

Official Journal

of the European Union

ISSN 1725-2555

L 262

Volume 46

14 October 2003

English edition

Legislation

Contents

I	<i>Acts whose publication is obligatory</i>	
	Commission Regulation (EC) No 1790/2003 of 13 October 2003 establishing the standard import values for determining the entry price of certain fruit and vegetables	1
	Commission Regulation (EC) No 1791/2003 of 13 October 2003 on the supply of cereals as food aid	3
	Commission Regulation (EC) No 1792/2003 of 13 October 2003 on the supply of vegetable oil as food aid	7
★	Commission Regulation (EC) No 1793/2003 of 13 October 2003 fixing the minimum natural alcoholic strength by volume of 'Vinho verde' quality wines psr originating in Portuguese wine-growing zone C I a) for the 2003/2004 and 2004/2005 wine years	10
★	Commission Regulation (EC) No 1794/2003 of 13 October 2003 fixing the estimated production of olive oil and the unit amount of the production aid that may be paid in advance for the 2002/03 marketing year	11
★	Commission Regulation (EC) No 1795/2003 of 13 October 2003 amending Annex VI to Council Regulation (EC) No 1493/1999 as regards quality wines produced in specified regions	13
	Commission Regulation (EC) No 1796/2003 of 13 October 2003 fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip	14
	Commission Regulation (EC) No 1797/2003 of 13 October 2003 determining the world market price for unginned cotton	16
★	Directive 2003/74/EC of the European Parliament and of the Council of 22 September 2003 amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists	17

★ Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use ⁽¹⁾	22
--	----

II Acts whose publication is not obligatory

Commission

2003/726/EC:

★ Commission Decision of 30 September 2003 concerning the validity of certain binding tariff information (notified under document number C(2003) 3516)	27
---	----

2003/727/EC:

★ Commission Decision of 30 September 2003 concerning the validity of certain binding tariff information (notified under document number C(2003) 3544)	29
---	----

2003/728/EC:

★ Commission Decision of 3 October 2003 on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rock-fall protection kits ⁽¹⁾ (notified under document number C(2003) 3452)	34
---	----

2003/729/EC:

★ Commission Decision of 6 October 2003 amending Decision 2002/300/EC establishing the list of approved zones with regard to <i>Bonamia ostreae</i> and/or <i>Marteilia refringens</i> ⁽¹⁾ (notified under document number C(2003) 3463)	37
--	----

I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 1790/2003
of 13 October 2003
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 1947/2002 ⁽²⁾, and in particular Article 4(1) thereof,

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 14 October 2003.

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

Done at Brussels, 13 October 2003.

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

⁽¹⁾ OJ L 337, 24.12.1994, p. 66.

⁽²⁾ OJ L 299, 1.11.2002, p. 17.

ANNEX

to the Commission Regulation of 13 October 2003 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)		
CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	97,8
	060	93,4
	064	110,4
	068	67,7
	096	60,8
	204	146,9
	999	96,2
0707 00 05	052	97,2
	999	97,2
0709 90 70	052	103,3
	999	103,3
0805 50 10	052	78,6
	388	60,7
	524	65,6
	528	55,0
	999	65,0
0806 10 10	052	103,8
	508	301,7
	999	202,8
0808 10 20, 0808 10 50, 0808 10 90	060	38,7
	388	72,5
	400	51,7
	508	108,4
	512	36,1
	720	48,9
	800	184,7
	804	105,8
	999	80,8
0808 20 50	052	105,4
	064	48,7
	388	170,0
	720	85,2
	999	102,3

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 2020/2001 (OJ L 273, 16.10.2001, p. 6). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 1791/2003
of 13 October 2003
on the supply of cereals as food aid

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security ⁽¹⁾, as modified by Regulation (EC) No 1726/2001 of the European Parliament and of the Council ⁽²⁾, and in particular Article 24(1)(b) thereof,

Whereas:

- (1) The abovementioned Regulation lays down the list of countries and organisations eligible for Community aid and specifies the general criteria on the transport of food aid beyond the fob stage.
- (2) Following the taking of a number of decisions on the allocation of food aid, the Commission has allocated cereals to certain beneficiaries.
- (3) It is necessary to make these supplies in accordance with the rules laid down by Commission Regulation (EC) No 2519/97 of 16 December 1997 laying down general rules for the mobilisation of products to be supplied

under Council Regulation (EC) No 1292/96 as Community food aid ⁽³⁾. It is necessary to specify the time limits and conditions of supply to determine the resultant costs,

HAS ADOPTED THIS REGULATION:

Article 1

Cereals shall be mobilised in the Community, as Community food aid for supply to the recipient listed in the Annex, in accordance with Regulation (EC) No 2519/97 and under the conditions set out in the Annex.

The tenderer is deemed to have noted and accepted all the general and specific conditions applicable. Any other condition or reservation included in his tender is deemed unwritten.

Article 2

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

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

Done at Brussels, 13 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 166, 5.7.1996, p. 1.

⁽²⁾ OJ L 234, 1.9.2001, p. 10.

⁽³⁾ OJ L 346, 17.12.1997, p. 23.

ANNEX

LOT A

1. **Action No:** 10/03
2. **Beneficiary** ⁽²⁾: EuronAid, PO Box 12, 2501 CA Den Haag, Nederland; tel.: (31-70) 330 57 57; fax: 364 17 01; telex 30960 EURON NL
3. **Beneficiary's representative:** to be designated by the beneficiary
4. **Country of destination:** Haiti
5. **Product to be mobilised:** common wheat flour
6. **Total quantity (tonnes net):** 220
7. **Number of lots:** 1
8. **Characteristics and quality of the product** ⁽³⁾ ⁽⁵⁾: see OJ C 312, 31.10.2000, p. 1 (A.10)
9. **Packaging** ⁽⁷⁾ ⁽⁸⁾: see OJ C 267, 13.9.1996, p. 1 (2.2 A 1.d, 2.d and B.4)
10. **Labelling or marking** ⁽⁶⁾: see OJ C 114, 29.4.1991, p. 1 (II.B.(3))
 - Language to be used for the markings: French
 - Supplementary markings: —
11. **Method of mobilisation of the product:** the Community market
12. **Specified delivery stage** ⁽⁹⁾: free at port of shipment
13. **Alternative delivery stage:** —
14. (a) **Port of shipment:** —
(b) **Loading address:** —
15. **Port of landing:** —
16. **Place of destination:**
 - port or warehouse of transit: —
 - overland transport route: —
17. **Period or deadline of supply at the specified stage:**
 - first deadline: 17.11-7.12.2003
 - second deadline: 1-21.12.2003
18. **Period or deadline of supply at the alternative stage:**
 - first deadline: —
 - second deadline: —
19. **Deadline for the submission of tenders (at 12 noon, Brussels time):**
 - first deadline: 28.10.2003
 - second deadline: 11.11.2003
20. **Amount of tendering guarantee:** EUR 5 per tonne
21. **Address for submission of tenders and tendering guarantees** ⁽¹⁾: M. Vestergaard, European Commission, Office: L130 7/46, B-1049 Brussels; fax: (32-2) 296 70 03/296 70 04
22. **Export refund** ⁽⁴⁾: refund applicable on 8.10.2003, fixed by Commission Regulation (EC) No 1704/2003 (OJ L 243, 27.9.2003, p. 82).

LOT B

1. **Action No:** 11/03
2. **Beneficiary** ^(?): EuronAid, PO Box 12, 2501 CA Den Haag, Nederland; tel.: (31-70) 330 57 57; fax: 364 17 01; telex: 30960 EURON NL
3. **Beneficiary's representative:** to be designated by the beneficiary
4. **Country of destination:** Haiti
5. **Product to be mobilised:** milled rice (product code 1006 30 96 9900, 1006 30 98 9900)
6. **Total quantity (tonnes net):** 1 320
7. **Number of lots:** 1
8. **Characteristics and quality of the product** ⁽³⁾ ⁽⁵⁾: see OJ C 312, 31.10.2000, p. 1 (A.7)
9. **Packaging** ⁽⁷⁾ ⁽⁸⁾: see OJ C 267, 13.9.1996, p. 1 (1.0 A 1.c, 2.c and B.6)
10. **Labelling or marking** ⁽⁶⁾: see OJ C 114, 29.4.1991, p. 1 (II.A(3))
 - Language to be used for the markings: French
 - Supplementary markings: —
11. **Method of mobilisation of the product:** the Community market
12. **Specified delivery stage** ⁽⁹⁾: free at port of shipment
13. **Alternative delivery stage:** —
14. (a) **Port of shipment:** —
(b) **Loading address:** —
15. **Port of landing:** —
16. **Place of destination:**
 - port or warehouse of transit: —
 - overland transport route: —
17. **Period or deadline of supply at the specified stage:**
 - first deadline: 17.11-7.12.2003
 - second deadline: 1-21.12.2003
18. **Period or deadline of supply at the alternative stage:**
 - first deadline: —
 - second deadline: —
19. **Deadline for the submission of tenders (at 12 noon, Brussels time):**
 - first deadline: 28.10.2003
 - second deadline: 11.11.2003
20. **Amount of tendering guarantee:** EUR 5 per tonne
21. **Address for submission of tenders and tendering guarantees** ⁽¹⁾: M. Vestergaard, European Commission, Office: L130 7/46, B-1049 Brussels; fax: (32-2) 296 70 03/296 70 04
22. **Export refund** ⁽⁴⁾: refund applicable on 8.10.2003, fixed by Commission Regulation (EC) No 1704/2003 (OJ L 243, 27.9.2003, p. 82).

Notes:

- (¹) Supplementary information: Torben Vestergaard (tel. (32-2) 299 30 50; fax (32-2) 296 20 05).
- (²) The supplier shall contact the beneficiary or its representative as soon as possible to establish which consignment documents are required.
- (³) The supplier shall deliver to the beneficiary a certificate from an official entity certifying that for the product to be delivered the standards applicable, relative to nuclear radiation, in the Member State concerned, have not been exceeded. The radioactivity certificate must indicate the caesium-134 and -137 and iodine-131 levels.
- (⁴) Commission Regulation (EC) No 2298/2001 (OJ L 308, 27.11.2001, p. 16), is applicable as regards the export refund. The date referred to in Article 2 of the said Regulation is that indicated in point 22 of this Annex.
- (⁵) The supplier shall supply to the beneficiary or its representative, on delivery, the following document:
— phytosanitary certificate.
- (⁶) Notwithstanding OJ C 114 of 29 April 1991, point II.A(3)(c) or II.B(3)(c) is replaced by the following: 'the words "European Community"'.

The supplier shall be responsible for the cost of making the container available in the stack position at the container terminal at the port of shipment. The beneficiary shall be responsible for all subsequent loading costs, including the cost of moving the containers from the container terminal.
- (⁷) Since the goods may be rebagged, the supplier must provide 1 % of empty bags of the same quality as those containing the goods, with the marking followed by a capital 'R'.

The supplier has to submit to the beneficiary's agent a complete packing list of each container, specifying the number of bags belonging to each action number as specified in the invitation to tender.
- (⁸) Shipment to take place in 20-foot containers, condition FCL/FCL.

The supplier has to seal each container with a numbered locktainer (Oneseal, Sysko Locktainer 180 or a similar high-security seal) the number of which is to be provided to the beneficiary's representative.
- (⁹) The tenderer's attention is drawn to the second subparagraph of Article 7(6) of Regulation (EC) No 2519/97.

Before the Commission can award the supply contract, it needs various items of information about the tenderer concerned (in particular the bank account to be credited). These details are contained in a form available on the Internet at the following website:

http://europa.eu.int/comm/budget/execution/ftiers_fr.htm.

If these details are missing, the tenderer designated as the supplier may not invoke the time limit for notification referred to in Article 9(4) of Regulation (EC) No 2519/97.

You should therefore include the above form with your bid after filling in the required details.

COMMISSION REGULATION (EC) No 1792/2003
of 13 October 2003
on the supply of vegetable oil as food aid

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1292/96 of 27 June 1996 on food-aid policy and food-aid management and special operations in support of food security ⁽¹⁾, as amended by Regulation (EC) No 1726/2001 of the European Parliament and of the Council ⁽²⁾, and in particular Article 24(1)(b) thereof,

Whereas:

- (1) The abovementioned Regulation lays down the list of countries and organisations eligible for Community aid and specifies the general criteria on the transport of food aid beyond the fob stage.
- (2) Following the taking of a number of decisions on the allocation of food aid, the Commission has allocated vegetable oil to certain beneficiaries.
- (3) It is necessary to make these supplies in accordance with the rules laid down by Commission Regulation (EC) No 2519/97 of 16 December 1997 laying down general rules for the mobilisation of products to be supplied under Council Regulation (EC) No 1292/96 as Community food aid ⁽³⁾. It is necessary to specify the time limits and conditions of supply to determine the resultant costs.

- (4) In order to ensure that the supplies are carried out for a given lot, provision should be made for tenderers to be able to mobilise either rapeseed oil or sunflower oil. The contract for the supply of each such lot is to be awarded to the tenderer submitting the lowest tender,

HAS ADOPTED THIS REGULATION:

Article 1

Vegetable oil shall be mobilised in the Community, as Community food aid for supply to the recipient listed in the Annex, in accordance with Regulation (EC) No 2519/97 and under the conditions set out in the Annex.

The supply shall cover the mobilisation of vegetable oil produced in the Community. Mobilisation may not involve a product manufactured and/or packaged under inward processing arrangements.

Tenders shall cover either rapeseed oil or sunflower oil. Tenders shall be rejected unless they specify the type of oil to which they relate.

The tenderer is deemed to have noted and accepted all the general and specific conditions applicable. Any other condition or reservation included in his tender is deemed unwritten.

Article 2

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

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

Done at Brussels, 13 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 166, 5.7.1996, p. 1.

⁽²⁾ OJ L 234, 1.9.2001, p. 10.

⁽³⁾ OJ L 346, 17.12.1997, p. 23.

ANNEX

LOT A

1. **Action Nos:** 8/03 (A1), 15/03 (A2)
2. **Beneficiary** ⁽²⁾: EuronAid, PO Box 12, 2501 CA Den Haag, Nederland; tel.: (31-70) 330 57 57; fax: 364 17 01; telex: 30960 EURON NL
3. **Beneficiary's representative:** to be designated by the beneficiary
4. **Country of destination:** A1: Haiti; A2: Niger
5. **Product to be mobilised:** refined rapeseed oil or refined sunflower oil
6. **Total quantity (tonnes net):** 276
7. **Number of lots:** 1 in 2 parts (A1: 216 tonnes; A2: 60 tonnes)
8. **Characteristics and quality of the product** ⁽³⁾ ⁽⁴⁾ ⁽⁶⁾: see OJ C 312, 31.10.2000, p. 1 (D.1 or D.2)
9. **Packaging** ⁽⁷⁾: see OJ C 267, 13.9.1996, p. 1 (10.8 A, B and C.2)
Weight of the empty container: 135 g minimum
10. **Labelling or marking** ⁽⁵⁾: see OJ C 114, 29.4.1991, p. 1 (III.A.(3))
 - language to be used for the markings: French
 - supplementary markings: —
11. **Method of mobilisation of the product:** the Community market
The mobilisation may not involve a product manufactured and/or packaged under inward-processing arrangements.
12. **Specified delivery stage** ⁽⁸⁾: free at port of shipment
13. **Alternative delivery stage:** —
14. (a) **Port of shipment:** —
(b) **Loading address:** —
15. **Port of landing:** —
16. **Place of destination:**
 - port or warehouse of transit: —
 - overland transport route: —
17. **Period or deadline of supply at the specified stage:**
 - first deadline: 17.11-7.12.2003
 - second deadline: 1-21.12.2003
18. **Period or deadline of supply at the alternative stage:**
 - first deadline: —
 - second deadline: —
19. **Deadline for the submission of tenders (at 12 noon, Brussels time):**
 - first deadline: 28.10.2003
 - second deadline: 11.11.2003
20. **Amount of tendering guarantee:** EUR 15 per tonne
21. **Address for submission of tenders and tendering guarantees** ⁽¹⁾: M. Vestergaard, European Commission, Bureau: L130 7/46, B-1049 Brussels; fax: (32-2) 296 70 03/296 70 04
22. **Export refund:** —

Notes:

- (¹) Supplementary information: Torben Vestergaard (tel. (32-2) 299 30 50; fax (32-2) 296 20 05).
- (²) The supplier shall contact the beneficiary or its representative as soon as possible to establish which consignment documents are required.
- (³) The supplier shall deliver to the beneficiary a certificate from an official entity certifying that for the product to be delivered the standards applicable, relative to nuclear radiation, in the Member State concerned, have not been exceeded. The radioactivity certificate must indicate the caesium-134 and -137 and iodine-131 levels.
- (⁴) The supplier shall supply to the beneficiary or its representative, on delivery, the following document:
— health certificate.
- (⁵) Notwithstanding OJ C 114, 29.4.1991, point III.A(3)(c) is replaced by the following: ‘the words “European Community”’.
The containers may be marked by the application of labels.
- (⁶) Tenders shall be rejected unless they specify the type of oil to which they relate.
- (⁷) Shipment to take place in 20-foot containers, condition FCL/FCL.
The supplier shall be responsible for the cost of making the container available in the stack position at the container terminal at the port of shipment. The beneficiary shall be responsible for all subsequent loading costs, including the cost of moving the containers from the container terminal.
The supplier has to submit to the beneficiary's agent a complete packing list of each container, specifying the number of cans belonging to each action number as specified in the invitation to tender.
The supplier has to seal each container with a numbered locktainer (Oneseal, Sysko, Locktainer 180 or a similar high-security seal) the number of which is to be provided to the beneficiary's representative.
- (⁸) The tenderer's attention is drawn to the second subparagraph of Article 7(6) of Regulation (EC) No 2519/97.

Before the Commission can award the supply contract, it needs various items of information about the tenderer concerned (in particular the bank account to be credited). These details are contained in a form available on the Internet at the following website:

http://europa.eu.int/comm/budget/execution/ftiers_fr.htm.

If these details are missing, the tenderer designated as the supplier may not invoke the time limit for notification referred to in Article 9(4) of Regulation (EC) No 2519/97.

You should therefore include the above form with your bid after filling in the required details.

**COMMISSION REGULATION (EC) No 1793/2003
of 13 October 2003**

fixing the minimum natural alcoholic strength by volume of 'Vinho verde' quality wines psr originating in Portuguese wine-growing zone C I a) for the 2003/2004 and 2004/2005 wine years

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ⁽¹⁾, as last amended by Regulation (EC) No 806/2003 ⁽²⁾, and in particular Article 58 thereof,

Whereas:

- (1) Annex VI(E)(3) to Regulation (EC) No 1493/1999 fixes the minimum natural alcoholic strength by volume of quality wines psr at 8,5 % vol. for zone C I a).
- (2) By derogation from that limit, Commission Regulation (EC) No 2358/2000 ⁽³⁾ fixes the minimum natural alcoholic strength by volume of quality wines psr originating in Portuguese zone C I a) at 7,5 % vol. Regulation (EC) No 2358/2000 expires at the end of the 2002/2003 wine year.
- (3) Given that the special conditions for traditional wine-growing and vine selection in Portuguese zone C I a) do not enable 'Vinho verde' quality wine psr to reach the

minimum natural alcoholic strength by volume of 8,5 % vol., a new derogation should be laid down for that wine for the 2003/2004 and 2004/2005 wine years.

- (4) The measure provided for in this Regulation is in accordance with the opinion of the Management Committee for Wine,

HAS ADOPTED THIS REGULATION:

Article 1

By derogation from the limits laid down for the alcoholic strengths by volume in Annex VI(E)(3) to Regulation (EC) No 1493/1999, the natural alcoholic strength by volume of the quality wines psr originating in Portuguese zone C I a) bearing the name 'Vinho verde' for the 2003/2004 and 2004/2005 wine years may be lower than 8,5 % vol. but may not be lower than 8 % vol.

Article 2

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

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

Done at Brussels, 13 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 179, 14.7.1999, p. 1.

⁽²⁾ OJ L 122, 16.5.2003, p. 1.

⁽³⁾ OJ L 272, 25.10.2000, p. 16.

**COMMISSION REGULATION (EC) No 1794/2003
of 13 October 2003**

**fixing the estimated production of olive oil and the unit amount of the production aid that may be
paid in advance for the 2002/03 marketing year**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation No 136/66/EEC of the Council of 22 September 1966 on the establishment of a common organisation of the market in oils and fats ⁽¹⁾, as last amended by Regulation (EC) No 1513/2001 ⁽²⁾,

Having regard to Council Regulation (EEC) No 2261/84 of 17 July 1984 laying down general rules on the granting of aid for the production of olive oil and of aid to olive oil producer organisations ⁽³⁾, as last amended by Regulation (EC) No 1639/98 ⁽⁴⁾, and in particular Article 17a(1) thereof,

Whereas:

- (1) Under Article 5 of Regulation No 136/66/EEC the unit production aid must be adjusted in each Member State where actual production exceeds the guaranteed national quantity referred to in paragraph 3 of that Article. In assessing the extent of the overrun, account should be taken of the estimates for the production of table olives expressed as olive-oil equivalent using the relevant coefficients referred to, for Greece, in Commission Decision 2001/649/EC ⁽⁵⁾, as amended by Decision 2001/880/EC ⁽⁶⁾, for Spain, in Commission Decision 2001/650/EC ⁽⁷⁾, as amended by Decision 2001/883/EC ⁽⁸⁾, for France, in Commission Decision 2001/648/EC ⁽⁹⁾, as amended by Decision 2001/879/EC ⁽¹⁰⁾, for Italy, in Commission Decision 2001/658/EC ⁽¹¹⁾, as amended by Decision 2001/884/EC ⁽¹²⁾ and, for Portugal, in Commission Decision 2001/670/EC ⁽¹³⁾, as amended by Decision 2001/878/EC ⁽¹⁴⁾.
- (2) Article 17a(1) of Regulation (EEC) No 2261/84 provides that in order to determine the unit amount of the production aid for olive oil that can be paid in advance, the estimated production for the marketing year concerned should be determined. That amount must be fixed at a level that avoids any risk of unwarranted payment to olive growers. The amount also applies to table olives, expressed as olive-oil equivalent.

- (3) In order to establish the estimated production, Member States must forward to the Commission data for the olive oil and, where appropriate, table olive production estimates for each marketing year. The Commission may use other sources of information. On the basis of that data, the estimated production of olive oil and table olives, expressed as olive-oil equivalent, should be fixed for each Member State.
- (4) In determining the amount of the advance, account must be taken of the amounts withheld for measures to improve the quality of olive oil and table olive production provided for in Article 5(9) of Regulation No 136/66/EEC and Article 4a(1) of Council Regulation (EC) No 1638/98 ⁽¹⁵⁾, as amended by Regulation (EC) No 1513/2001 ⁽¹⁶⁾.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Oils and Fats,

HAS ADOPTED THIS REGULATION:

Article 1

1. For the 2002/03 marketing year, the estimated production of olive oil, including that referred to in paragraph 2, is:

- 458 202 tonnes for Greece,
- 972 130 tonnes for Spain,
- 3 357 tonnes for France,
- 686 338 tonnes for Italy,
- 28 459 tonnes for Portugal.

2. For the 2002/03 marketing year, the estimated production of table olives, expressed as olive-oil equivalent, is:

- 11 000 tonnes for Greece, using a coefficient of equivalence of 13 %,
- 49 142 tonnes for Spain, using a coefficient of equivalence of 11,5 %,

⁽¹⁾ OJ L 72, 30.9.1966, p. 3025/66.

⁽²⁾ OJ L 201, 26.7.2001, p. 4.

⁽³⁾ OJ L 208, 3.8.1984, p. 3.

⁽⁴⁾ OJ L 210, 28.7.1998, p. 38.

⁽⁵⁾ OJ L 229, 25.8.2001, p. 16.

⁽⁶⁾ OJ L 326, 11.12.2001, p. 42.

⁽⁷⁾ OJ L 229, 25.8.2001, p. 20.

⁽⁸⁾ OJ L 327, 12.12.2001, p. 43.

⁽⁹⁾ OJ L 229, 25.8.2001, p. 12.

⁽¹⁰⁾ OJ L 326, 11.12.2001, p. 41.

⁽¹¹⁾ OJ L 231, 29.8.2001, p. 16.

⁽¹²⁾ OJ L 327, 12.12.2001, p. 44.

⁽¹³⁾ OJ L 235, 4.9.2001, p. 16.

⁽¹⁴⁾ OJ L 326, 11.12.2001, p. 40.

⁽¹⁵⁾ OJ L 210, 28.7.1998, p. 32.

⁽¹⁶⁾ OJ L 201, 26.7.2001, p. 4.

- 165 tonnes for France, using a coefficient of equivalence of 13 %,
- 1 611 tonnes for Italy, using a coefficient of equivalence of 13 %,
- 530 tonnes for Portugal, using a coefficient of equivalence of 11,5 %.

3. For the 2002/03 marketing year, the unit amount of the production aid that may be advanced shall be:

- EUR 110,72 per 100 kilograms for Greece,
- EUR 91,92 per 100 kilograms for Spain,

- EUR 117,36 per 100 kilograms for France,
- EUR 93,05 per 100 kilograms for Italy,
- EUR 117,36 per 100 kilograms for Portugal.

Article 2

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

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

Done at Brussels, 13 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

COMMISSION REGULATION (EC) No 1795/2003
of 13 October 2003
amending Annex VI to Council Regulation (EC) No 1493/1999 as regards quality wines produced
in specified regions

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ⁽¹⁾, as last amended by Regulation (EC) No 806/2003 ⁽²⁾, and in particular Article 58 thereof,

Whereas:

- (1) Annex VI.D.1 of Regulation (EC) No 1493/1999 stipulates that quality wines psr may be produced only from grapes of wine varieties which appear on the list of the Member State of production and are harvested within the specified region.
- (2) However, point D.2 of that Annex provides that, until 31 August 2003 at the latest, in the case of a traditional practice governed by special provisions of the Member State of production, that Member State may permit on certain conditions, by means of express authorisations and subject to suitable controls, that a quality sparkling wine psr be obtained by adding to the basic product from which the wine is made one or more wine-sector products which do not originate in the specified region whose name the wine bears.
- (3) Italy has applied this derogation for the preparation of 'Conegliano-Valdobbiadene' and 'Montello e Colli Asolani' quality sparkling wines psr. Since the derogation expires on 31 August 2003 and the wine producers have justified that they need a limited extension to this derogation to allow them to make the necessary struc-

tural adjustments to the traditional method for producing these wines, the derogation should be extended until 31 August 2005.

- (4) Regulation (EC) No 1493/1999 should therefore be amended accordingly.
- (5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Wine,

HAS ADOPTED THIS REGULATION:

Article 1

The first subparagraph of Annex VI.D.2 to Regulation (EC) No 1493/1999 is hereby replaced by the following:

'As an exception to paragraph 1(a), in the case of a traditional practice governed by special provisions of the Member State of production, that Member State may until 31 August 2005 at the latest, by means of express authorisations and subject to suitable controls, permit that a quality sparkling wine psr be obtained by adding to the basic product from which the wine is made one or more wine-sector products which do not originate in the specified region whose name the wine bears, provided that:'

Article 2

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

It shall apply from 1 September 2003.

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

Done at Brussels, 13 October 2003.

For the Commission

Franz FISCHLER

Member of the Commission

⁽¹⁾ OJ L 179, 14.7.1999, p. 1.

⁽²⁾ OJ L 122, 16.5.2003, p. 1.

**COMMISSION REGULATION (EC) No 1796/2003
of 13 October 2003**

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

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 4088/87 of 21 December 1987 fixing conditions for the application of preferential customs duties on imports of certain flowers originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip ⁽¹⁾, as last amended by Regulation (EC) No 1300/97 ⁽²⁾, and in particular Article 5(2)(a) thereof,

Whereas:

Pursuant to Article 2(2) and Article 3 of abovementioned Regulation (EEC) No 4088/87, Community import and producer prices are fixed each fortnight for uniflorous (bloom) carnations, multiflorous (spray) carnations, large-flowered roses and small-flowered roses and apply for two-weekly periods. Pursuant to Article 1b of Commission Regulation (EEC) No 700/88 of 17 March 1988 laying down detailed rules for the application of the arrangements for the import into the Community of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the

Gaza Strip ⁽³⁾, as last amended by Regulation (EC) No 2062/97 ⁽⁴⁾, those prices are determined for fortnightly periods on the basis of weighted prices provided by the Member States. Those prices should be fixed immediately so the customs duties applicable can be determined. To that end, provision should be made for this Regulation to enter into force immediately,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 14 October 2003.

It shall apply from 15 to 28 October 2003.

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

Done at Brussels, 13 October 2003.

For the Commission

J. M. SILVA RODRÍGUEZ
Agriculture Director-General

⁽¹⁾ OJ L 382, 31.12.1987, p. 22.

⁽²⁾ OJ L 177, 5.7.1997, p. 1.

⁽³⁾ OJ L 72, 18.3.1988, p. 16.

⁽⁴⁾ OJ L 289, 22.10.1997, p. 1.

ANNEX

to the Commission Regulation of 13 October 2003 fixing Community producer and import prices for carnations and roses with a view to the application of the arrangements governing imports of certain floricultural products originating in Cyprus, Israel, Jordan, Morocco and the West Bank and the Gaza Strip

(EUR/100 pieces)

Period: from 15 to 28 October 2003				
Community producer price	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
	16,31	16,53	25,30	12,04
Community import prices	Uniflorous (bloom) carnations	Multiflorous (spray) carnations	Large-flowered roses	Small-flowered roses
Israel	—	—	7,50	7,33
Morocco	—	—	—	—
Cyprus	—	—	—	—
Jordan	—	—	—	—
West Bank and Gaza Strip	—	—	—	—

COMMISSION REGULATION (EC) No 1797/2003
of 13 October 2003
determining the world market price for unginned cotton

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Protocol 4 on cotton, annexed to the Act of Accession of Greece, as last amended by Council Regulation (EC) No 1050/2001 ⁽¹⁾,

Having regard to Council Regulation (EC) No 1051/2001 of 22 May 2001 on production aid for cotton ⁽²⁾, and in particular Article 4 thereof,

Whereas:

- (1) In accordance with Article 4 of Regulation (EC) No 1051/2001, a world market price for unginned cotton is to be determined periodically from the price for ginned cotton recorded on the world market and by reference to the historical relationship between the price recorded for ginned cotton and that calculated for unginned cotton. That historical relationship has been established in Article 2(2) of Commission Regulation (EC) No 1591/2001 of 2 August 2001 ⁽³⁾, as amended by Regulation (EC) No 1486/2002 ⁽⁴⁾. Where the world market price cannot be determined in this way, it is to be based on the most recent price determined.
- (2) In accordance with Article 5 of Regulation (EC) No 1051/2001, the world market price for unginned cotton is to be determined in respect of a product of specific characteristics and by reference to the most favourable

offers and quotations on the world market among those considered representative of the real market trend. To that end, an average is to be calculated of offers and quotations recorded on one or more European exchanges for a product delivered cif to a port in the Community and coming from the various supplier countries considered the most representative in terms of international trade. However, there is provision for adjusting the criteria for determining the world market price for ginned cotton to reflect differences justified by the quality of the product delivered and the offers and quotations concerned. Those adjustments are specified in Article 3(2) of Regulation (EC) No 1591/2001.

- (3) The application of the above criteria gives the world market price for unginned cotton determined hereinafter,

HAS ADOPTED THIS REGULATION:

Article 1

The world price for unginned cotton as referred to in Article 4 of Regulation (EC) No 1051/2001 is hereby determined as equalling EUR 31,807/100 kg.

Article 2

This Regulation shall enter into force on 14 October 2003.

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

Done at Brussels, 13 October 2003.

For the Commission

J. M. SILVA RODRÍGUEZ

Agriculture Director-General

⁽¹⁾ OJ L 148, 1.6.2001, p. 1.

⁽²⁾ OJ L 148, 1.6.2001, p. 3.

⁽³⁾ OJ L 210, 3.8.2001, p. 10.

⁽⁴⁾ OJ L 223, 20.8.2002, p. 3.

DIRECTIVE 2003/74/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 22 September 2003

amending Council Directive 96/22/EC concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 152(4)(b) thereof,

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

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

After consulting the Committee of the Regions,

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

Whereas:

- (1) Article 3(a) of Directive 96/22/EC ⁽⁴⁾ requires Member States to prohibit the administration to farm animals of substances having, *inter alia*, an oestrogenic, androgenic or gestagenic action. Nevertheless administration of those substances to farm animals may be authorised but only if they are used for therapeutic purposes or zootechnical treatment, in accordance with the provisions of Articles 4, 5 and 7 of that Directive.
- (2) Article 11(2) of Directive 96/22/EC requires Member States to prohibit the importation from third countries of farm or aquaculture animals to which substances or products referred to in Article 3(a) of that Directive have been administered, unless those products were administered in compliance with the provisions and requirements laid down in Articles 4, 5 and 7 thereof, as well as of meat or products obtained from animals the importation of which is prohibited.
- (3) In the light of the results of a dispute settlement case brought before the World Trade Organisation (WTO) by the United States of America and by Canada (the Hormones case) ⁽⁵⁾ and recommendations made in that respect by the WTO Dispute Settlement Body on 13 February 1998, the Commission immediately initiated a complementary risk assessment, in accordance with the requirements of the Agreement on the application of sanitary and phytosanitary measures (WTO-GATT) ⁽⁶⁾ as

interpreted by the appellate body in the Hormones case, of the six hormonal substances (oestradiol 17 β , testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate) whose administration for animal growth promotion purposes is prohibited by Directive 96/22/EC.

- (4) In parallel, the Commission initiated and funded a number of specific scientific studies and research projects on these six hormones in order to obtain as much as possible of the missing scientific information, as identified in the interpretations and findings of the WTO panel and appellate body reports in the Hormones case. Moreover, the Commission addressed specific requests to the USA, Canada and other third countries, which authorise the use of these six hormones for animal growth promotion, and published an open call for documentation ⁽⁷⁾ requesting any interested party, including the industry, to provide any relevant and recent scientific data and information in their possession to be taken into account in the complementary risk assessment.
- (5) On 30 April 1999, as requested by the Commission, the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH) issued an opinion concerning the assessment of potential adverse effects to human health from hormone residues in bovine meat and meat products. The major conclusions of that opinion were, first, that, as concerns excess intake of hormone residues and their metabolites, and in view of the intrinsic properties of hormones and the epidemiological findings, a risk to the consumer has been identified with different levels of conclusive evidence for the six hormones evaluated. Secondly, for the six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genotoxic and carcinogenic effects could be envisaged and, of the various susceptible risk groups, prepubertal children constitute the group of greatest concern and, third, in view of the intrinsic properties of the hormones and taking into account epidemiological findings, no threshold levels and, therefore, no acceptable daily intake (ADI) can be established for any of the six hormones evaluated when they are administered to bovine animals for growth promotion purposes.
- (6) As regards, in particular, the use of oestradiol 17 β , with the aim of promoting growth, the SCVPH assessment is that a substantial body of recent evidence suggests that it has to be considered as a complete carcinogen, as it exerts both tumour-initiating and tumour-promoting effects and that the data currently available do not make it possible to give a quantitative estimate of the risk.

⁽¹⁾ OJ C 337 E, 28.11.2000 and OJ C 180 E, 26.6.2001, p. 190.

⁽²⁾ OJ C 14, 16.1.2001, p. 47.

⁽³⁾ Opinion of the European Parliament of 1 February 2001 (OJ C 267, 21.9.2001, p. 53), Council Common Position of 20 February 2003 (OJ C 90 E, 15.4.2003, p. 1) and Decision of the European Parliament of 2 July 2003 (not yet published in the Official Journal). Council Decision of 22 July 2003.

⁽⁴⁾ OJ L 125, 23.5.1996, p. 3.

⁽⁵⁾ WT/DS26/R/USA and WT/DS48/R/CAN (panel reports), and AB-1997-4 (appellate body report).

⁽⁶⁾ OJ L 336, 23.12.1994, p. 40.

⁽⁷⁾ OJ C 56, 26.2.1999, p. 17.

- (7) As regards the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate), the SCVPH assessment is that, in spite of the individual toxicological and epidemiological data available, which were taken into account, the current state of knowledge does not make it possible to give a quantitative estimate of the risk to consumers.
- (8) Subsequent to the opinion of the SCVPH of 30 April 1999, new and more recent scientific information on some of the six hormones under consideration was made available to the Commission from the United Kingdom's Veterinary Products Committee, in October 1999, the Committee on Veterinary Medicinal Products of the European Community (CVM), in December 1999, and the Joint FAO/WHO Expert Committee on Food Additives (JECFA), in February 2000. The CVM has noted in particular that oestradiol 17 β has a carcinogenic effect only after prolonged exposure and at levels which are considerably higher than those needed for a physiological (oestrogenic) response. All this latest scientific information was brought to the attention of the SCVPH, which reviewed it and, on 3 May 2000, concluded that it did not provide convincing data and arguments requiring revision of the conclusions drawn in its opinion of 30 April 1999. The SCVPH confirmed in its opinion of 10 April 2002 the validity of its previous opinion, after revising it in the light of the most recent scientific data.
- (9) As regards, in particular, oestradiol 17 β , this substance can potentially be used in all farm animals and residue intake for all segments of the human population and in particular the susceptible groups at high risk can therefore be especially relevant. The avoidance of such intake is of absolute importance to safeguard human health. Furthermore, the routine use of the above substances for animal growth promotion purposes is likely to lead to increased concentration of those substances in the environment.
- (10) Taking into account the results of the risk assessment and all other available pertinent information, it has to be concluded that, in order to achieve the chosen level of protection in the Community from the risks posed, in particular to human health, by the routine use of these hormones for growth promotion and the consumption of residues found in meat derived from animals to which these hormones have been administered for growth promotion, it is necessary to maintain the permanent prohibition laid down in Directive 96/22/EC on oestradiol 17 β and to continue provisionally to apply the prohibition to the other five hormones (testosterone, progesterone, trenbolone acetate, zeranol and melengestrol acetate). Furthermore, according to Article 7 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety ⁽¹⁾, the provisional prohibition of these five hormones should apply while the Community seeks more complete scientific information from any source, which could shed light and clarify the gaps in the present state of knowledge of these substances.
- (11) However, the use of certain of the above substances, where this is necessary, for therapeutic purposes or zootechnical treatment may continue to be authorised as it is not likely to constitute a hazard for public health owing to the nature and the limited duration of the treatments, the limited quantities administered and the strict conditions laid down in Directive 96/22/EC in order to prevent any possible misuse.
- (12) However, in the light of the existing information it is appropriate to limit as far the exposure to oestradiol 17 β and only authorise those treatments for which no viable effective alternatives exist. In general, there are alternative treatments or strategies available to replace most of the uses of oestradiol 17 β for therapeutic or zootechnical purposes. Nonetheless, studies appear to show that at present no viable effective alternatives exist in all the Member States for certain treatments which are currently authorised. In order to allow for the necessary adjustments and in particular for the authorisation or the mutual recognition of the pharmaceutical products needed, it is appropriate to phase out the use of oestradiol 17 β for oestrus induction over a given period. It is also appropriate to maintain the possibility of authorising, under strict and verifiable conditions so as to prevent any possible misuse and any unacceptable risk for public health, its use for the treatment of certain conditions (foetus maceration or mummification and pyometra in cattle) which have serious consequences for animal health and welfare. It is necessary to review this possibility within a given time.
- (13) The proposed amendments to Directive 96/22/EC are necessary to achieve the chosen level of health protection from the residues in meat of farm animals treated with these hormones for growth promotion purposes, whilst respecting the general principles of food law set out in Regulation (EC) No 178/2002 and the international obligations of the Community. Moreover, there is no other means that is reasonably available at present, taking into account technical and economic feasibility, which is significantly less restrictive of trade and can achieve equally effectively the chosen level of health protection. In addition, minor drafting amendments are equally necessary in particular in view of the replacement of a number of Directives by Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products ⁽²⁾,

⁽¹⁾ OJ L 31, 1.2.2002, p. 1.

⁽²⁾ OJ L 311, 28.11.2001, p. 1.

HAVE ADOPTED THIS DIRECTIVE:

Article 1

Directive 96/22/EC is hereby amended as follows:

1. Articles 2 and 3 are replaced by the following:

'Article 2

Member States shall prohibit:

- (a) the placing on the market of the substances listed in Annex II, list A, for administering to animals of all species;
- (b) the placing on the market of the substances listed in Annex II, list B, for administering to animals, the flesh and products of which are intended for human consumption, for purposes other than those provided for in point 2 of Article 4 and in Article 5a.

Article 3

Member States shall prohibit, for substances listed in Annex II, and shall provisionally prohibit, for substances listed in Annex III:

- (a) the administering of those substances to farm or aquaculture animals, by any means whatsoever;
- (b) — the holding, except under official control, of animals referred to in point (a) on a farm, and
— the placing on the market or the slaughter for human consumption of farm animals,

which contain the substances referred to in Annex II and Annex III or in which the presence of such substances has been established, unless proof can be given that the animals in question have been treated in accordance with Articles 4, 5 or 5a;

- (c) the placing on the market for human consumption of aquaculture animals to which substances referred to above have been administered and of processed products derived from such animals;
- (d) the placing on the market of meat from animals referred to in point (b);
- (e) the processing of the meat referred to in (d).'

2. in Article 4, point 1, 'oestradiol 17 β ' are deleted;

3. in Article 5, first paragraph, the first sentence is replaced by the following:

'Notwithstanding Article 3(a) and without prejudice to Article 2, Member States may authorise the administering to farm animals, for the purpose of zootechnical treatment, of veterinary medicinal products having an oestrogenic (other than oestradiol 17 β and its ester-like derivatives), androgenic or gestagenic action which are authorised in accordance with Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products (*).

(*) OJ L 311, 28.11.2001, p. 1.'

4. the following Article is added:

'Article 5a

1. Notwithstanding Article 3(a) and without prejudice to Articles 2 and 11a, Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17 β or its ester-like derivatives for:

- the treatment of foetus maceration or mummification in cattle, or
- the treatment of pyometra in cattle,

in accordance with Directive 2001/82/EC.

2. Notwithstanding Article 3(a) and without prejudice to Article 2, Member States may authorise the administering to farm animals of veterinary medicinal products containing oestradiol 17 β or its ester-like derivatives for oestrus induction in cattle, horses, sheep or goats until 14 October 2006, in accordance with Directive 2001/82/EC.

3. The treatment must be carried out by the veterinarian himself or herself on farm animals which have been clearly identified. This treatment must be registered by the veterinarian responsible. The latter must record at least the following details in a register, which may be that provided for in Directive 2001/82/EC:

- the type of product administered,
- the nature of the treatment,
- the date of treatment,
- the identity of the animals treated,
- the date of expiry of the withdrawal period.

The register must be made available to the competent authority at its request.

Stockfarmers shall be prohibited from holding on their farms veterinary medicinal products containing oestradiol 17 β or its ester-like derivatives.'

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

'1. Hormonal products and beta-agonists the administration of which to farm animals is authorised in accordance with Articles 4, 5 or 5a must meet the requirements of Directive 2001/82/EC.'

6. Article 7(1), first subparagraph, is replaced by the following:

'1. For the purpose of trade, Member States may authorise the placing on the market of animals for breeding and breeding animals at the end of their reproductive life which, during the latter period, have undergone a treatment referred to in Articles 4, 5 or 5a and may authorise the affixing of the Community stamp to meat from such animals where the conditions laid down in Articles 4, 5 or 5a and the withdrawal periods provided for in the authorisation to place on the market are complied with.'

7. Article 8 is amended as follows:

(a) point 1 is replaced by the following:

‘1. at the time of the import, manufacture, storage, distribution, sale and use of the substances referred to in Articles 2 and 3, their possession is restricted to the persons authorised by national legislation in accordance with Article 68 of Directive 2001/82/EC.’

(b) in point 2(a), ‘Article 2’ is replaced by ‘Articles 2 and 3’;

(c) in point 2(d), ‘in Articles 4 and 5’ is replaced by ‘in Articles 4, 5 and 5a’;

(d) footnote 2 is deleted and footnote 3 becomes footnote 2;

8. Article 11(2)(a) is amended as follows:

(a) in point (i), ‘point (a) of Article 2’ is replaced by ‘Annex II, List A,’;

(b) point (ii) is replaced by the following:

‘(ii) to which substances referred to in Annex II, List B, and Annex III have been administered, unless those substances were administered in compliance with the provisions and requirements laid down in Articles 4, 5, 5a and 7 and the withdrawal periods allowed in international recommendations have been observed;’

9. the following Article is added:

‘Article 11a

The Commission shall present within two years from 14 October 2003 to the European Parliament and to the Council, a report on the availability of alternative veterinary medicinal products to those containing oestradiol 17 β or its ester-like derivatives for the treatment of foetus maceration or mummification in cattle, and for the treatment of pyometra in cattle, and present to them the following year any necessary proposals intending to replace these substances in due time.

Likewise, with regard to the substances listed in Annex III, the Commission shall seek additional information, taking into account recent scientific data from all possible sources, and keep the measures applied under regular review with a view to timely presentation to the European Parliament and to the Council of any necessary proposals.’

10. the following Article is added:

‘Article 14a

Notwithstanding Articles 3 and 5a, and without prejudice to Article 2, farm animals for which it can be certified that they have been administered oestradiol 17 β or its ester-like derivatives for therapeutic or zootechnical purposes prior to 14 October 2004 shall be subject to the same provisions as those laid down for the substances authorised in accordance with Article 4(1) as regards therapeutic use and Article 5 as regards zootechnical use.’

11. all references to ‘Directive 81/851/EEC’ and ‘Directive 81/852/EEC’ are construed as references to ‘Directive 2001/82/EC’;

12. the Annex to Directive 96/22/EC become ‘Annex I’, and Annexes II and III in the Annex to this Directive are added.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 14 October 2004 at the latest. They shall forthwith inform the Commission thereof.

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

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

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 22 September 2003.

For the European Parliament

The President

P. COX

For the Council

The President

R. BUTTIGLIONE

*ANNEX**'ANNEX II*

List of prohibited substances:

List A:

- thyrostatic substances
- stilbenes, stilbene derivatives, their salts and esters

List B:

- oestradiol 17 β and its ester-like derivatives
- beta-agonists

ANNEX III

List of provisionally prohibited substances:

substances having oestrogenic (other than oestradiol 17 β and its ester-like derivatives), androgenic or gestagenic action.'

COMMISSION DIRECTIVE 2003/94/EC**of 8 October 2003****laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use ⁽¹⁾, as last amended by Commission Directive 2003/63/EC ⁽²⁾, and in particular Article 47 thereof,

Whereas:

- (1) All medicinal products for human use manufactured or imported into the Community, including medicinal products intended for export, are to be manufactured in accordance with the principles and guidelines of good manufacturing practice.
- (2) Those principles and guidelines are set out in Commission Directive 91/356/EEC of 13 June 1991 laying down the principles and guidelines of good manufacturing practice for medicinal products for human use ⁽³⁾.
- (3) Article 13(3) of Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ⁽⁴⁾ requires that detailed guidance be drawn up, in accordance with the guidelines on good manufacturing practice, on the elements to be taken into account when evaluating investigational medicinal products for human use with the object of releasing batches within the Community.
- (4) It is therefore necessary to extend and adapt the provisions of Directive 91/356/EEC to cover good manufacturing practice of investigational medicinal products.
- (5) Since most of the provisions of Directive 91/356/EEC need to be adjusted, for the sake of clarity that Directive should be replaced.
- (6) In order to ensure conformity with the principles and guidelines of good manufacturing practice, it is necessary to lay down detailed provisions on inspections by the competent authorities and on certain obligations of the manufacturer.

- (7) All manufacturers should operate an effective quality management system of their manufacturing operations, which requires the implementation of a pharmaceutical quality assurance system.
- (8) Principles and guidelines of good manufacturing practice should be set out in relation to quality management, personnel, premises and equipment, documentation, production, quality control, contracting out, complaints and product recall, and self-inspection.
- (9) In order to protect the human beings involved in clinical trials and to ensure that investigational medicinal products can be traced, specific provisions on the labelling of those products are necessary.
- (10) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use, set up under Article 121 of Directive 2001/83/EC,

HAS ADOPTED THIS DIRECTIVE:

*Article 1***Scope**

This Directive lays down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use whose manufacture requires the authorisation referred to in Article 40 of Directive 2001/83/EC and in respect of investigational medicinal products for human use whose manufacture requires the authorisation referred to in Article 13 of Directive 2001/20/EC.

*Article 2***Definitions**

For the purposes of this Directive, the following definitions shall apply:

1. 'medicinal product' means any product as defined in Article 1(2) of Directive 2001/83/EC;
2. 'investigational medicinal product' means any product as defined in Article 2(d) of Directive 2001/20/EC;
3. 'manufacturer' means any person engaged in activities for which the authorisation referred to in Article 40(1) and (3) of Directive 2001/83/EC or the authorisation referred to in Article 13(1) of Directive 2001/20/EC is required;

⁽¹⁾ OJ L 311, 28.11.2001, p. 67.

⁽²⁾ OJ L 159, 27.6.2003, p. 46.

⁽³⁾ OJ L 193, 17.7.1991, p. 30.

⁽⁴⁾ OJ L 121, 1.5.2001, p. 34.

4. 'qualified person' means the person referred to in Article 48 of Directive 2001/83/EC or in Article 13(2) of Directive 2001/20/EC;
5. 'pharmaceutical quality assurance' means the total sum of the organised arrangements made with the object of ensuring that medicinal products or investigational medicinal products are of the quality required for their intended use;
6. 'good manufacturing practice' means the part of quality assurance which ensures that products are consistently produced and controlled in accordance with the quality standards appropriate to their intended use;
7. 'blinding' means the deliberate disguising of the identity of an investigational medicinal product in accordance with the instructions of the sponsor;
8. 'unblinding' means the disclosure of the identity of a blinded product.

Article 3

Inspections

1. By means of the repeated inspections referred to in Article 111(1) of Directive 2001/83/EC and by means of the inspections referred to in Article 15(1) of Directive 2001/20/EC, the Member States shall ensure that manufacturers respect the principles and guidelines of good manufacturing practice laid down by this Directive. Member States shall also take into account the compilation, published by the Commission, of Community procedures on inspections and exchange of information.
2. For the interpretation of the principles and guidelines of good manufacturing practice, the manufacturers and the competent authorities shall take into account the detailed guidelines referred to in the second paragraph of Article 47 of Directive 2001/83/EC, published by the Commission in the 'Guide to good manufacturing practice for medicinal products and for investigational medicinal products'.

Article 4

Conformity with good manufacturing practice

1. The manufacturer shall ensure that manufacturing operations are carried out in accordance with good manufacturing practice and with the manufacturing authorisation. This provision shall also apply to medicinal products intended only for export.
2. For medicinal products and investigational medicinal products imported from third countries, the importer shall ensure that the products have been manufactured in accordance with standards which are at least equivalent to the good manufacturing practice standards laid down by the Community.

In addition, an importer of medicinal products shall ensure that such products have been manufactured by manufacturers duly authorised to do so. An importer of investigational medicinal products shall ensure that such products have been manufactured by a manufacturer notified to the competent authorities and accepted by them for that purpose.

Article 5

Compliance with marketing authorisation

1. The manufacturer shall ensure that all manufacturing operations for medicinal products subject to a marketing authorisation are carried out in accordance with the information provided in the application for marketing authorisation as accepted by the competent authorities.

In the case of investigational medicinal products, the manufacturer shall ensure that all manufacturing operations are carried out in accordance with the information provided by the sponsor pursuant to Article 9(2) of Directive 2001/20/EC as accepted by the competent authorities.

2. The manufacturer shall regularly review his manufacturing methods in the light of scientific and technical progress and the development of the investigational medicinal product.

If a variation to the marketing authorisation dossier or an amendment to the request referred to in Article 9(2) of Directive 2001/20/EC is necessary, the application for modification shall be submitted to the competent authorities.

Article 6

Quality assurance system

The manufacturer shall establish and implement an effective pharmaceutical quality assurance system, involving the active participation of the management and personnel of the different departments.

Article 7

Personnel

1. At each manufacturing site, the manufacturer shall have a sufficient number of competent and appropriately qualified personnel at his disposal to achieve the pharmaceutical quality assurance objective.
2. The duties of the managerial and supervisory staff, including the qualified persons, responsible for implementing and operating good manufacturing practice, shall be defined in job descriptions. Their hierarchical relationships shall be defined in an organisation chart. Organisation charts and job descriptions shall be approved in accordance with the manufacturer's internal procedures.
3. The staff referred to in paragraph 2 shall be given sufficient authority to discharge their responsibility correctly.

4. The personnel shall receive initial and ongoing training, the effectiveness of which shall be verified, covering in particular the theory and application of the concept of quality assurance and good manufacturing practice, and, where appropriate, the particular requirements for the manufacture of investigational medicinal products.

5. Hygiene programmes adapted to the activities to be carried out shall be established and observed. These programmes shall, in particular, include procedures relating to health, hygiene practice and clothing of personnel.

Article 8

Premises and equipment

1. Premises and manufacturing equipment shall be located, designed, constructed, adapted and maintained to suit the intended operations.

2. Premises and manufacturing equipment shall be laid out, designed and operated in such a way as to minimise the risk of error and to permit effective cleaning and maintenance in order to avoid contamination, cross contamination and, in general, any adverse effect on the quality of the product.

3. Premises and equipment to be used for manufacturing operations, which are critical to the quality of the products, shall be subjected to appropriate qualification and validation.

Article 9

Documentation

1. The manufacturer shall establish and maintain a documentation system based upon specifications, manufacturing formulae and processing and packaging instructions, procedures and records covering the various manufacturing operations performed. Documents shall be clear, free from error and kept up to date. Pre-established procedures for general manufacturing operations and conditions shall be kept available, together with specific documents for the manufacture of each batch. That set of documents shall enable the history of the manufacture of each batch and the changes introduced during the development of an investigational medicinal product to be traced.

For a medicinal product, the batch documentation shall be retained for at least one year after the expiry date of the batches to which it relates or at least five years after the certification referred to in Article 51(3) of Directive 2001/83/EC, whichever is the longer period.

For an investigational medicinal product, the batch documentation shall be retained for at least five years after the completion or formal discontinuation of the last clinical trial in which the batch was used. The sponsor or marketing authorisation holder, if different, shall be responsible for ensuring that

records are retained as required for marketing authorisation in accordance with the Annex I to Directive 2001/83/EC, if required for a subsequent marketing authorisation.

2. When electronic, photographic or other data processing systems are used instead of written documents, the manufacturer shall first validate the systems by showing that the data will be appropriately stored during the anticipated period of storage. Data stored by those systems shall be made readily available in legible form and shall be provided to the competent authorities at their request. The electronically stored data shall be protected, by methods such as duplication or back-up and transfer on to another storage system, against loss or damage of data, and audit trails shall be maintained.

Article 10

Production

1. The different production operations shall be carried out in accordance with pre-established instructions and procedures and in accordance with good manufacturing practice. Adequate and sufficient resources shall be made available for the in-process controls. All process deviations and product defects shall be documented and thoroughly investigated.

2. Appropriate technical or organisational measures shall be taken to avoid cross contamination and mix-ups. In the case of investigational medicinal products, particular attention shall be paid to the handling of products during and after any blinding operation.

3. For medicinal products, any new manufacture or important modification of a manufacturing process of a medicinal product shall be validated. Critical phases of manufacturing processes shall be regularly re-validated.

4. For investigational medicinal products, the manufacturing process shall be validated in its entirety in so far as is appropriate, taking into account the stage of product development. At least the critical process steps, such as sterilisation, shall be validated. All steps in the design and development of the manufacturing process shall be fully documented.

Article 11

Quality control

1. The manufacturer shall establish and maintain a quality control system placed under the authority of a person who has the requisite qualifications and is independent of production.

That person shall have at his disposal, or shall have access to, one or more quality control laboratories appropriately staffed and equipped to carry out the necessary examination and testing of the starting materials and packaging materials and the testing of intermediate and finished products.

2. For medicinal products, including those imported from third countries, contract laboratories may be used if authorised in accordance with Article 12 of this Directive and point (b) of Article 20 of Directive 2001/83/EC.

For investigational medicinal products, the sponsor shall ensure that the contract laboratory complies with the content of the request referred to in Article 9(2) of Directive 2001/20/EC, as accepted by the competent authority. When the products are imported from third countries, analytical control shall not be mandatory.

3. During the final control of the finished product before its release for sale or distribution or for use in clinical trials, the quality control system shall take into account, in addition to analytical results, essential information such as the production conditions, the results of in-process controls, the examination of the manufacturing documents and the conformity of the product to its specifications, including the final finished pack.

4. Samples of each batch of finished medicinal product shall be retained for at least one year after the expiry date.

For an investigational medicinal product, sufficient samples of each batch of bulk formulated product and of key packaging components used for each finished product batch shall be retained for at least two years after completion or formal discontinuation of the last clinical trial in which the batch was used, whichever period is the longer.

Unless a longer period is required under the law of the Member State of manufacture, samples of starting materials, other than solvents, gases or water, used in the manufacturing process shall be retained for at least two years after the release of product. That period may be shortened if the period of stability of the material, as indicated in the relevant specification, is shorter. All those samples shall be maintained at the disposal of the competent authorities.

Other conditions may be defined, by agreement with the competent authority, for the sampling and retaining of starting materials and certain products manufactured individually or in small quantities, or when their storage could raise special problems.

Article 12

Work contracted out

1. Any manufacturing operation or operation linked thereto which is carried out under contract shall be the subject of a written contract.

2. The contract shall clearly define the responsibilities of each party and shall define, in particular, the observance of good manufacturing practice to be followed by the contract-acceptor and the manner in which the qualified person responsible for certifying each batch is to discharge his responsibilities.

3. The contract-acceptor shall not subcontract any of the work entrusted to him under the contract without written authorisation from the contract-giver.

4. The contract-acceptor shall comply with the principles and guidelines of good manufacturing practice and shall submit to inspections carried out by the competent authorities pursuant to Article 111 of Directive 2001/83/EC and Article 15 of Directive 2001/20/EC.

Article 13

Complaints, product recall and emergency unblinding

1. In the case of medicinal products, the manufacturer shall implement a system for recording and reviewing complaints together with an effective system for recalling, promptly and at any time, medicinal products in the distribution network. Any complaint concerning a defect shall be recorded and investigated by the manufacturer. The manufacturer shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply and, in so far as is possible, indicate the countries of destination.

Any recall shall be made in accordance with the requirements referred to in Article 123 of Directive 2001/83/EC.

2. In the case of investigational medicinal products, the manufacturer shall, in cooperation with the sponsor, implement a system for recording and reviewing complaints together with an effective system for recalling promptly and at any time investigational medicinal products which have already entered the distribution network. The manufacturer shall record and investigate any complaint concerning a defect and shall inform the competent authority of any defect that could result in a recall or abnormal restriction on supply.

In the case of investigational medicinal products, all trial sites shall be identified and, in so far as is possible, the countries of destination shall be indicated.

In the case of an investigational medicinal product for which a marketing authorisation has been issued, the manufacturer of the investigational medicinal product shall, in cooperation with the sponsor, inform the marketing authorisation holder of any defect that could be related to the authorised medicinal product.

3. The sponsor shall implement a procedure for the rapid unblinding of blinded products, where this is necessary for a prompt recall as referred to in paragraph 2. The sponsor shall ensure that the procedure discloses the identity of the blinded product only in so far as is necessary.

Article 14

Self-inspection

The manufacturer shall conduct repeated self-inspections as part of the quality assurance system in order to monitor the implementation and respect of good manufacturing practice and to propose any necessary corrective measures. Records shall be maintained of such self-inspections and any corrective action subsequently taken.

*Article 15***Labelling**

In the case of an investigational medicinal product, labelling shall be such as to ensure protection of the subject and traceability, to enable identification of the product and trial, and to facilitate proper use of the investigational medicinal product.

*Article 16***Repeal of Directive 91/356/EEC**

Directive 91/356/EEC is repealed.

References to the repealed Directive shall be construed as references to this Directive.

*Article 17***Transposition**

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 30 April 2004 at the latest. They shall forthwith communicate to the Commission the text of the provisions and correlation table between those provisions and the provisions of this Directive.

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

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

*Article 18***Entry into force**

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

*Article 19***Addressees**

This Directive is addressed to the Member States.

Done at Brussels, 8 October 2003.

For the Commission

Erkki LIIKANEN

Member of the Commission

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 30 September 2003

concerning the validity of certain binding tariff information

(notified under document number C(2003) 3516)

(Only the Finnish and Swedish texts are authentic)

(2003/726/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾, as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council ⁽²⁾, and in particular Article 12(5)(a)(iii) and Article 248 thereof,

Having regard to Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽³⁾, as last amended by Regulation (EC) No 1335/2003 ⁽⁴⁾, and in particular the second indent of Article 9(1) thereof,

Whereas:

(1) The binding tariff information referred to in the Annex is inconsistent with other binding tariff information, and the tariff classification it contains is incompatible with the general rules for the interpretation of the Combined Nomenclature set out in Part I, Section I A of Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽⁵⁾, as last amended by Commission Regulation (EC) No 2176/2002 ⁽⁶⁾.

(2) The binding tariff information referred to in the Annex concerns a woven fabric, cut to the length, of synthetic filaments (34 % polyester, 52 % polyamides with 14 % polyurethane coating). As the coating is not visible to the naked eye, this fabric has to be classified under heading 5407, by application of General Rules 1 and 6 for the interpretation of the Combined Nomenclature and note 2(a)(1) to Chapter 59.

(3) The said binding tariff information should cease to be valid. The customs administration which issued the information should therefore revoke it as soon as possible and notify the Commission to that effect.

(4) According to Article 12(6) of Regulation (EEC) No 2913/92 the holder should be given, during a certain period of time, the possibility of invoking binding tariff information which has ceased to be valid subject to the conditions laid down in Article 14(1) of Regulation (EEC) No 2454/93.

(5) The measures provided for in this Decision are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. The binding tariff information referred to in column 1 of the table set out in the Annex, which has been issued by the customs authorities specified in column 2 for the tariff classification specified in column 3 shall cease to be valid.

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 311, 12.12.2000, p. 17.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 187, 26.7.2003, p. 16.

⁽⁵⁾ OJ L 256, 7.9.1987, p. 1.

⁽⁶⁾ OJ L 331, 7.12.2002, p. 3.

2. The customs authorities specified in column 2 shall revoke the BTI referred to in column 1 at the earliest possible date and in any case not later than 10 days from the notification of this Decision.

3. The customs authority which revokes the binding tariff information shall notify this to the Commission.

Article 2

The binding tariff information referred to in the Annex can continue to be invoked under Article 12(6) of Regulation (EEC) No 2913/92 for a certain period of time provided that the conditions laid down in Article 14(1) of Regulation (EEC) No 2454/93 are met.

Article 3

This Decision is addressed to the Republic of Finland.

Done at Brussels, 30 September 2003.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

ANNEX

	Binding Tariff Information (reference)	Customs authority	Tariff classification
	1	2	3
1	FI 178/301/01	Tullihallitus Helsinki Finland	5903 20 90 90

COMMISSION DECISION
of 30 September 2003
concerning the validity of certain binding tariff information

(notified under document number C(2003) 3544)

(Only the English text is authentic)

(2003/727/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾, as last amended by Regulation (EC) No 2700/2000 of the European Parliament and of the Council ⁽²⁾, and in particular Article 12(5)(a)(iii) and Article 248 thereof,

Having regard to Commission Regulation (EEC) No 2454/93 of 2 July 1993 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code ⁽³⁾, as last amended by Regulation (EC) No 1335/2003 ⁽⁴⁾, and in particular the second indent of Article 9(1) thereof,

Whereas:

- (1) The binding tariff information referred to in the Annex is inconsistent with other binding tariff information, and the tariff classification it contains is incompatible with the general rules for the interpretation of the Combined Nomenclature set out in Part I, Section IA of Annex I to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽⁵⁾, as last amended by Commission Regulation (EC) No 2176/2002 ⁽⁶⁾.
- (2) The binding tariff information referred to in the Annex concerns garments intended to cover the lower part of the body, enclosing each leg separately. The garments are not in accordance with the definition for pyjamas as set out in the Explanatory Notes to the Combined Nomenclature, subheadings 6107 21 00 to 6107 29 00, 6108 31 10 to 6108 39 00, 6207 21 00 to 6207 29 00 and 6208 21 00 to 6208 29 00, which state that pyjamas have to consist of two garments. Furthermore, they cannot be regarded as 'similar articles' to the products mentioned under headings 6107, 6108, 6207 and 6208 as they only cover the lower part of the body. The articles in question are therefore regarded as 'trousers' and should be classified within CN headings 6103,

6104, 6203 or 6204, by application of General Rules 1 and 6 for the interpretation of the Combined Nomenclature.

- (3) The said binding tariff information should cease to be valid. The customs administration which issued the information should therefore revoke it as soon as possible and notify the Commission to that effect.
- (4) According to Article 12(6) of Regulation (EEC) No 2913/92 the holder should be given, during a certain period of time, the possibility of invoking binding tariff information which has ceased to be valid, subject to the conditions laid down in Article 14(1) of Regulation (EEC) No 2454/93.
- (5) The measures provided for in this Decision are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS DECISION:

Article 1

1. The binding tariff information referred to in column 1 of the table set out in the Annex, which has been issued by the customs authorities specified in column 2 for the tariff classification specified in column 3 shall cease to be valid.
2. The customs authorities specified in column 2 shall revoke the BTI referred to in column 1 at the earliest possible date and in any case not later than 10 days from the notification of this Decision.
3. The customs authority which revokes the binding tariff information shall notify this to the Commission.

Article 2

The binding tariff information referred to in the Annex can continue to be invoked under Article 12(6) of Regulation (EEC) No 2913/92 for a certain period of time provided that the conditions laid down in Article 14(1) of Regulation (EEC) No 2454/93 are met.

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 311, 12.12.2000, p. 17.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 187, 26.7.2003, p. 16.

⁽⁵⁾ OJ L 256, 7.9.1987, p. 1.

⁽⁶⁾ OJ L 331, 7.12.2002, p. 3.

Article 3

This Decision is addressed to the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 30 September 2003.

For the Commission
Frederik BOLKESTEIN
Member of the Commission

ANNEX

	Binding Tariff Information (reference)	Customs authority	Tariff classification
	1	2	3
1	UK 105599852	HM Customs & Excise Southend-on-Sea United Kingdom	6107 91 90
2	UK 105594965	HM Customs & Excise Southend-on-Sea United Kingdom	6107 91 90
3	UK 103848774	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
4	UK 104570502	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
5	UK 105343411	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
6	UK 105434701	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
7	UK 106483971	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
8	UK 106485867	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90
9	UK 107265781	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
10	UK 107278572	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
11	UK 107277771	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
12	UK 107279177	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
13	UK 107277477	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
14	UK 107494566	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
15	UK 109015800	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
16	UK 109074680	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90

	Binding Tariff Information (reference)	Customs authority	Tariff classification
	1	2	3
17	UK 109844358	HM Customs & Excise Southend-on-Sea United Kingdom	6207 91 90 90
18	UK 102018833	HM Customs & Excise Southend-on-Sea United Kingdom	6207 92 00
19	UK 102673989	HM Customs & Excise Southend-on-Sea United Kingdom	6207 92 00
20	UK 102769088	HM Customs & Excise Southend-on-Sea United Kingdom	6207 92 00
21	UK 106260215	HM Customs & Excise Southend-on-Sea United Kingdom	6207 92 00
22	UK 107653575	HM Customs & Excise Southend-on-Sea United Kingdom	6207 92 00
23	UK 104515217	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
24	UK 104602617	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
25	UK 105129215	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
26	UK 105215912	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
27	UK 105272407	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
28	UK 105465685	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
29	UK 105934087	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
30	UK 106640496	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
31	UK 106917766	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
32	UK 107064305	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90

	Binding Tariff Information (reference)	Customs authority	Tariff classification
	1	2	3
33	UK 107702300	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
34	UK 108713090	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
35	UK 108713580	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
36	UK 109149378	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
37	UK 109241887	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
38	UK 109275667	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
39	UK 109776051	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
40	UK 110099803	HM Customs & Excise Southend-on-Sea United Kingdom	6208 91 90
41	UK 105995942	HM Customs & Excise Southend-on-Sea United Kingdom	6208 92 00

COMMISSION DECISION

of 3 October 2003

on the procedure for attesting the conformity of construction products pursuant to Article 20(2) of Council Directive 89/106/EEC as regards metal frame building kits, concrete frame building kits, prefabricated building units, cold storage room kits and rock-fall protection kits

*(notified under document number C(2003) 3452)***(Text with EEA relevance)**

(2003/728/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/106/EEC of 21 December 1988 on the approximation of laws, regulations and administrative provisions of the Member States relating to construction products ⁽¹⁾, as amended by Directive 93/68/EEC ⁽²⁾, and in particular Article 13(4) thereof,

Whereas:

- (1) The Commission is required to select, between the two procedures under Article 13(3) of Directive 89/106/EEC for attesting the conformity of a product, the least onerous possible procedure consistent with safety. Whereas this means that it is necessary to decide whether, for a given product or family of products, the existence of a factory production control system under the responsibility of the manufacturer is a necessary and sufficient condition for an attestation of conformity, or whether, for reasons related to compliance with the criteria mentioned in Article 13(4), the intervention of an approved certification body is required.
- (2) Article 13(4) requires that the procedure thus determined shall be indicated in the mandates and in the technical specifications. Therefore, it is desirable to define the concept of products or family of products as used in the mandates and in the technical specifications.
- (3) The two procedures provided for in Article 13(3) are described in detail in Annex III to Directive 89/106/EEC. It is necessary therefore to specify clearly the methods by which the two procedures shall be implemented, by reference to Annex III, for each product or family of products, since Annex III gives preference to certain systems.
- (4) The procedure referred to in Article 13(3)(a) corresponds to the systems set out in the first possibility, without continuous surveillance, and the second and third possi-

bilities of Annex III(2)(ii). The procedure referred to in Article 13(3)(b) corresponds to the systems set out in Annex III(2)(i), and in the first possibility, with continuous surveillance, of III(2)(ii).

- (5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Construction,

HAS ADOPTED THIS DECISION:

Article 1

The products and families of products set out in Annex I shall have their conformity attested by a procedure whereby, in addition to a factory production control system operated by the manufacturer, an approved certification body is involved in assessment and surveillance of the production control and the product itself.

Article 2

The procedure for attesting conformity as set out in Annex II shall be indicated in the mandates for Guidelines for European technical approvals.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 3 October 2003.

For the Commission

Erkki LIIKANEN

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 12.

⁽²⁾ OJ L 220, 30.8.1993, p. 1.

ANNEX I

1. Metal frame building kits

This Decision covers those industrially prepared kits, marketed as a building, that are made of predesigned and prefabricated components intended for production in series. This Decision covers only those kits for which the minimum requirements defined below are met. Partial kits falling below these minimum requirements are outside the scope of this Decision. The minimum requirements comprise all of the following: the structural elements of the building, the connection of the building to the substructure and the specification of the essential components of the external envelope as thermal insulation, cladding, roof covering, internal lining, windows and external doors in so far as they are necessary for the satisfaction of the essential requirements applied to the building.

Although some components may be prepared in different factories, only the final kit for delivery, and not the different components, are considered by this Decision.

— *for use in building works*

2. Concrete frame building kits

This Decision covers those industrially prepared kits, marketed as a building, that are made of predesigned and prefabricated components intended for production in series. This Decision covers only those kits for which the minimum requirements defined below are met. Partial kits falling below these minimum requirements are outside the scope of this Decision. The minimum requirements comprise all of the following: the structural elements of the building, the connection of the building to the substructure and the specification of the essential components of the external envelope as thermal insulation, cladding, roof covering, internal lining, windows and external doors in so far as they are necessary for the satisfaction of the essential requirements applied to the building.

Although some components may be prepared in different factories, only the final kit for delivery, and not the different components, are considered by this Decision.

— *for use in building works*

3. Prefabricated building units

This Decision covers prefabricated building units capable of being transported to site in self-contained or volumetric format and rapidly providing a weatherproof envelope, possibly subject to final weatherproofing, jointing between units, connection to services and any foundation connections.

Although some components may be prepared in different factories, only the final kit for delivery, and not the different components, are considered by this Decision.

— *for use in building works*

4. Cold storage room kits

This Decision covers prefabricated cold storage room kits for installation inside an existing building or at least protected from external climate exposure, i.e. the cold storage room kits are not exposed to an external climate. The assembled kits do not contribute to the load-bearing capacity of the works, but a load-bearing supporting system may be foreseen, to support the whole assembled kit or parts of it. The technical equipment (e.g. cooling systems) is excluded.

Although some components may be prepared in different factories, only the final kit for delivery, and not the different components, are considered by this Decision.

— *for use in building works*

5. Rock-fall protection kits

This Decision covers rock-fall protection kits consisting of a single or multiple net or mesh or similar, supported by a metallic or wooden structure (e.g. metal posts) and, possibly, cables.

Although some components may be prepared in different factories, only the final kit for delivery, and not the different components, are considered by this Decision.

— *for use in civil engineering works*

ANNEX II

Systems of attestation of conformity

For the product(s) and intended use(s) listed below, EOTA is requested to specify the following system(s) of attestation of conformity in the relevant guideline for European technical approvals:

Product(s) (as defined in Annex I)	Intended use(s)	Level(s) or class(es) (reaction to fire)	Attestation of conformity system(s)
Metal frame building kits Concrete frame building kits Prefabricated building units Cold storage room kits	In building works	Any	1
Rockfall protection kits	In civil engineering works	Any	1

System 1: see Directive 89/106/EEC Annex III.2.(i), without audit-testing of samples.

The specification for the system should be such that it can be implemented even where performance does not need to be determined for a certain characteristic, because at least one Member State has no legal requirement at all for such characteristic (see Article 2(1) of Directive 89/106/EEC and, where applicable, clause 1.2.3 of the interpretative document).

In those cases the verification of such a characteristic must not be imposed on the manufacturer if he does not wish to declare the performance of the product in that respect.

COMMISSION DECISION

of 6 October 2003

amending Decision 2002/300/EC establishing the list of approved zones with regard to *Bonamia ostreae* and/or *Marteilia refringens*

(notified under document number C(2003) 3463)

(Text with EEA relevance)

(2003/729/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products ⁽¹⁾, as last amended by Regulation (EC) No 806/2003 ⁽²⁾, and in particular Article 5 thereof,

Whereas:

- (1) Commission Decision 2002/300/EC ⁽³⁾, as last amended by Decision 2003/378/EC ⁽⁴⁾, lays down the areas in Ireland considered to be free of the diseases *Bonamia ostreae* and/or *Marteilia refringens*.
- (2) Ireland informed the Commission by letter dated 24 June 2003 of the detection of *Bonamia ostreae* at the Blacksod Bay on the County Mayo coastline, an area previously considered to be free of that disease. That area can therefore no longer be considered free of *Bonamia ostreae*.
- (3) Decision 2002/300/EC should therefore be amended accordingly.

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

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 2002/300/EC is replaced by the text in the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 October 2003.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 46, 19.2.1991, p. 1.⁽²⁾ OJ L 122, 16.5.2003, p. 1.⁽³⁾ OJ L 103, 19.4.2002, p. 24.⁽⁴⁾ OJ L 130, 27.5.2003, p. 27.

ANNEX

‘ANNEX

ZONES APPROVED FOR ONE OR MORE OF THE MOLLUSC DISEASES *BONAMIA OSTREA* AND *MARTELLIA REFRINGENS***1.A. Zones in Ireland approved with regard to *B. Ostreae***

- The whole coastline of Ireland except the following six areas:
 - Cork Harbour
 - Galway Bay
 - Ballinakill Harbour
 - Clew Bay
 - Achill Sound
 - Loughmore, Blacksod Bay

1.B. Zones in Ireland approved with regard to *M. Refringens*

- The whole coastline of Ireland

2.A. Zones in the United Kingdom, the Channel Islands and the Isle of Man approved with regard to *B. Ostreae*

- The whole coastline of Great Britain, except the following areas:
 - the south coast of Cornwall from the Lizard to Start Point
 - the area around the Solent estuary from Portland Bill to Selsey Bill
 - the area along the coast in Essex from Shoeburyness to Landguard point.
- The whole coastline of Northern Ireland
- The whole coastline of Guernsey and Herm
- The zone of the States of Jersey: the zone consists of the intertidal and immediate coastal area between the mean high-water mark on the Island of Jersey and an imaginary line drawn three nautical miles from the mean low-water mark of the Island of Jersey. The zone is situated in the Normano-Breton Gulf, on the south side of the English Channel
- The whole coastline of the Isle of Man

2.B. Zones in the United Kingdom, the Channel Islands and the Isle of Man approved with regard to *M. Refringens*

- The whole coastline of Great Britain
 - The whole coastline of Northern Ireland
 - The whole coastline of Guernsey and Herm
 - The zone of the States of Jersey: the zone consists of the intertidal and immediate coastal area between the mean high-water mark on the Island of Jersey and an imaginary line drawn three nautical miles from the mean low-water mark of the Island of Jersey. The zone is situated in the Normano-Breton Gulf, on the south side of the English Channel
 - The whole coastline of the Isle of Man
-