

Official Journal

of the European Communities

ISSN 0378-6978

L 153

Volume 41

27 May 1998

English edition

Legislation

Contents

I *Acts whose publication is obligatory*

- Commission Regulation (EC) No 1064/98 of 26 May 1998 establishing the standard import values for determining the entry price of certain fruit and vegetables 1
- ★ **Commission Regulation (EC) No 1065/98 of 26 May 1998 repealing certain regulations concerning beef** 3
- ★ **Commission Regulation (EC) No 1066/98 of 26 May 1998 amending Regulation (EEC) No 1913/92 laying down detailed implementing rules for the specific measures for supplying the Azores and Madeira with products from the beef and veal sector** 5
- ★ **Commission Regulation (EC) No 1067/98 of 26 May 1998 amending Regulation (EC) No 1248/97 establishing the forecast supply balance of the Canary Islands for products of the processed fruit and vegetable sector** 7
- ★ **Commission Regulation (EC) No 1068/98 of 26 May 1998 fixing the intervention thresholds for cauliflowers, peaches, nectarines, lemons and table grapes for the 1998/99 marketing year** 9
- ★ **Commission Regulation (EC) No 1069/98 of 26 May 1998 amending Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93** 11
- Commission Regulation (EC) No 1070/98 of 26 May 1998 amending Regulation (EC) No 2645/97 increasing to 171 019 tonnes the quantity of maize held by the Austrian intervention agency for which a standing invitation to tender for export has been opened 15

Commission

98/343/ECSC, Euratom:

- ★ **Commission Decision of 30 April 1998 concerning the conclusion on behalf of the European Coal and Steel Community and the European Atomic Energy Community of the Interim Agreement between the European Community, the European Coal and Steel Community and the European Atomic Energy Community, of the one part and the Republic of Uzbekistan of the other part on trade and trade-related matters 17**
-

Corrigenda

- ★ **Corrigendum to Commission Regulation (EC) No 2301/97 of 20 November 1997 on the entry of certain names in the 'Register of certificates of specific character' provided for in Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs (OJ L 319 of 21. 11. 1997) 18**
-

Notice to readers (see page 3 of the cover)

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1064/98
of 26 May 1998
establishing the standard import values for determining the entry price of certain
fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Commission Regulation (EC) No 3223/94 of 21 December 1994 on detailed rules for the application of the import arrangements for fruit and vegetables ⁽¹⁾, as last amended by Regulation (EC) No 2375/96 ⁽²⁾, and in particular Article 4 (1) thereof,

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

Whereas Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commis-

sion fixes the standard values for imports from third countries, in respect of the products and periods stipulated in the Annex thereto;

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 27 May 1998.

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

Done at Brussels, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 337, 24. 12. 1994, p. 66.

⁽²⁾ OJ L 325, 14. 12. 1996, p. 5.

⁽³⁾ OJ L 387, 31. 12. 1992, p. 1.

⁽⁴⁾ OJ L 22, 31. 1. 1995, p. 1.

ANNEX

to the Commission Regulation of 26 May 1998 establishing the standard import values for determining the entry price of certain fruit and vegetables

(ECU/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	204	43,7
	999	43,7
0707 00 05	052	83,7
	068	81,9
	999	82,8
0709 90 70	052	75,8
	999	75,8
0805 10 10, 0805 10 30, 0805 10 50	052	63,3
	204	39,5
	212	60,1
	388	64,5
	528	53,1
	600	69,3
	624	49,4
	999	57,0
0805 30 10	382	56,5
	388	64,1
	999	60,3
0808 10 20, 0808 10 50, 0808 10 90	060	23,4
	388	79,4
	400	96,5
	404	94,0
	508	107,8
	512	68,5
	524	90,6
	528	68,9
	804	103,7
	999	81,4

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

COMMISSION REGULATION (EC) No 1065/98
of 26 May 1998
repealing certain regulations concerning beef

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 805/68 of 27 June 1968 on the common organisation of the market in beef and veal ⁽¹⁾, as last amended by Regulation (EEC) No 2634/97 ⁽²⁾, and in particular Articles 6(7), 7(3) and 13(12) thereof,

Whereas a good many legislative instruments in the beef sector have become devoid of purpose as a result mainly of amendments to the basic legislation, the performance of the regulated acts for which the instruments were introduced, the adoption of new international agreements between the Community and its trading partners, and major changes which have taken place on the market; whereas, for reasons of clarity and legal certainty and for the sake of simplification, the legislative instruments in question should be formally repealed;

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 regulations set out in the Annex hereto are repealed.

Article 2

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

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

Done at Brussels, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 148, 28. 6. 1968, p. 24.

⁽²⁾ OJ L 356, 31. 12. 1997, p. 13.

ANNEX

- Commission Regulation (EEC) No 1256/77 of 13 June 1977 on the sale by periodic tendering procedure of canned beef held by the intervention agencies (OJ L 146, 14.6.1977, p. 23).
 - Commission Regulation (EEC) No 732/78 of 11 April 1978 on detailed rules for the sale to the armed forces of Member States of beef held by the intervention agencies and amending Regulation (EEC) No 1687/76 (OJ L 99, 12.4.1978, p. 14), as amended by Regulation (EEC) No 1809/87 (OJ L 170, 30.6.1987, p. 23).
 - Commission Regulation (EEC) No 988/80 of 23 April 1980 on the application of the lowest rate of the export refund on certain beef and veal products (OJ L 106, 24.4.1980, p. 27), as amended by Regulation (EEC) No 3988/87 (OJ L 376, 31.12.1987, p. 31).
 - Commission Regulation (EEC) No 985/81 of 9 April 1981 laying down detailed rules on the sale of frozen beef and veal for export from intervention stocks and amending Regulation (EEC) No 1687/76 (OJ L 99, 10.4.1981, p. 38), as last amended by Regulation (EC) No 2417/95 (OJ L 248, 14.10.1995, p. 39).
 - Commission Regulation (EEC) No 287/89 of 3 February 1989 suspending Regulation (EEC) No 732/78 on detailed rules for the sale to the armed forces of Member States of beef held by the intervention agencies (OJ L 33, 4.2.1989, p. 22).
 - Commission Regulation (EC) No 443/96 of 11 March 1996 on the sale by the procedure laid down in Regulation (EEC) No 2539/84 of beef held by certain intervention agencies and intended for processing within the Community and repealing Regulation (EC) No 1181/95 (OJ L 61, 12.3.1996, p. 16), as amended by Regulation (EC) No 608/96 (OJ L 86, 4.4.1996, p. 30).
 - Commission Regulation (EC) No 1124/96 of 21 June 1996 opening intervention in accordance with Article 6(4) of Council Regulation (EEC) No 805/68 (OJ L 149, 22.6.1996, p. 23), as amended by Regulation (EC) No 1401/96 (OJ L 180, 19. 7. 1996, p. 14).
 - Commission Regulation (EC) No 1680/96 of 26 August 1996 opening intervention in accordance with Article 6(4) of Council Regulation (EEC) No 805/68 (OJ L 216, 27.8.1996, p. 1).
 - Commission Regulation (EC) No 1825/96 of 20 September 1996 opening intervention in accordance with Article 6(4) of Council Regulation (EEC) No 805/68 (OJ L 241, 21.9.1996, p. 18).
 - Commission Regulation (EC) No 1922/96 of 4 October 1996 opening intervention in accordance with Article 6(4) of Council Regulation (EEC) No 805/68 (OJ L 253, 5.10.1996, p. 4).
 - Commission Regulation (EC) No 2002/96 of 18 October 1996 opening intervention in accordance with Article 6(4) of Council Regulation (EEC) No 805/68 (OJ L 267, 19.10.1996, p. 10).
-

COMMISSION REGULATION (EC) No 1066/98**of 26 May 1998****amending Regulation (EEC) No 1913/92 laying down detailed implementing rules for the specific measures for supplying the Azores and Madeira with products from the beef and veal sector**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1600/92 of 15 June 1992 introducing specific measures for the Azores and Madeira concerning agricultural products⁽¹⁾, as last amended by Commission Regulation (EC) No 562/98⁽²⁾, and in particular Article 10 thereof,

Whereas the forecast supply balance for fresh and chilled beef and veal for Madeira was fixed by Commission Regulation (EEC) No 1913/92⁽³⁾, as last amended by Regulation (EC) No 2518/97⁽⁴⁾; whereas 75 % of the quantities laid down were used during the first eight months of the period 1 July 1997 to 30 June 1998;

Whereas to ensure supplies to the Madeiran market up until the end of the said period, the quantities originally laid down for fresh meat should be increased by reducing those laid down for frozen meat;

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

Annex I to Regulation (EEC) No 1913/92 is hereby replaced by the Annex hereto.

Article 2

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

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

Done at Brussels, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 173, 27. 6. 1992, p. 1.

⁽²⁾ OJ L 76, 13. 3. 1998, p. 6.

⁽³⁾ OJ L 192, 11. 7. 1992, p. 35.

⁽⁴⁾ OJ L 346, 17. 12. 1997, p. 21.

*ANNEX**ANNEX I*

Madeira: Forecast supply balance for beef and veal sector products for the period 1 July 1997 to 30 June 1998

(tonnes)

CN code	Descripción of goods	Quantity
0201	Meat of bovine animals, fresh or chilled	4 000
0202	Meat of bovine animals, frozen	2 000'

COMMISSION REGULATION (EC) No 1067/98
of 26 May 1998
amending Regulation (EC) No 1248/97 establishing the forecast supply balance of
the Canary Islands for products of the processed fruit and vegetable sector

THE COMMISSION OF THE EUROPEAN COMMUNITIES,
Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1601/92 of 15 June 1992 concerning specific measures for the Canary Islands with regard to certain agricultural products ⁽¹⁾, as last amended by Commission Regulation (EC) No 2348/96 ⁽²⁾, and in particular Article 3(4) thereof,

Whereas Commission Regulation (EC) No 1248/97 ⁽³⁾ establishes the forecast supply balance for processed fruit and vegetables for the Canary Islands for the period 1 July 1997 to 30 June 1998; whereas that balance can be revised; whereas the quantities fixed for certain products are in the process of being completely exhausted; whereas it therefore appears necessary to increase the quantities of certain products for the current marketing year, on the basis of the updated requirements of the Canary Islands;

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

The Annex to Regulation (EC) No 1248/97 is hereby replaced by the Annex hereto.

Article 2

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

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

Done at Brussels, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 173, 27. 6. 1992, p. 13.

⁽²⁾ OJ L 320, 11. 12. 1996, p. 1.

⁽³⁾ OJ L 173, 1. 7. 1997, p. 88.

ANNEX

Establishing the forecast supply balance of the Canary Islands for products of the processed fruit and vegetable sector for the period 1 July 1997 to 30 June 1998

<i>(tonnes)</i>		
CN code	Description	Quantity
<i>Part I</i>		
2007 99	Preparations other than homogenised, containing fruit other than citrus fruit	6 050 ⁽¹⁾
<i>Part II</i>		
2008	Fruit, nuts and other edible parts of plants, otherwise prepared or preserved, whether or not containing added sugar or sweetening matter or spirit, not elsewhere specified or included:	
2008 20	— pineapples	3 200
2008 30	— citrus fruit	500
2008 40	— pears	2 900 ⁽²⁾
2008 50	— apricots	370
2008 70	— peaches	7 600
2008 80	— strawberries	1 000 ⁽³⁾
	— other, including mixtures other than those of subheading No 2008 19:	
2008 92	— — mixtures	2 450 ⁽⁴⁾
2008 99	— — other than palm hearts and mixtures	650
Total		18 670

⁽¹⁾ Of which 1 133 tonnes for the processing and/or packaging sector.

⁽²⁾ Of which 2 050 tonnes for the processing and/or packaging sector.

⁽³⁾ Of which 790 tonnes for the processing and/or packaging sector.

⁽⁴⁾ Of which 680 tonnes for the processing and/or packaging sector.

COMMISSION REGULATION (EC) No 1068/98

of 26 May 1998

fixing the intervention thresholds for cauliflowers, peaches, nectarines, lemons
and table grapes for the 1998/99 marketing year

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS REGULATION:

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 2200/96 of 28 October 1996 on the common organisation of the market in fruit and vegetables ⁽¹⁾ as amended by Commission Regulation (EC) No 2520/97 ⁽²⁾, and in particular Article 27(1) and (2) thereof,

Whereas the first paragraph of Article 27 of Regulation (EC) No 2200/96 provides for an intervention threshold to be fixed if the market in a product listed in Annex II is suffering or at risk of suffering from widespread structural imbalances giving or liable to give rise to too large a volume of withdrawals; whereas such a development might cause budget problems for the Community;

Whereas the conditions laid down in the abovementioned Article 27 have been met for certain products; whereas intervention thresholds for cauliflowers, peaches, nectarines, table grapes and lemons should therefore be fixed;

Whereas this intervention threshold for each of those products should be fixed on the basis of a percentage of the average production intended for consumption in the natural state over the last five marketing years for which data are available; whereas the period to be taken into account for assessing the overrun of the intervention threshold must also be established for each product in question;

Whereas pursuant to the abovementioned Article 27, an overrun of the intervention threshold gives rise to reduction in the Community withdrawal compensation in the marketing year following the overrun; whereas the implications of this overrun for each of the products in question should be determined and a reduction proportional to the size of the overrun should be fixed, up to a certain percentage;

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

⁽¹⁾ OJ L 297, 21. 11. 1996, p. 1.

⁽²⁾ OJ L 346, 17. 12. 1997, p. 41.

Article 1

The following intervention thresholds are fixed for the 1998/99 marketing year:

— cauliflowers:	111 300 tonnes,
— peaches:	260 800 tonnes,
— nectarines:	81 600 tonnes,
— table grapes:	158 700 tonnes,
— lemons:	58 500 tonnes.

Article 2

The overrun of the intervention threshold for the above products shall be assessed on the basis of the withdrawals carried out in the following periods:

- for cauliflowers:
between 1 March 1998 and 28 February 1999,
- for peaches and nectarines:
between 1 March 1998 and 28 February 1999,
- for table grapes:
between 1 March 1998 and 28 February 1999,
- for lemons:
between 1 April 1998 and 31 March 1999.

Article 3

If the quantity subject to withdrawals of one of the products listed in Article 1 in the period laid down in Article 2 exceeds the threshold fixed in Article 1, the Community withdrawal compensation fixed pursuant to Article 26 of Regulation (EC) No 2200/96 shall be reduced in the following marketing year in proportion to the size of the overrun based on the production used to calculate the threshold in question.

The Community withdrawal compensation shall not, however, be reduced by more than 30 %.

Article 4

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, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 1069/98

of 26 May 1998

amending Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products⁽¹⁾, as amended by Commission Regulation (EC) No 649/98⁽²⁾, and in particular Articles 15(4) and 37(4) thereof,

Whereas following practical experience in the application of Commission Regulation (EC) No 542/95 of 10 March 1995 concerning the examination of variations to the terms of a marketing authorisation falling within the scope of Council Regulation (EEC) No 2309/93⁽³⁾, appropriate adaptations should be adopted to the terms of this Regulation;

Whereas, it is appropriate to provide for a procedure to be followed in the case that the Commission imposes urgent safety restrictions;

Whereas, moreover, it is necessary to introduce some changes to the Annexes to this Regulation;

Whereas, the measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use and the Standing Committee on Veterinary Medicinal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 542/95 is hereby amended as follows:

1. the following paragraph 3 is added to Article 1:

‘3. Where the Commission imposes provisional urgent safety restrictions on the marketing authorisa-

tion holder, the marketing authorisation holder shall be obliged to submit an application for a variation taking account of the safety restrictions imposed by the Commission. This application shall be submitted without delay to the Agency for the application of the procedures set out in Articles 6 and 7 of this Regulation. This paragraph is without prejudice to Article 18 of Regulation (EEC) No 2309/93.’;

2. paragraphs 1 and 2 of Article 8 are replaced by the following:

‘1. Where the competent Committee delivers an opinion, the Agency shall inform the marketing authorisation holder and the Commission forthwith and shall send to the Commission the amendments to be made to the terms of the marketing authorisation accompanied by the documents set out in Article 9(3) and 31(3) of Regulation (EEC) No 2309/93.

2. Article 9(1) and (2) or Article 31(1) and (2) of Regulation (EEC) No 2309/93 shall apply to the opinion adopted by the competent Committee.’;

3. in Annex I, point A is replaced by the following:

‘A. By derogation, the procedure set out in Articles 6, 7 and 8 of the present Regulation shall apply:

— to the minor variations Nos 11, 12, 13, 15 and 16 as referred to below and to minor variations Nos 24 and 25 if the test procedure used is not a physico-chemical method for medicinal products falling within the scope of Council Directive 89/342/EEC^(*), or 89/381/EEC^(**), or 90/667/EEC^(***), or for medicinal products which had been considered as arising under Part A of the Annex to Regulation (EEC) No 2309/93,

— to any minor variation when a specific inspection of a manufacturing site needs to be carried out.

⁽¹⁾ OJ L 214, 24. 8. 1993, p. 1.

⁽²⁾ OJ L 88, 24. 3. 1998, p. 7.

⁽³⁾ OJ L 55, 11. 3. 1995, p. 15.

^(*) OJ L 142, 25.5.1989, p. 14.

^(**) OJ L 181, 28.6.1989, p. 44.

^(***) OJ L 373, 31.12.1990, p. 26.’;

4. in Annex I, variation No 1 is replaced by the following:

'1. — *Change following modifications(s) of the manufacturing authorization(s)*

General condition: the modified manufacturing authorization must be submitted to the competent authority.

— *Change in the name of a manufacturer of the medicinal product*

Condition to be fulfilled: the manufacturing site shall remain the same.

— *Change of the manufacturing site(s) for part or all of the manufacturing process of the medicinal product*

Condition to be fulfilled: no change either in the manufacturing process or in the specifications, including test methods.

— *Withdrawal of the manufacturing authorization for a site of manufacture;*

5. in Annex I, variation No 5 is replaced by the following:

'5. *Change in the colouring system of the product (addition, deletion or replacement of colorant(s))*

Condition to be fulfilled: same functional characteristics, no change in dissolution profile for solid dosage forms. Any minor adjustment to the formulation to maintain the total weight should be made by an excipient which currently makes up a major part of the formulation.;

6. in Annex I, variation No 6 is replaced by the following:

'6. *Change in the flavouring system of the product (addition, deletion or replacement of flavour(s))*

Condition to be fulfilled: proposed flavour must be in accordance with Council Directive 88/388/EEC (*). Any minor adjustment to the formulation to maintain the total weight should be made by an excipient which currently makes up a major part of the formulation.

(*) OJ L 184, 15.7.1988, p. 61.;

7. in Annex I, after variation No 10, the following variation is added:

'10a. *Addition or replacement of measuring device for oral liquid dosage forms and other dosage forms*

Condition to be fulfilled: the size and, where applicable, the accuracy of the proposed measuring device must be compatible with approved posology.;

8. in Annex I, after variation No 11, the following variations are added:

'11a. *Change in the name of a manufacturer of the active substance*

Condition to be fulfilled: the manufacturer of the active substance shall remain the same.

11b. *Change in supplier of an intermediate compound used in the manufacture of the active substance*

Condition to be fulfilled: the specifications, synthetic route and quality control procedures are the same as those already approved.;

9. in Annex I, after variation No 12 the following text is added:

'Alternative condition: "... or a certificate of suitability from the European *Pharmacopeia* is provided."

12a. *Change in specification of starting material or intermediate used in the manufacture of the active substance*

Condition to be fulfilled: specification must be tightened or addition of new test and limits.;

10. in Annex I, after variation No 15 the following variation is added:

'15a. *Change in in-process controls applied during the manufacture of the product*

Condition to be fulfilled: specification must be tightened or addition of new test and limits.;

11. in Annex I, after variation No 20 the following variation is added:

'20a. *Extension of the shelf life or retest period of the active substance*

Condition to be fulfilled: stability studies have been done to the protocol which was approved at the time of the issue of the marketing authorisation; the studies must show that the agreed end of shelf life specifications are still met.;

12. in Annex I, after variation No 24, the following variation is added:

'24a. *Change in test procedure for a starting material or intermediate used in the manufacture of the active substance*

Condition to be fulfilled: results of method validation show new test procedure to be at least equivalent to the former procedure. Specification not adversely affected.;

13. in Annex I, the footnote to variation No 26 is amended as follows:

'In cases where the marketing authorisation holder refers to the current edition of the pharmacopeia, no variation application is required provided the change is introduced within six months of adoption of the revised monograph.;

14. in Annex I, the heading of variation No 30 is replaced by the following:

'30. *Change in pack size for a medicinal product*'

A supplementary condition is added: 'The packaging material remains the same.;

15. in Annex I, a new condition is added to variation No 31:

'The change does not concern a fundamental component of the packaging material which affects the delivery or use of the product.;

16. in Annex I, the heading of variation No 32 is replaced by the following:

'32. *Change of imprints, bossing or other markings (except scoring) on tablets or printing on capsules, including addition or change of inks used for product marking*

17. in Annex I, after variation No 33, the following variation is added:

'34. — *Change in the manufacturing process of a non-proteinaceous component due to a subsequent introduction of a biotechnology step*

General remarks:

— This specific variation is provided to supplement the variations already existing which can be applied in this particular

context, notably the variations Nos 4, 11, 12, 18, 19 and 26.

— Community legislation applicable to specific groups of products (*) has to be complied with.

— The medicinal products containing proteinaceous component obtained through a biotechnology process fall under the scope of Part A of Regulation (EEC) No 2309/93.

— *Change in the manufacturing process for components compliant with a European Pharmacopoeia monograph and verified by means of a certificate of suitability from the European Pharmacopoeia*

Conditions to be fulfilled: the specifications and physico-chemical properties and all characteristics of the component remain the same.

— *Change in the manufacturing process for components requesting a new impurities test procedure*

Conditions to be fulfilled: the specifications and physico-chemical properties and all characteristics of the component remain the same. The manufacturing method is liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities must be declared and a suitable test procedure must be described. This supplementary test must be specified in a certificate of suitability from the European Pharmacopoeia.

(*) Food and food ingredients compliant with Regulation (EC) No 258/97 of the European Parliament and of the Council (OJ L 43 14.2.1997, p. 1). Colours for use in foodstuffs within the scope of European Parliament and Council Directive 94/36/EEC (OJ L 237, 10.9.1994, p. 13), food additives of Directive 88/388/EEC, extraction solvents within the meaning of Council Directive 88/344/EEC (OJ L 157, 24.6.1988, p. 28), as last amended by Directive 92/115/EEC (OJ L 409, 31.12.1992, p. 31) and foods or food ingredients derived from biotechnology step which has been introduced in the manufacture/production shall not require to be notified as a variation to the terms of the marketing authorisation.;

18. in Annex II, after the heading, the first paragraph and the following subparagraph are replaced as follows:

‘Certain changes to a marketing authorisation have to be considered to fundamentally alter the terms of this authorisation and therefore cannot be considered as a variation in the meaning of Article 15 paragraph 4 of Regulation (EEC) No 2309/93 and cannot be granted following a variation procedure. For these changes, listed below, any new application has to be considered within a complete scientific evaluation procedure (as for the granting of a marketing authorisation). As the case may be, an authorisation of a modification of the existing marketing authorisation will have to be granted by the Community.

This Annex is without prejudice to the provisions of Article 4 of Directive 65/65/EEC and Article 5 of Directive 81/851/EEC.’;

19. in Annex II, variation No 4, paragraph (ii) is replaced by the following:

‘(ii) shortening of the withdrawal period of a veterinary medicinal product if the change is not linked to the establishment or a modification of a maximum residue limit in accordance with Council Regulation (EEC) No 2377/90 (*).

(*) OJ L 224, 18.8.1990, p. 1.’

Article 2

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

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

Done at Brussels, 26 May 1998.

For the Commission

Martin BANGEMANN

Member of the Commission

**COMMISSION REGULATION (EC) No 1070/98
of 26 May 1998**

**amending Regulation (EC) No 2645/97 increasing to 171 019 tonnes the quantity
of maize held by the Austrian intervention agency for which a standing
invitation to tender for export has been opened**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 1766/92 of 30 June 1992 on the common organisation of the market in cereals⁽¹⁾, as last amended by Commission Regulation (EC) No 923/96⁽²⁾, and in particular Article 5 thereof,

Whereas Commission Regulation (EEC) No 2131/93⁽³⁾, as last amended by Regulation (EC) No 2193/96⁽⁴⁾, lays down the procedures and conditions for the disposal of cereals held by the intervention agencies;

Whereas Commission Regulation (EC) No 2645/97⁽⁵⁾, as last amended by Regulation (EC) No 670/98⁽⁶⁾, opened a standing invitation to tender for the export of 150 993 tonnes of maize held by the Austrian intervention agency to be exported to all third countries; whereas Austria informed the Commission of the intention of its intervention agency to increase by 20 026 tonnes the quantity for which a standing invitation to tender for export has been opened; whereas the total quantity of maize held by the Austrian intervention agency for which a standing invitation to tender for export has been opened should be increased to 171 019 tonnes;

Whereas the last partial invitation to tender pursuant to Regulation (EC) No 2645/97 should be postponed;

Whereas this increase in the quantity put out to tender makes it necessary to alter the list of regions and quantities in store;

whereas Annex I to Regulation (EC) No 2645/97 must therefore 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

Regulation (EC) No 2645/97 is hereby amended as follows:

1. Article 2 is replaced by the following:

'Article 2

1. The invitation to tender shall cover a maximum of 171 019 tonnes of maize to be exported to all third countries.

2. The regions in which the 171 019 tonnes of maize are stored are stated in Annex I to this Regulation.';

2. Article 5(3) is replaced by the following:

'3. The last partial invitation to tender shall expire on 30 July 1998 at 9 a.m. (Brussels time).';

3. Annex I is replaced by the Annex hereto.

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, 26 May 1998.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 181, 1. 7. 1992, p. 21.

⁽²⁾ OJ L 126, 24. 5. 1996, p. 37.

⁽³⁾ OJ L 191, 31. 7. 1993, p. 76.

⁽⁴⁾ OJ L 293, 16. 11. 1996, p. 1.

⁽⁵⁾ OJ L 356, 31. 12. 1997, p. 36.

⁽⁶⁾ OJ L 93, 26. 3. 1998, p. 18.

*ANNEX**ANNEX I*

<i>(tonnes)</i>	
Place of storage	Quantity
Niederösterreich/nördliches Burgenland	70 500
Steiermark/südliches Burgenland	52 380
Kärnten	10 772
Oberösterreich	37 367

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 30 April 1998

concerning the conclusion on behalf of the European Coal and Steel Community and the European Atomic Energy Community of the Interim Agreement between the European Community, the European Coal and Steel Community and the European Atomic Energy Community, of the one part and the Republic of Uzbekistan of the other part on trade and trade-related matters

(98/343/ECSC, Euratom)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS DECIDED AS FOLLOWS:

Having regard to the Treaty establishing the European Coal and Steel Community, and in particular the first paragraph of Article 95 thereof,

Having regard to the Treaty establishing the European Atomic Energy Community, and in particular the second paragraph of Article 101 thereof,

Whereas pending the entry into force of the Partnership and Cooperation Agreement signed in Brussels on 21 June 1996, it is necessary to approve the Interim Agreement signed in Brussels on 14 November 1996 between the European Community, the European Coal and Steel Community and the European Atomic Energy Community, of the one part, and the Republic of Uzbekistan of the other part, on trade and related matters;

Whereas the conclusion of the Interim Agreement is necessary to attain the objectives of the Community set out in Articles 2 and 3 of the Treaty establishing the European Coal and Steel Community and whereas the Treaty did not make provision for all the cases covered by the Decision;

Having consulted the Consultative Committee and with the assent and approval of the Council, given on 26 January 1998,

Article 1

The Interim Agreement between the European Community, the European Coal and Steel Community and the European Atomic Energy Community, of the one part, and the Republic of Uzbekistan, of the other part, on trade and trade-related matters, together with the Protocol and the declarations hereby approved on behalf of the European Coal and Steel Community and the European Atomic Energy Community.

These texts are attached to this Decision (⁽¹⁾).

Article 2

The President of the Commission shall give the notification provided for in the Article 32 of the Interim Agreement on behalf of the European Coal and Steel Community and the European Atomic Energy Community.

Done at Brussels, 30 April 1998.

For the Commission

Hans VAN DEN BROEK

Member of the Commission

(¹) OJ L 43, 14. 2. 1998, pp. 2 and 12.

CORRIGENDA

Corrigendum to Commission Regulation (EC) No 2301/97 of 20 November 1997 on the entry of certain names in the 'Register of certificates of specific character' provided for in Council Regulation (EEC) No 2082/92 on certificates of specific character for agricultural products and foodstuffs

(Official Journal of the European Communities L 319 of 21 November 1997)

On page 9, the Annex reads as follows:

'ANNEX

- Vieille Kriek, Vieille Kriek-Lambic, Vieille Framboise-Lambic, Vieux fruit-Lambic/Oude Kriek, Oude Kriekenlambiek, Oude Frambozenlambiek, Oude Fruit-lambiek (Article 13(1) of Regulation (EEC) No 2082/92) ⁽¹⁾,
- Vieille Gueuze, Vieille Gueuze-Lambic, Vieux Lambic/Oude Geuze, Oude Geuze-Lambiek, Oude Lambiek (Article 13(1) of Regulation (EEC) No 2082/92) ⁽¹⁾,
- Faro (Article 13(1) of Regulation (EEC) No 2082/92) ⁽¹⁾.

⁽¹⁾ The main aspects of the terms and conditions are published in *Official Journal of the European Communities*, C 21 of 21 January 1997, pages 5 to 16.'

NOTICE TO READERS

Legal acts whose publication is not obligatory are not given an official number forming an integral part of their title but, if published in the Official Journal, are allocated a publication number by the Office for Official Publications.

Since such acts are often notified or transmitted to the addressees bearing the number of the procedure under which they were adopted (number C(1998) . . .), it has been decided to establish a link between the publication numbers.

Accordingly, from 1 June the procedure numbers will be inserted after the title of the relevant acts of the Commission.