
(6) OJ No L 317, 6. 11. 1981, p. 1.

the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, in accordance with their competence, for an opinion. Any such request shall be submitted in writing to the competent authorities concerned at the same time as the application for marketing authorization and a copy shall be sent to the Committee concerned.

2. As soon as they receive an application for marketing authorization relating to a medicinal product developed by means of new biotechnological processes and referred to in List A in the Annex, the competent authorities shall be required to bring the matter before the Committee for Proprietary Medicinal Products or the Committee for Veterinary Medicinal Products, in accordance with their competence, for an opinion.

3. Paragraph 2 shall not apply if, when submitting the application for marketing authorization, the applicant certifies to the competent authorities of the Member State concerned that :

(i) neither he nor any other natural or legal person with whom he is connected has, during the preceding five years, applied for authorization to place a product containing the same active principle(s) on the market of another Member State ; and

(ii) neither he nor any other natural or legal person with whom he is connected intends, within the five years following the date of the application, to seek authorization to place a product containing the same active principle(s) on the market of another Member State.

In this case, the competent authorities shall notify the appropriate Committee of the application and forward to it a summary of product characteristics as described in Article 4a of Directive 65/65/EEC (1), as last amended by Directive 87/21/EEC (2) or an equivalent document provided by the applicant if a proprietary medicinal product referred to in the second paragraph of Article 34 of Directive 75/319/EEC or a veterinary medicinal product is involved.

If, within five years of the first application, one or more subsequent applications for authorization to place a product containing the same active principle derived from the same route of synthesis on the market are made to the competent authorities of the other Member States by the person responsible for placing the original product on the market or with his consent, that person shall forthwith in form the competent authorities of the Member State to whom the first application was made and the matter shall be brought before the appropriate Committee for an opinion.

(1) OJ No 22, 9. 2. 1965, p. 369/65.
(2) See page 36 of this Official Journal.

4. Where the Committee has, in accordance with this Directive, issued a favourable opinion on the placing on the market of a high-technology medicinal product, the competent authorities shall refer the matter to the Committee for a new opinion before deciding on the withdrawal or, subject to Article 4 (2), suspension of the marketing authorization for the medicinal product in question.

5. The competent authorities or the Commission may also consult the Committee for Proprietary Medicinal Products on any technical question concerning the proprietary medicinal products referred to in the second paragraph of Article 34 of Directive 75/319/EEC.

6. The competent authorities or the Commission may also consult the Committee for Veterinary Medicinal Products on any technical question concerning the veterinary medicinal products referred to in the second and third indents of Article 2 (2) of Directive 81/851/EEC.

Article 3

1. The representative of the Member State which initiated the procedure referred to in Article 2 shall act as rapporteur and shall provide all information relevant to the evaluation of the medicinal product. Information thus disclosed shall strictly confidential.

2. The person responsible for placing the medicinal product in question on the market shall immediately be informed of the referral to the Committee. He may, at this own request, provide the Committee with oral or written explanations.

3. When placing the matter before the Committee, the Member State concerned shall ensure that the person responsible for placing the medicinal product on the market transmits to all the members of the Committee an identical summary of the dossier consisting of the summary of the product characteristics together with the reports of the analytical, pharmaco-toxicological and clinical experts.

In addition, a complete and updated copy of the dossier for the application for marketing authorization lodged with the Member State or Member States concerned shall be transmitted to the Committee by the person responsible for placing the product on the market, who shall certify that all the dossiers submitted to the competent authorities and to the Committee in respect of the medicinal product in question are identical.

4. All available evaluation reports and drug-monitoring reports relating to the same medicinal product shall be forwarded to the Committee by the authorities of the Member States and by the person responsible for placing the product in question on the market.

Article 4

1. When the questions referred to it relate to an application for marketing authorization, the Committee shall issue its opinion thirty days before the expiry of the time limits provided for in Article 7 of Directive 65/65/EEC and Article 4 (c) of Directive 75/319/EEC, or in Articles 8 and 9 (3) of Directive 81/851/EEC, as appropriate. To this end, the Member State which referred the matter shall inform the Committee without delay of any extension and of the beginning and end of any suspension of the time limits concerned.

2. When a proposal to suspend or withdraw a marketing authorization is referred to it, the Committee shall fix an appropriate time limit for issuing its reasoned opinion, having regard to the requirements for the protection of public health. However, in cases of urgency, the Member States may suspend the mrketing authorization in question without waiting for the opinion of the Committee provided that they forthwith inform the Committee thereof, indicating the reasons for the suspension and justifying the urgency of this measure.

3. The Committee shall forthwith notify its opinion and, where relevant, any dissenting opinions expressed therein, to the Member State concerned and the person responsible for placing the product on the market.

4. The Member State concerned shall reach a decision on the action it intends to take following the Committee's opinion not later than 30 days after receipt of the information provided for in paragraph 3. It shall forthwith inform the Committee of its decision.

Article 5

Subject to the application of other Community provisions, Member States shall communicate to the Commission in accordance with Articles 8 and 9 of Council Directive 83/189/EEC of 28 March 1983 laying down a procedure for the provision of information in the field of technical standards regulations [1], draft technical regulations relating to the production and marketing or proprietary medicinal products as defined in Article 1 of Directive 65/65/EEC.

Within one year of adoption of this Directive, the Commission will submit to the Council proposals for Regulations to harmonize, along the lines of Directive 75/319/EEC, the conditions for authorizing the manufacture and placing on the market of the proprietary medicinal products excluded by Article 34 of Directive 75/319/EEC and of the veterinary medicinal products referred to in Article 2 (2) of Directive 81/851/EEC, in view of in particular of the safety problems arising in production and use.

Article 6

Member States shall take the measures necessary to comply with this Directive not later than 1 July 1987. They shall forthwith inform the Commission thereof.

Article 7

This Directive is addressed to the Member States.

Done at Brussels, 22 December 1986.

For the Council

The President

G. SHAW

[1] OJ No L 109, 26. 4. 1983, p. 8.

ANNEX

LIST OF HIGH-TECHNOLOGY MEDICINAL PRODUCTS

A. **Medicinal products developed by means of the following biotechnological processes :**

— recombinant DNA technology,

— controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes, including transformed mammalian cells,

— hybridoma and monoclonal antibody methods.

B. **Other high-technology medicinal products**

— other biotechnological processes which, in the opinion of the competent authority concerned constitute a significant innovation,

— medicinal products administered by means of new delivery systems which, in the opinion of the competent authority concerned, constitute a significant innovation,

— medicinal products containing a new substance or an entirely new indication which, in the opinion of the competent authority concerned, is of significant therapeutic interest,

— new medicinal products based on radio-isotopes which, in the opinion of the competent authority concerned, are of significant therapeutic interest,

— medicinal products the manufacture of which employs processes which, in the opinion of the competent authority concerned, demonstrate a significant technical advance such as two-dimensional electrophoresis under micro-gravity.

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YEAR 1985

Brussels — Luxembourg / April 1986

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