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I Acts whose publication is obligatory

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⁽¹⁾ Text with EEA relevance

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 212/2006
of 8 February 2006
establishing the standard import values for determining the entry price of certain fruit and vegetables

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

(1) Regulation (EC) No 3223/94 lays down, pursuant to the outcome of the Uruguay Round multilateral trade negotiations, the criteria whereby the Commission fixes the

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 337, 24.12.1994, p. 66. Regulation as last amended by Regulation (EC) No 386/2005 (OJ L 62, 9.3.2005, p. 3).

ANNEX

to Commission Regulation of 8 February 2006 establishing the standard import values for determining the entry price of certain fruit and vegetables

| <i>(EUR/100 kg)</i> | | |
|---|-----------------------------------|-----------------------|
| CN code | Third country code ⁽¹⁾ | Standard import value |
| 0702 00 00 | 052 | 84,2 |
| | 204 | 47,8 |
| | 212 | 113,2 |
| | 624 | 111,0 |
| | 999 | 89,1 |
| 0707 00 05 | 052 | 98,6 |
| | 204 | 101,8 |
| | 628 | 167,7 |
| | 999 | 122,7 |
| 0709 10 00 | 220 | 72,5 |
| | 624 | 101,9 |
| | 999 | 87,2 |
| 0709 90 70 | 052 | 158,8 |
| | 204 | 99,3 |
| | 999 | 129,1 |
| 0805 10 20 | 052 | 53,6 |
| | 204 | 51,8 |
| | 212 | 46,9 |
| | 220 | 42,6 |
| | 448 | 47,8 |
| | 624 | 60,7 |
| | 999 | 50,6 |
| 0805 20 10 | 204 | 89,3 |
| | 999 | 89,3 |
| 0805 20 30, 0805 20 50, 0805 20 70, 0805 20 90 | 052 | 61,1 |
| | 204 | 110,2 |
| | 400 | 79,6 |
| | 464 | 145,9 |
| | 624 | 92,1 |
| | 662 | 45,3 |
| | 999 | 89,0 |
| 0805 50 10 | 052 | 52,1 |
| | 999 | 52,1 |
| 0808 10 80 | 400 | 133,2 |
| | 404 | 103,9 |
| | 720 | 86,4 |
| | 999 | 107,8 |
| 0808 20 50 | 388 | 89,3 |
| | 400 | 82,4 |
| | 528 | 111,0 |
| | 720 | 45,5 |
| | 999 | 82,1 |

⁽¹⁾ Country nomenclature as fixed by Commission Regulation (EC) No 750/2005 (OJ L 126, 19.5.2005, p. 12). Code '999' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 213/2006
of 8 February 2006
fixing the export refunds on poultrymeat

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organisation of the market in poultrymeat⁽¹⁾, and in particular the third subparagraph of Article 8(3) thereof,

Whereas:

- (1) Article 8(1) of Regulation (EEC) No 2777/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that Regulation and prices for those products on the Community market may be covered by an export refund.
- (2) Given the present situation on the market in poultrymeat, export refunds should therefore be fixed in accordance with the rules and criteria provided for in Article 8 of Regulation (EEC) No 2777/75.
- (3) Article 8(3), second subparagraph of Regulation (EEC) No 2777/75 provides that the world market situation or the specific requirements of certain markets may make it necessary to vary the refund according to destination.
- (4) Refunds should be granted only on products that are allowed to move freely in the Community and that bear the identification mark as provided for in Article

5(1)(b) of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin⁽²⁾. Those products should also comply with the requirements of Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs⁽³⁾.

- (5) The Management Committee for Poultrymeat and Eggs has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

1. Export refunds as provided for in Article 8 of Regulation (EEC) No 2777/75 shall be granted on the products and for the amounts set out in the Annex to this Regulation subject to the condition provided for in paragraph 2 of this Article.

2. The products eligible for a refund under paragraph 1 must meet the relevant requirements of Regulations (EC) No 852/2004 and (EC) No 853/2004, notably preparation in an approved establishment and compliance with the identification marking requirements laid down in Annex II, Section I to Regulation (EC) No 853/2004.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 282, 1.11.1975, p. 77. Regulation as last amended by Regulation (EC) No 1913/2005 (OJ L 307, 25.11.2005, p. 2).

⁽²⁾ OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22.

⁽³⁾ OJ L 139, 30.4.2004, p. 1, as corrected by OJ L 226, 25.6.2004, p. 3.

ANNEX

Export refunds on poultrymeat applicable from 9 February 2006

| Product code | Destination | Unit of measurement | Amount of refund |
|-----------------|-------------|---------------------|------------------|
| 0105 11 11 9000 | A02 | EUR/100 pcs | 0,80 |
| 0105 11 19 9000 | A02 | EUR/100 pcs | 0,80 |
| 0105 11 91 9000 | A02 | EUR/100 pcs | 0,80 |
| 0105 11 99 9000 | A02 | EUR/100 pcs | 0,80 |
| 0105 12 00 9000 | A02 | EUR/100 pcs | 1,60 |
| 0105 19 20 9000 | A02 | EUR/100 pcs | 1,60 |
| 0207 12 10 9900 | V03 | EUR/100 kg | 26,00 |
| 0207 12 90 9190 | V03 | EUR/100 kg | 26,00 |
| 0207 12 90 9990 | V03 | EUR/100 kg | 26,00 |
| 0207 14 20 9900 | V03 | EUR/100 kg | 10,00 |
| 0207 14 60 9900 | V03 | EUR/100 kg | 10,00 |
| 0207 14 70 9190 | V03 | EUR/100 kg | 10,00 |
| 0207 14 70 9290 | V03 | EUR/100 kg | 10,00 |

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 750/2005 (OJ L 126, 19.5.2005, p. 12).

The other destinations are defined as follows:

V03 A24, Angola, Saudi Arabia, Kuwait, Bahrain, Qatar, Oman, United Arab Emirates, Jordan, Yemen, Lebanon, Iraq and Iran.

COMMISSION REGULATION (EC) No 214/2006**of 7 February 2006****establishing unit values for the determination of the customs value of certain perishable goods**

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⁾,

Having regard to Commission Regulation (EEC) No 2454/93 ⁽²⁾ laying down provisions for the implementation of Regulation (EEC) No 2913/92, and in particular Article 173(1) thereof,

Whereas:

- (1) Articles 173 to 177 of Regulation (EEC) No 2454/93 provide that the Commission shall periodically establish unit values for the products referred to in the classification in Annex 26 to that Regulation.

- (2) The result of applying the rules and criteria laid down in the abovementioned Articles to the elements communicated to the Commission in accordance with Article 173(2) of Regulation (EEC) No 2454/93 is that unit values set out in the Annex to this Regulation should be established in regard to the products in question,

HAS ADOPTED THIS REGULATION:

Article 1

The unit values provided for in Article 173(1) of Regulation (EEC) No 2454/93 are hereby established as set out in the table in the Annex hereto.

Article 2

This Regulation shall enter into force on 10 February 2006.

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

Done at Brussels, 7 February 2006.

For the Commission
Günter VERHEUGEN
Vice-President

⁽¹⁾ OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 648/2005 (OJ L 117, 4.5.2005, p. 13).

⁽²⁾ OJ L 253, 11.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 883/2005 (OJ L 148, 11.6.2005, p. 5).

ANNEX

| Code | Description Species, varieties, CN code | Amount of unit values per 100 kg | | | | | |
|-------|--|----------------------------------|-------------------|------------|------------|------------|------------|
| | | EUR LTL SEK | CYP LVL GBP | CZK MTL | DKK PLN | EEK SIT | HUF SKK |
| 1.10 | New potatoes 0701 90 50 | 42,82 | 24,57 | 1 221,30 | 319,61 | 669,93 | 10 749,96 |
| | | 147,84 | 29,80 | 18,38 | 164,12 | 10 252,86 | 1 599,84 |
| | | 397,25 | 29,08 | | | | |
| 1.30 | Onions (other than seed) 0703 10 19 | 23,69 | 13,60 | 675,73 | 176,84 | 370,67 | 5 947,85 |
| | | 81,80 | 16,49 | 10,17 | 90,80 | 5 672,81 | 885,18 |
| | | 219,80 | 16,09 | | | | |
| 1.40 | Garlic 0703 20 00 | 166,64 | 95,64 | 4 753,27 | 1 243,91 | 2 607,36 | 41 838,53 |
| | | 575,38 | 115,98 | 71,54 | 638,73 | 39 903,83 | 6 226,54 |
| | | 1 546,09 | 113,17 | | | | |
| 1.50 | Leeks ex 0703 90 00 | 73,65 | 42,27 | 2 100,72 | 549,75 | 1 152,33 | 18 490,65 |
| | | 254,29 | 51,26 | 31,62 | 282,29 | 17 635,61 | 2 751,84 |
| | | 683,30 | 50,01 | | | | |
| 1.60 | Cauliflowers 0704 10 00 | — | — | — | — | — | — |
| 1.80 | White cabbages and red cabbages 0704 90 10 | 48,65 | 27,92 | 1 387,69 | 363,15 | 761,21 | 12 214,56 |
| | | 167,98 | 33,86 | 20,89 | 186,48 | 11 649,73 | 1 817,81 |
| | | 451,37 | 33,04 | | | | |
| 1.90 | Sprouting broccoli or calabrese (<i>Brassica oleracea</i> L. convar. <i>botrytis</i> (L.) Alef var. <i>italica</i> Plenck) ex 0704 90 90 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | | | | |
| 1.100 | Chinese cabbage ex 0704 90 90 | 100,54 | 57,70 | 2 867,80 | 750,49 | 1 573,11 | 25 242,58 |
| | | 347,14 | 69,98 | 43,16 | 385,37 | 24 075,31 | 3 756,68 |
| | | 932,81 | 68,28 | | | | |
| 1.110 | Cabbage lettuce (head lettuce) 0705 11 00 | — | — | — | — | — | — |
| 1.130 | Carrots ex 0706 10 00 | 38,44 | 22,06 | 1 096,46 | 286,94 | 601,46 | 9 651,13 |
| | | 132,73 | 26,75 | 16,50 | 147,34 | 9 204,84 | 1 436,31 |
| | | 356,65 | 26,10 | | | | |
| 1.140 | Radishes ex 0706 90 90 | 69,15 | 39,69 | 1 972,51 | 516,20 | 1 082,01 | 17 362,19 |
| | | 238,77 | 48,13 | 29,69 | 265,06 | 16 559,33 | 2 583,89 |
| | | 641,60 | 46,96 | | | | |
| 1.160 | Peas (<i>Pisum sativum</i>) 0708 10 00 | 426,42 | 244,72 | 12 163,24 | 3 183,06 | 6 672,04 | 107 061,55 |
| | | 1 472,35 | 296,79 | 183,06 | 1 634,47 | 102 110,80 | 15 933,22 |
| | | 3 956,33 | 289,58 | | | | |

| Code | Description Species, varieties, CN code | Amount of unit values per 100 kg | | | | | |
|---------|---|----------------------------------|----------------------------|---------------------|----------------------|------------------------|-------------------------|
| | | EUR LTL SEK | CYP LVL GBP | CZK MTL | DKK PLN | EKK SIT | HUF SKK |
| 1.170 | Beans: | | | | | | |
| 1.170.1 | — Beans (<i>Vigna</i> spp., <i>Phaseolus</i> spp.) ex 0708 20 00 | 191,84 662,37 1 779,86 | 110,10 133,52 130,28 | 5 471,96 82,36 | 1 431,99 735,31 | 3 001,60 45 937,26 | 48 164,49 7 167,99 |
| 1.170.2 | — Beans (<i>Phaseolus</i> spp., <i>vulgaris</i> var. <i>Compressus Savi</i>) ex 0708 20 00 | 432,00 1 491,61 4 008,10 | 247,92 300,67 293,37 | 12 322,37 185,46 | 3 224,71 1 655,86 | 6 759,33 103 446,72 | 108 462,24 16 141,68 |
| 1.180 | Broad beans ex 0708 90 00 | — | — | — | — | — | — |
| 1.190 | Globe artichokes 0709 10 00 | — | — | — | — | — | — |
| 1.200 | Asparagus: | | | | | | |
| 1.200.1 | — green ex 0709 20 00 | 263,01 908,11 2 440,19 | 150,94 183,05 178,61 | 7 502,03 112,91 | 1 963,25 1 008,11 | 4 115,18 62 979,85 | 66 033,37 9 827,29 |
| 1.200.2 | — other ex 0709 20 00 | 172,09 594,19 1 596,65 | 98,76 119,77 116,87 | 4 908,70 73,88 | 1 284,58 659,62 | 2 692,62 41 208,67 | 43 206,64 6 430,14 |
| 1.210 | Aubergines (eggplants) 0709 30 00 | 186,94 645,47 1 734,43 | 107,28 130,11 126,95 | 5 332,28 80,25 | 1 395,43 716,54 | 2 924,98 44 764,65 | 46 935,03 6 985,01 |
| 1.220 | Ribbed celery (<i>Apium graveolens</i> L., var. <i>dulce</i> (Mill.) Pers.) ex 0709 40 00 | 67,46 232,92 625,87 | 38,71 46,95 45,81 | 1 924,16 28,96 | 503,54 258,57 | 1 055,48 16 153,42 | 16 936,60 2 520,56 |
| 1.230 | Chantarelles 0709 59 10 | 334,34 1 154,41 3 102,01 | 191,88 232,70 227,05 | 9 536,71 143,53 | 2 495,71 1 281,53 | 5 231,28 80 061,06 | 83 942,74 12 492,61 |
| 1.240 | Sweet peppers 0709 60 10 | 128,43 443,44 1 191,57 | 73,71 89,39 87,22 | 3 663,31 55,13 | 958,67 492,27 | 2 009,48 30 753,63 | 32 244,69 4 798,75 |
| 1.250 | Fennel 0709 90 50 | — | — | — | — | — | — |
| 1.270 | Sweet potatoes, whole, fresh (intended for human consumption) 0714 20 10 | 78,30 270,37 726,51 | 44,94 54,70 53,18 | 2 233,55 33,62 | 584,51 300,14 | 1 225,19 18 750,70 | 19 659,81 2 925,83 |
| 2.10 | Chestnuts (<i>Castanea</i> spp.) fresh ex 0802 40 00 | — | — | — | — | — | — |
| 2.30 | Pineapples, fresh ex 0804 30 00 | 59,70 206,12 553,88 | 34,26 41,55 40,54 | 1 702,82 25,63 | 445,62 228,82 | 934,07 14 295,26 | 14 988,35 2 230,61 |

| Code | Description Species, varieties, CN code | Amount of unit values per 100 kg | | | | | |
|--------|--|----------------------------------|-------------------|------------|------------|------------|------------|
| | | EUR LTL SEK | CYP LVL GBP | CZK MTL | DKK PLN | EEK SIT | HUF SKK |
| 2.40 | Avocados, fresh ex 0804 40 00 | 181,73 | 104,29 | 5 183,58 | 1 356,52 | 2 843,41 | 45 626,20 |
| | | 627,47 | 126,48 | 78,02 | 696,56 | 43 516,35 | 6 790,23 |
| | | 1 686,06 | 123,41 | | | | |
| 2.50 | Guavas and mangoes, fresh ex 0804 50 | — | — | — | — | — | — |
| 2.60 | Sweet oranges, fresh: | | | | | | |
| 2.60.1 | — Sanguines and semi-sanguines ex 0805 10 20 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.60.2 | — Navels, navelines, navelates, salustianas, vernas, Valencia lates, Maltese, shamoutis, ovalis, trovita and hamlins ex 0805 10 20 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.60.3 | — Others ex 0805 10 20 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.70 | Mandarins (including tangerines and satsumas), fresh; clementines, wilkins and similar citrus hybrids, fresh: | | | | | | |
| 2.70.1 | — Clementines ex 0805 20 10 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.70.2 | — Monreales and satsumas ex 0805 20 30 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.70.3 | — Mandarines and wilkins ex 0805 20 50 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.70.4 | — Tangerines and others ex 0805 20 70 ex 0805 20 90 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.85 | Limes (<i>Citrus aurantifolia</i> , <i>Citrus latifolia</i>), fresh 0805 50 90 | 75,00 | 43,04 | 2 139,20 | 559,82 | 1 173,44 | 18 829,35 |
| | | 258,95 | 52,20 | 32,20 | 287,46 | 17 958,64 | 2 802,24 |
| | | 695,82 | 50,93 | | | | |
| 2.90 | Grapefruit, fresh: | | | | | | |
| 2.90.1 | — white ex 0805 40 00 | 73,83 | 42,37 | 2 105,80 | 551,08 | 1 155,12 | 18 535,37 |
| | | 254,90 | 51,38 | 31,69 | 282,97 | 17 678,25 | 2 758,49 |
| | | 684,95 | 50,13 | | | | |
| 2.90.2 | — pink ex 0805 40 00 | 82,02 | 47,07 | 2 339,48 | 612,23 | 1 283,30 | 20 592,21 |
| | | 283,19 | 57,08 | 35,21 | 314,37 | 19 639,98 | 3 064,60 |
| | | 760,96 | 55,70 | | | | |

| Code | Description | Amount of unit values per 100 kg | | | | | |
|---------|---|----------------------------------|-------------------|------------|------------|------------|------------|
| | Species, varieties, CN code | EUR LTL SEK | CYP LVL GBP | CZK MTL | DKK PLN | EEK SIT | HUF SKK |
| 2.100 | Table grapes 0806 10 10 | 163,85 | 94,04 | 4 673,79 | 1 223,11 | 2 563,77 | 41 138,97 |
| | | 565,76 | 114,04 | 70,34 | 628,05 | 39 236,62 | 6 122,43 |
| | | 1 520,24 | 111,27 | | | | |
| 2.110 | Water melons 0807 11 00 | 63,37 | 36,37 | 1 807,57 | 473,03 | 991,53 | 15 910,31 |
| | | 218,80 | 44,11 | 27,20 | 242,90 | 15 174,58 | 2 367,82 |
| | | 587,95 | 43,03 | | | | |
| 2.120 | Melons (other than water melons): | | | | | | |
| 2.120.1 | — Amarillo, cuper, honey dew (including cantalene), onte- niente, piel de sapo (including verde liso), rochet, tendral, futuro ex 0807 19 00 | 46,72 | 26,81 | 1 332,68 | 348,76 | 731,03 | 11 730,34 |
| | | 161,32 | 32,52 | 20,06 | 179,08 | 11 187,91 | 1 745,75 |
| | | 433,48 | 31,73 | | | | |
| 2.120.2 | — Other ex 0807 19 00 | 92,06 | 52,83 | 2 625,91 | 687,19 | 1 440,42 | 23 113,40 |
| | | 317,86 | 64,07 | 39,52 | 352,86 | 22 044,59 | 3 439,81 |
| | | 854,13 | 62,52 | | | | |
| 2.140 | Pears | | | | | | |
| 2.140.1 | — Pears — nashi (<i>Pyrus pyrifolia</i>), Pears — Ya (<i>Pyrus bretschneideri</i>) ex 0808 20 50 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.140.2 | — Other ex 0808 20 50 | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| | | — | — | — | — | — | — |
| 2.150 | Apricots 0809 10 00 | 149,08 | 85,56 | 4 252,44 | 1 112,84 | 2 332,64 | 37 430,22 |
| | | 514,75 | 103,76 | 64,00 | 571,43 | 35 699,37 | 5 570,48 |
| | | 1 383,19 | 101,24 | | | | |
| 2.160 | Cherries 0809 20 05 0809 20 95 | 324,28 | 186,10 | 9 249,71 | 2 420,61 | 5 073,85 | 81 416,50 |
| | | 1 119,67 | 225,70 | 139,21 | 1 242,96 | 77 651,63 | 12 116,65 |
| | | 3 008,65 | 220,22 | | | | |
| 2.170 | Peaches 0809 30 90 | 188,34 | 108,09 | 5 372,11 | 1 405,86 | 2 946,83 | 47 285,65 |
| | | 650,29 | 131,08 | 80,85 | 721,89 | 45 099,06 | 7 037,19 |
| | | 1 747,39 | 127,90 | | | | |
| 2.180 | Nectarines ex 0809 30 10 | 150,11 | 86,15 | 4 281,85 | 1 120,54 | 2 348,77 | 37 689,10 |
| | | 518,31 | 104,48 | 64,44 | 575,39 | 35 946,27 | 5 609,01 |
| | | 1 392,76 | 101,94 | | | | |
| 2.190 | Plums 0809 40 05 | 165,49 | 94,97 | 4 720,37 | 1 235,30 | 2 589,32 | 41 549,00 |
| | | 571,40 | 115,18 | 71,04 | 634,31 | 39 627,68 | 6 183,45 |
| | | 1 535,39 | 112,38 | | | | |
| 2.200 | Strawberries 0810 10 00 | 254,12 | 145,84 | 7 248,44 | 1 896,88 | 3 976,07 | 63 801,26 |
| | | 877,42 | 176,87 | 109,09 | 974,03 | 60 850,95 | 9 495,10 |
| | | 2 357,70 | 172,57 | | | | |

| Code | Description Species, varieties, CN code | Amount of unit values per 100 kg | | | | | |
|-------|--|----------------------------------|-------------------|------------|------------|------------|------------|
| | | EUR LTL SEK | CYP LVL GBP | CZK MTL | DKK PLN | EEK SIT | HUF SKK |
| 2.205 | Raspberries 0810 20 10 | 530,81 | 304,63 | 15 140,82 | 3 962,28 | 8 305,37 | 133 270,47 |
| | | 1 832,78 | 369,44 | 227,88 | 2 034,59 | 127 107,76 | 19 833,72 |
| | | 4 924,86 | 360,47 | | | | |
| 2.210 | Fruit of the species <i>Vaccinium myrtillus</i> 0810 40 30 | 1 068,17 | 613,02 | 30 468,48 | 7 973,46 | 16 713,23 | 268 185,44 |
| | | 3 688,18 | 743,45 | 458,57 | 4 094,30 | 255 783,99 | 39 912,17 |
| | | 9 910,48 | 725,39 | | | | |
| 2.220 | Kiwi fruit (<i>Actinidia chinensis</i> Planch.) 0810 50 00 | 178,63 | 102,52 | 5 095,24 | 1 333,40 | 2 794,95 | 44 848,63 |
| | | 616,77 | 124,33 | 76,69 | 684,69 | 42 774,74 | 6 674,51 |
| | | 1 657,33 | 121,31 | | | | |
| 2.230 | Pomegranates ex 0810 90 95 | 140,90 | 80,86 | 4 019,03 | 1 051,76 | 2 204,61 | 35 375,76 |
| | | 486,50 | 98,07 | 60,49 | 540,07 | 33 739,91 | 5 264,73 |
| | | 1 307,27 | 95,69 | | | | |
| 2.240 | Khakis (including sharon fruit) ex 0810 90 95 | 181,50 | 104,16 | 5 177,03 | 1 354,80 | 2 839,82 | 45 568,53 |
| | | 626,67 | 126,32 | 77,92 | 695,68 | 43 461,34 | 6 781,65 |
| | | 1 683,93 | 123,25 | | | | |
| 2.250 | Lychees ex 0810 90 | — | — | — | — | — | — |

COMMISSION REGULATION (EC) No 215/2006

of 8 February 2006

amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code and amending Regulation (EC) No 2286/2003

(Text with EEA relevance)

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⁾, and in particular Article 247 thereof,

Whereas:

(1) Articles 173 to 177 of Commission Regulation (EEC) No 2454/93 ⁽²⁾ provide for specific rules for the determination of the customs value of certain perishable goods. The system in its current form has proved problematic, taking into account trade flows and general valuation rules. In order to simplify, in accordance with Article 19 of Regulation (EEC) No 2913/92, the application of customs legislation, this system should be replaced by a system whereby unit prices notified by the Member States and disseminated by the Commission may be directly used to determine the customs value of certain perishable goods imported on consignment.

(2) The information on the nature of the transaction recorded in box 24 of the Single Administrative Document identifies different types of transaction for the purposes of compiling statistics on trade of the Community with non-member countries and on trade between its Member States. The codes to be used for this information are laid down in the current Community rules on statistics, and in particular Commission Regulation (EC) No 1917/2000 of 7 September 2000 laying down certain provisions for the implementation of Council Regulation (EC) No 1172/95 as regards statistics on external trade ⁽³⁾. In the interests of consistency and efficiency, a reference should be made to these rules in respect of the codes to be entered in box 24 (Nature of the transaction) of the Single Administrative Document.

(3) Commission Regulation (EC) No 2286/2003 ⁽⁴⁾ introduced into Regulation (EEC) No 2454/93 new rules on the Single Administrative Document and its use. These measures were to be applied from 1 January 2006. Pursuant to Article 2 of Regulation (EC) No 2286/2003, the Commission has evaluated Member States' plans for implementation of the measures concerned on the basis of a report drawn up from contributions from Member States. This report shows that some Member States are not in a position to adapt their computer systems by 1 January 2006. It is therefore necessary to postpone, on certain conditions, the date of application of these measures to 1 January 2007.

(4) Regulations (EEC) No 2454/93 and (EC) No 2286/2003 should therefore be amended accordingly.

(5) The list of transactions laid down in Regulation (EC) No 1917/2000 to be used for entering codes in box 24 of the Single Administrative Document has been amended with effect from 1 January 2006. The deadline for the Member States to adapt their computer clearance systems expires on the same date. The related provisions of this Regulation should therefore apply from 1 January 2006.

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

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EEC) No 2454/93 is amended as follows:

1. In Article 152(1) the following point (a)a is inserted:

'(a)a The customs value of certain perishable goods imported on consignment may be directly determined in accordance with Article 30(2)(c) of the Code. For this purpose the unit prices shall be notified to the Commission by the Member States and disseminated by the Commission via TARIC in accordance with Article 6 of Council Regulation (EEC) No 2658/87 (*).

The unit prices shall be calculated and notified as follows:

⁽¹⁾ OJ L 302, 19.10.1992, p. 1. Regulation as last amended by Regulation (EC) No 648/2005 of the European Parliament and of the Council (OJ L 117, 4.5.2005, p. 13).

⁽²⁾ OJ L 253, 11.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 883/2005 (OJ L 148, 11.6.2005, p. 5).

⁽³⁾ OJ L 229, 9.9.2000, p. 14. Regulation as last amended by Regulation (EC) No 1949/2005 (OJ L 312, 29.11.2005, p. 10).

⁽⁴⁾ OJ L 343, 31.12.2003, p. 1.

- (i) After the deductions provided for in point (a), a unit price per 100 kg net for each category of goods shall be notified by the Member States to the Commission. The Member States may fix standard amounts for the costs referred to in point (a)(ii) which shall be made known to the Commission.
- (ii) The unit price may be used to determine the customs value of the imported goods for periods of 14 days, each period beginning on a Friday.
- (iii) The reference period for determining the unit prices shall be the preceding period of 14 days which ends on the Thursday preceding the week during which new unit prices are to be established.
- (iv) The unit prices shall be notified by the Member States to the Commission in euro not later than 12 noon on the Monday of the week in which they are disseminated by the Commission. If that day is a non-working day, notification shall be made on the working day immediately preceding that day. Unit prices shall only apply if this notification is disseminated by the Commission.

The goods referred to in the first subparagraph of this point are set out in Annex 26.

(*) OJ L 256, 7.9.1987, p. 1.

2. Articles 173 to 177 are deleted.

3. Annex 26 is replaced by the text in Annex I to this Regulation.
4. Annex 27 is deleted.
5. Annex 38 is amended in accordance with Annex II to this Regulation.

Article 2

Article 3(4) of Regulation (EC) No 2286/2003 is replaced by the following:

'4. Article 1(3) to (9), (17) and (18) shall apply from 1 January 2006. However, Member States may implement these provisions before that date.

In addition, Member States having difficulty adapting their customs clearance computer systems may defer the adaptation of these systems until 1 January 2007. In such cases, Member States shall notify the Commission of the method by which and the date on which they implement Article 1(3) to (9), (17) and (18). The Commission shall publish that information.'

Article 3

1. This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.
2. Article 1(1) to (4) shall apply from 19 May 2006.
3. Article 1(5) and Article 2 shall apply from 1 January 2006.

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

Done at Brussels, 8 February 2006.

For the Commission
László KOVÁCS
Member of the Commission

ANNEX I

ANNEX 26

LIST OF GOODS REFERRED TO IN ARTICLE 152(1)(a)

Simplified procedure for the valuation of certain perishable goods imported on consignment in accordance with Article 30(2)(c) of the Code ⁽¹⁾

| CN (TARIC) Code | Description of goods | Period of validity |
|---|---|--------------------|
| 0701 90 50 | New potatoes | 1.1. to 30.6. |
| 0703 10 19 | Onions | 1.1. to 31.12. |
| 0703 20 00 | Garlic | 1.1. to 31.12. |
| 0708 20 00 | Beans | 1.1. to 31.12. |
| 0709 20 00 10 | Asparagus: — green | 1.1. to 31.12. |
| 0709 20 00 90 | Asparagus: — other | 1.1. to 31.12. |
| 0709 60 10 | Sweet peppers | 1.1. to 31.12. |
| ex 0714 20 | Sweet potatoes, fresh or chilled, whole | 1.1. to 31.12. |
| 0804 30 00 90 | Pineapples | 1.1. to 31.12. |
| 0804 40 00 10 | Avocados | 1.1. to 31.12. |
| 0805 10 20 | Sweet oranges | 1.6. to 30.11. |
| 0805 20 10 05 | Clementines | 1.3. to 31.10. |
| 0805 20 30 05 | Monreales and satsumas | 1.3. to 31.10. |
| 0805 20 50 07 0805 20 50 37 | Mandarins and wilkings | 1.3. to 31.10. |
| 0805 20 70 05 0805 20 90 05 0805 20 90 09 | Tangerines and other | 1.3. to 31.10. |
| 0805 40 00 11 | Grapefruit: — white | 1.1. to 31.12. |
| 0805 40 00 19 | Grapefruit: — pink | 1.1. to 31.12. |
| 0805 50 90 11 0805 50 90 19 | Limes (<i>Citrus aurantifolia</i> , <i>Citrus latifolia</i>) | 1.1. to 31.12. |
| 0806 10 10 | Table grapes | 21.11. to 20.7. |
| 0807 11 00 | Watermelons | 1.1. to 31.12. |
| 0807 19 00 10 0807 19 00 30 | Amarillo, cuper, honey dew (including Cantalene), Onteniente, Piel de Sapo, (including Verde Liso), Rochet, Tendral, Futuro | 1.1. to 31.12. |

⁽¹⁾ Notwithstanding the rules for the interpretation of the combined nomenclature, the wording for the description of the goods is to be considered as having no more than an indicative value, the list of goods being established, within the context of this Annex, by the coverage of the CN and TARIC codes as they exist at the time of adoption of this Regulation. Where ex codes are indicated, the codes and corresponding description shall be read together.

| CN (TARIC) Code | Description of goods | Period of validity |
|--------------------------------|--|--------------------------------------|
| 0807 19 00 91 0807 19 00 99 | Other melons | 1.1. to 31.12. |
| 0808 20 50 10 | Pears: — Nashi (<i>Pyrus pyrifolia</i>) — Ya (<i>Pyrus bretschneideri</i>) | 1.5. to 30.6. |
| 0808 20 50 90 | Pears: — other | 1.5. to 30.6. |
| 0809 10 00 | Apricots | 1.1. to 30.5. and 1.8. to 31.12. |
| 0809 30 10 | Nectarines | 1.1. to 10.6. and 1.10. to 31.12. |
| 0809 30 90 | Peaches | 1.1. to 10.6. and 1.10. to 31.12. |
| 0809 40 05 | Plums | 1.10. to 10.6. |
| 0810 10 00 | Strawberries | 1.1. to 31.12. |
| 0810 20 10 | Raspberries | 1.1. to 31.12. |
| 0810 50 00 | Kiwifruit | 1.1. to 31.12.' |

ANNEX II

In Annex 38 to Regulation (EEC) No 2454/93, the note to box 24 is replaced by the following:

'Box 24: Nature of the transaction

The Member States which require this item of information must use the single digit codes listed in column A of the table provided for under Article 13(2) of Commission Regulation (EC) No 1917/2000 (*) (excluding, where appropriate, code 9), this digit being entered in the left-hand side of the box. They may also provide for a second digit from the list in column B of that table to be entered in the right-hand side of the box.

(*) OJ L 229, 9.9.2000, p. 14.'

COMMISSION REGULATION (EC) No 216/2006**of 8 February 2006****amending Regulation (EC) No 2184/97 concerning the classification of certain goods in the Combined Nomenclature**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2658/87 of 23 July 1987 on the tariff and statistical nomenclature and on the Common Customs Tariff ⁽¹⁾, and in particular Article 9(1)(a) thereof,

Whereas:

- (1) The classification of a video conferencing system consisting of various components including two installation diskettes in Commission Regulation (EC) No 2184/97 of 3 November 1997 concerning the classification of certain goods in the Combined Nomenclature ⁽²⁾ has led to classifications under CN code 8517 50 90 for the video conferencing system and 8524 91 10 for the two installation diskettes. Since Note 6 to Chapter 85 of the Combined Nomenclature was amended with effect from 1 January 2002 and in view of the fact that the HS Committee agreed in

October 2004 on the interpretation of this Note, Regulation (EC) No 2184/97 is to be considered as incorrect.

- (2) Regulation (EC) No 2184/97 should therefore be amended accordingly.
- (3) The measures provided for in this Regulation are in accordance with the opinion of the Customs Code Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Point 4 of the table set out in the Annex to Regulation (EC) No 2184/97 is replaced by the text set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the 20th 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, 8 February 2006.

For the Commission

László KOVÁCS

Member of the Commission

⁽¹⁾ OJ L 256, 7.9.1987, p. 1. Regulation as last amended by Regulation (EC) No 2175/2005 (OJ L 347, 30.12.2005, p. 9).

⁽²⁾ OJ L 299, 4.11.1997, p. 6.

ANNEX

| Description of the goods | Classification (CN code) | Reasons |
|--|-----------------------------|---|
| (1) | (2) | (3) |
| <p>Set put up for retail sale comprising:</p> <ul style="list-style-type: none"> — an audio unit with a telephone handset, — a telecommunication card, — a video camera connectable to an automatic data-processing machine, — a network connection unit, and — two diskettes with video telephony application software. <p>The set enables an automatic data-processing machine to perform an additional function (video telephony).</p> | 8517 50 90 | <p>Classification is determined by General Rules 1, 3(b) and 6 for the interpretation of the Combined Nomenclature, and by the wording of CN codes 8517, 8517 50 and 8517 50 90.</p> <p>The essential character of the set is given by the telecommunication apparatus (the audio unit and telecommunication card).</p> |

COMMISSION REGULATION (EC) No 217/2006

of 8 February 2006

laying down rules for the application of Council Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC as regards the authorisation of Member States to permit temporarily the marketing of seed not satisfying the requirements in respect of the minimum germination

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 66/401/EEC of 14 June 1966 on the marketing of fodder plant seed ⁽¹⁾, and in particular Article 17(3) thereof,

Having regard to Council Directive 66/402/EEC of 14 June 1966 on the marketing of cereal seed ⁽²⁾, and in particular Article 17(3) thereof,

Having regard to Council Directive 2002/54/EC of 13 June 2002 on the marketing of beet seed ⁽³⁾, and in particular Article 24(3) thereof,

Having regard to Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed ⁽⁴⁾, and in particular Article 38(3) thereof,

Having regard to Council Directive 2002/57/EC of 13 June 2002 on the marketing of seed of oil and fibre plants ⁽⁵⁾, and in particular Article 21(3) thereof.

Whereas:

- (1) Pursuant to Directives 66/401/EEC, 66/402/EEC, 2002/54/EC, 2002/55/EC and 2002/57/EC, seed can be marketed only where the requirements in respect of the minimum germination capacity have been met, or in cases where the quantity of available seed which satisfies the germination capacity requirements is insufficient, the Commission has permitted, for a limited period, the marketing of prescribed maximum quantities of seed which does not satisfy the requirements laid down in those directives in respect of the minimum germination capacity.
- (2) The process of granting the authorisations is currently too slow.
- (3) In order to simplify and accelerate the authorisation procedure while ensuring that the Commission and the

Member States have all the information necessary to evaluate and respond to the application, a consultation procedure between the Commission and the Member State appears to be the appropriate instrument.

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

HAS ADOPTED THIS REGULATION:

Article 1

1. This Regulation lays down the rules applying to requests by Member States for authorisation to permit temporarily the marketing of seed which does not satisfy the requirements in respect of minimum germination made under:

- (a) Article 17(1) of Directive 66/401/EEC;
- (b) Article 17(1) of Directive 66/402/EEC;
- (c) Article 24(1) of Directive 2002/54/EC;
- (d) Article 38(1) of Directive 2002/55/EC; and
- (e) Article 21(1) of Directive 2002/57/EC.

2. This Regulation does not apply to the marketing of 'basic seeds' as defined by the Directives referred to in paragraph 1.

Article 2

1. A Member State which is affected by supply difficulties and wishes to permit temporarily the marketing of seed which does not satisfy the requirements in respect of minimum germination (hereinafter 'the requesting Member State') shall submit to the Commission a request setting out the information referred to in Article 3. At the same time the other Member States shall be notified by the requesting Member State. Contact points shall be designated by each Member State.

⁽¹⁾ OJ L 125, 11.7.1966, p. 2298/66. Directive as last amended by Directive 2004/117/EC (OJ L 14, 18.1.2005, p. 18).

⁽²⁾ OJ L 125, 11.7.1966, p. 2309/66. Directive as last amended by Directive 2004/117/EC.

⁽³⁾ OJ L 193, 20.7.2002, p. 12. Directive as last amended by Directive 2004/117/EC.

⁽⁴⁾ OJ L 193, 20.7.2002, p. 33. Directive as last amended by Directive 2004/117/EC.

⁽⁵⁾ OJ L 193, 20.7.2002, p. 74. Directive as last amended by Directive 2004/117/EC.

2. Within 15 days after the communication provided for in paragraph 1, other Member States may notify the Commission and the requesting Member State of:

- (a) either an offer of available seeds which can overcome the temporary difficulties in supply; or
- (b) objections to the marketing of seed not satisfying the requirements of the Directives referred to in Article 1(1).

3. Seeds covered by the request up to the quantity requested by the requesting Member State may be marketed throughout the Community without satisfying the requirements of the Directives referred to in Article 1(1) if, within the period referred to in paragraph 2, no offers or objections are notified to the requesting Member State(s) and to the Commission, or where offers are made and the requesting Member State and the offering Member State(s) can agree that the offers are unsuitable, unless within the same period the Commission has informed the requesting Member State that it considers that the request is not justified.

The Commission shall communicate to the contact points designated by each Member State, and shall publish on its website, the conditions under which the marketing is authorised, including the quantity allowed.

4. If the conditions under paragraph 3 cannot be met, or the Commission considers that the request is not justified, the Commission shall inform the contact points designated by each Member State.

The matter shall be submitted to the Standing Committee on Seeds and Propagating Material for Agriculture, Horticulture and Forestry and, where appropriate, a decision approving or rejecting the request shall forthwith be adopted in accordance with the procedure referred to in the provisions referred to in Article 1(1).

Article 3

The information required in accordance with Article 2(1) shall include the following:

- (a) species and varieties, notably the characteristics in respect of cultivation and use;
- (b) the expected minimum germination;
- (c) the quantities involved;

- (d) supporting documentation explaining the reason for the request;
- (e) the proposed marketing destination, identifying those regions of the requesting Member State affected by the seed supply difficulties;
- (f) the period of application requested for the authorisation.

Article 4

Without prejudice to any labelling required by the Directives referred to in Article 1(1), the official label on seed shall contain the statement that the seed in question is of a category satisfying less stringent requirements than those laid down by those Directives, and details of the minimum germination capacity of the seed.

Article 5

1. Subject to the conditions set out in this Regulation, the Member States shall allow suppliers to place on the market seed authorised in accordance with Article 3. They may require suppliers to seek permission in advance, which may be refused if:

- (a) there is sufficient evidence to doubt whether the supplier is able to place on the market the amount of seed for which he has sought permission; or
- (b) the total quantity for which the supplier seeks permission pursuant to the derogation concerned would exhaust the maximum quantity authorised for the Community under Article 2.

2. The requesting Member State shall coordinate the work of the other Member States in order to ensure that the total amount authorised is not exceeded.

3. The Member States shall assist each other administratively in the application of this Regulation. They shall inform the Commission and the other Member States of the contact points referred to in Article 2(1) within one month of entry into force of this Regulation.

Article 6

This Regulation shall enter into force on the seventh 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, 8 February 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

COMMISSION REGULATION (EC) No 218/2006

of 8 February 2006

amending Regulation (EC) No 1262/2001 laying down detailed rules for implementing Council Regulation (EC) No 1260/2001 as regards the buying in and sale of sugar by intervention agencies

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector ⁽¹⁾, and in particular Articles 7(5) and 9(3) thereof,

Whereas:

(1) Commission Regulation (EC) No 1262/2001 ⁽²⁾ lays down detailed rules for applying the intervention arrangements in the sugar sector. Experience has shown that adjustments are needed in order to simplify the arrangements and harmonise them with current practice for other products such as cereals and milk powder.

(2) Regulation (EC) No 1260/2001 guarantees prices and disposal only for sugar produced under quota. Access to intervention should therefore be restricted to manufacturers who are holders of a quota and who, in return for the price guarantee, are required to pay the minimum price for beet, while respecting the legitimate expectations of specialist traders who have already been granted the necessary approval to offer sugar for intervention.

(3) Recent experience in sugar intervention operations has shown that the criteria for the intervention storage of sugar and the approval of warehouses and silos should be made more stringent, in particular by giving the intervention agencies greater discretionary powers. It is also accepted that sugar can be stored for a very long time without risk of deterioration in quality where the storage conditions are right. Therefore the rules on the final dates for removal should be amended, whilst, to take account of legitimate expectations, the rules on sugar offered for intervention before a certain date should be maintained.

(4) Intervention procedures for sugar must be brought into line with those followed in other sectors such as cereals and milk powder, in particular as regards time limits for payment from the submission of tenders for intervention.

(5) Regulation (EC) No 1262/2001, as amended by Regulation (EC) No 1498/2005, lays down the requirements to be met by certain forms of packaging in which sugar bought in must be delivered. Certain clarifications are needed to ensure that this provision is properly applied.

(6) In order to facilitate the day-to-day management of intervention, in particular by creating uniform lots, the minimum quantity below which the intervention agency is not obliged to accept a tender should be increased.

(7) Regulation (EC) No 1262/2001 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Sugar,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 1262/2001 is hereby amended as follows:

1. Article 1 is amended as follows:

(a) paragraph 1 is replaced by the following:

'1. The intervention agency shall buy in the sugar only if it is offered by:

(a) a manufacturer with a production quota;

(b) a specialist sugar trader who is approved before 1 March 2006 by the Member State on whose territory they are established.;

(b) paragraph 3 is replaced by the following:

'3. Sugar may only be taken over where it is under quota and at the time of the offer is stored separately in an approved store or silo that has not been used most recently to store products other than sugar.;

⁽¹⁾ OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 16).

⁽²⁾ OJ L 178, 30.6.2001, p. 48. Regulation as amended by Regulation (EC) No 1498/2005 (OJ L 240, 16.9.2005, p. 39).

2. Article 2 is amended as follows:
- (a) the following subparagraph is added to paragraph 1:
- ‘Additional conditions for approval of silos and warehouses may be laid down by the intervention agencies.’;
- (b) paragraph 2(c) is replaced by the following:
- ‘(c) a total quantity, in the case of silos and warehouses for the bulk storage of sugar, not exceeding 50 times the daily removal capacity for bulk sugar that the applicant undertakes to place at the disposal of the intervention agency concerned for the removal of the sugar.’;
- (c) in the first subparagraph of paragraph 3, the second sentence is deleted;
3. Article 3 is amended as follows:
- (a) paragraph 2 is replaced by the following:
- ‘2. In order to offer sugar for intervention, specialised traders as referred to in paragraph 1 must have been approved by the Member State concerned. Approval shall be granted by the Member State on whose territory the trader’s establishment is located before 1 March 2006, to all applicants meeting or deemed able to meet the conditions laid down in paragraph 1 of this Article for the marketing year in question and, where applicable, any additional conditions which the Member State might attach to the grant of approval.’;
- (b) the second subparagraph of paragraphs 3 and 4 is deleted;
- (c) paragraph 5 is replaced by the following:
- ‘5. Approval shall be withdrawn if it is found that the person concerned no longer satisfies, or is no longer capable of satisfying, any of the conditions laid down in paragraphs 1 and 2. Withdrawal of approval may take place in the course of the marketing year. It shall not have retroactive effect.’;
- (d) paragraph 6 is replaced by the following:
- ‘6. Approval granted or withdrawn under this Article shall be notified in writing to the person concerned.’;
4. Article 4(1) is replaced by the following:
- ‘1. Sugar offered to intervention shall meet the following requirements:
- (a) it must have been produced within a quota during the marketing year in which the offer is made;
- (b) it must be in crystal form.’;
5. the second paragraph of Article 6 is replaced by the following:
- ‘For the purposes of this Regulation “lot” means at least 2 000 tonnes of sugar of uniform quality and packing, all of which is stored in the same place.’;
6. Article 9 is amended as follows:
- (a) paragraph 2 is replaced by the following:
- ‘2. Storage contracts shall take effect five weeks after the date of acceptance of the offer referred to in Article 8(2) and shall expire at the end of the 10-day period during which removal of the quantity of sugar concerned is completed.’;
- (b) paragraph 4 is replaced by the following:
- ‘4. The intervention agency shall bear the storage costs from the beginning of the 10-day period within which the contract takes effect as referred to in paragraph 2 until the expiry of the contract.’;
- (c) the second subparagraph of paragraph 5 is deleted;
7. Article 10(1) is replaced by the following:
- ‘1. The transfer of ownership of sugar covered by a storage contract shall take place when the sugar in question is paid for.’;
8. Article 16 is replaced by the following:
- ‘Article 16
- The intervention agency shall make payment no earlier than 120 days from the day on which the offer is accepted, provided the checks to verify the weight and quality of the offered lots have been conducted.’;

9. Article 17(4) is replaced by the following:
- ‘4. Sugar bought in shall be removed:
- (a) in the case of offers accepted before 30 September 2005, not later than the end of the seventh month following that in which the offer was accepted, without prejudice to Article 34;
- (b) in the case of offers accepted from 1 October 2005 to 9 February 2006, not later than 30 September 2006, without prejudice to Article 34;
- (c) in the case of offers accepted from 10 February 2006, not later than the date of removal laid down in Article 34.’
10. Article 18 is amended as follows:
- (a) the third subparagraph of paragraph 3 is replaced by the following:
- ‘The flat-rate amount to cover the cost of the packing required or accepted by the intervention agency referred to in the second subparagraph of paragraph 2 shall be EUR 15,70 per tonne of sugar.’;
- (b) paragraph 4 is deleted;
11. the first sentence of Article 19(1) is replaced by the following:
- ‘1. At the time of removal in the case of sugar as referred to in Article 17(4)(a) and (b) and within the time limit referred to in Article 16 in the case of sugar as referred to in Article 17(4)(c), four samples shall be taken for analysis either by experts approved by the competent authorities of the Member State concerned or by experts agreed upon by the intervention agency and the seller.’;
12. Article 23(2) is replaced by the following:
- ‘2. The price to be paid by the successful tenderer shall be:
- (a) in the case of paragraph 1(a), the price indicated in the tender;
- (b) in the case of paragraph 1(b) and (c), the price indicated in the terms of the invitation to tender.’

Article 2

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

Article 1(1)(b) and (4) to (8) shall apply to sugar offered to intervention from the date of entry into force.

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

Done at Brussels, 8 February 2006.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

COMMISSION REGULATION (EC) No 219/2006

of 8 February 2006

opening and providing for the administration of the tariff quota for bananas falling under CN code 0803 00 19 originating in ACP countries for the period 1 March to 31 December 2006

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1964/2005 of 29 November 2005 on the tariff rates for bananas ⁽¹⁾, and in particular Article 2 thereof,

Whereas:

- (1) Article 1(2) of Regulation (EC) No 1964/2005 provides that each year from 1 January, with effect from 1 January 2006, an autonomous tariff quota of 775 000 tonnes net weight subject to a zero-duty rate is to be opened for imports of bananas under CN code 0803 00 19 originating in ACP countries.
- (2) Commission Regulation (EC) No 2015/2005 of 9 December 2005 on imports during January and February 2006 of bananas originating in ACP countries under the tariff quota opened by Council Regulation (EC) No 1964/2005 on the tariff rates for bananas ⁽²⁾, adopts the interim measures needed to ensure Community market supplies and continuity of trade with the ACP countries and to avoid disruptions of trade flows during those two months. To that end, an overall amount of 160 000 tonnes has been made available for the purpose of issuing import licences under that tariff quota.
- (3) The tariff quota provided for by Regulation (EC) No 1964/2005 for 2006 should therefore be opened and the provisions for its administration laid down for the period 1 March to 31 December 2006.
- (4) As is the case for non-preferential imports, a method of administering the tariff quota should be adopted so as to favour international trade and smoother trade flows. The most appropriate method for this purpose would be that using the quota by chronological order of acceptance of the declarations of release for free circulation (the 'first

come, first served' method). Nevertheless, in order to ensure continuity of trade with ACP countries and, therefore, satisfactory supplies for the Community market while avoiding disturbances in trade flows, part of the tariff quota should for the time being be reserved for operators who supplied the Community with ACP bananas under the import arrangements previously in force.

- (5) Provision should therefore be made for a total quantity of 146 850 tonnes of the tariff quota to be reserved for the operators who actually imported bananas originating in ACP countries into the Community during 2005. That proportion of the tariff quota should be administered by means of import licences issued to each operator in proportion to the quantities released for free circulation during 2005.
- (6) In view of the quantities available, a ceiling should be set for the licence application which each operator may lodge for the period 1 March to 31 December 2006.
- (7) Access to the rest of the tariff quota should be open to all operators established in the Community on a 'first come, first served' basis in accordance with Articles 308a, 308b and 308c of 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⁾.
- (8) As a result of the entry into force of the common customs tariff rate for bananas established by Regulation (EC) No 1964/2005, the import tariff quota arrangements established by Title IV of Council Regulation (EEC) No 404/93 of 13 February 1993 on the common organisation of the market in bananas ⁽⁴⁾ ceased applying on 31 December 2005 as provided for in Article 16(1) of that Regulation. The rules for administering tariff quotas provided for in Title IV of Regulation (EEC) No 404/93, adopted by Commission Regulation (EC) No 896/2001 ⁽⁵⁾ are therefore null and void.

⁽¹⁾ OJ L 316, 2.12.2005, p. 1.

⁽²⁾ OJ L 324, 10.12.2005, p. 5.

⁽³⁾ OJ L 253, 11.10.1993, p. 1. Regulation as last amended by Regulation (EC) No 883/2005 (OJ L 148, 11.6.2005, p. 5).

⁽⁴⁾ OJ L 47, 25.2.1993, p. 1. Regulation as last amended by the 2003 Act of Accession.

⁽⁵⁾ OJ L 126, 8.5.2001, p. 6. Regulation as last amended by Regulation (EC) No 838/2004 (OJ L 127, 29.4.2004, p. 52).

- (9) For reasons of clarity and legal certainty, Regulation (EC) No 896/2001 should therefore be repealed. Nevertheless, some of its provisions should remain in force, particularly as regards the communication of information by the Member States which has been found useful for the purposes of administering the imports under this Regulation.
- (10) This Regulation should enter into force immediately in order to enable licence applications to be lodged in time.
- (11) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Bananas,

HAS ADOPTED THIS REGULATION:

CHAPTER I

GENERAL PROVISIONS

Article 1

Subject

The zero-duty tariff quota for the import of bananas falling under CN code 0803 00 19 originating in ACP countries provided for in Article 1(2) of Regulation (EC) No 1964/2005 is hereby opened for the period 1 March to 31 December 2006.

Article 2

Available quantities

The quantities available under the tariff quota are set at 615 000 tonnes, of which:

- (a) 146 850 tonnes is to be administered in accordance with Chapter II and have the serial number 09.4164.
- (b) 468 150 tonnes is to be administered in accordance with Chapter III and have the serial numbers: 09.1638, 09.1639, 09.1640, 09.1642 and 09.1644.

CHAPTER II

IMPORTS OF THE QUANTITIES PROVIDED FOR IN ARTICLE 2(A)

Article 3

Import licences

1. All imports under the quantity referred to in Article 2(a) shall be subject to the lodging of an import licence issued in accordance with the provisions of this Chapter.

2. Commission Regulation (EC) No 1291/2000 ⁽¹⁾ shall be applicable, with the exception of Article 8(4) and (5), subject to the provisions of this Regulation.

Article 4

Lodging licence applications

1. Economic operators established in the Community who actually imported bananas originating in ACP countries into the Community in 2005 shall be entitled to lodge import licence applications.

2. The quantities applied for by each operator may not exceed 40 % of the quantities of bananas originating in ACP countries which he released for free circulation in the Community during 2005.

3. Import licence applications must be lodged by each operator on 15 and 16 February 2006 with the competent authorities of the Member State which issued him in 2005 with the import licences for the quantities referred to in paragraph 2.

The competent authorities shall be those listed in the Annex to Regulation (EC) No 896/2001.

4. Licence applications shall be accompanied by a copy of the licence(s) used in 2005 to import bananas originating in ACP countries, duly endorsed, and the documents proving the ACP origin of the quantities under those licences, and the proof of lodging of a security in accordance with Title III of Commission Regulation (EEC) No 2220/85 ⁽²⁾. The security shall be EUR 150 per tonne.

5. Applications not lodged in accordance with this Article shall not be admissible.

6. Box 20 of licence applications and licences shall contain the entry 'licence under Chapter II of Regulation (EC) No 219/2006'.

⁽¹⁾ OJ L 152, 24.6.2000, p. 1.

⁽²⁾ OJ L 205, 3.8.1985, p. 5.

*Article 5***Issuing of licences**

1. Member States shall notify the Commission not later than 21 February 2006 of the total quantity for which admissible licence applications have been lodged.
2. If the quantities applied for exceed the quantity referred to in Article 2(a) the Commission shall, not later than 24 February 2006, set a reduction coefficient to be applied to each application.
3. The competent authorities shall issue the import licences from 27 February 2006, where appropriate applying the reduction coefficient referred to in paragraph 2.
4. Where, if a reduction coefficient is applied, a licence is issued for a quantity less than that applied for, the security referred to in Article 4(4) shall be released without delay for the quantity not awarded.

*Article 6***Period of validity of licences and Member State notifications**

1. The import licences issued in accordance with Article 5(3) shall be valid from 1 March to 31 December 2006.
2. From April 2006 to January 2007 inclusive, Member States shall notify the Commission, not later than the 15th of each month, of the quantities of bananas imported during the preceding month on the basis of licences issued in accordance with Article 5(3).

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

Done at Brussels, 8 February 2006.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

CHAPTER III

IMPORTS OF THE QUANTITIES PROVIDED FOR IN ARTICLE 2(B)*Article 7***Administration**

1. The quantity provided for in Article 2(b) shall be divided into five tranches, each of 93 630 tonnes, as follows:

| Serial number | Quota period |
|---------------|---------------------------|
| 09.1638 | 1 March to 30 April |
| 09.1639 | 1 May to 30 June |
| 09.1640 | 1 July to 31 August |
| 09.1642 | 1 September to 31 October |
| 09.1644 | 1 November to 31 December |

2. The tranches provided for in paragraph 1 shall be administered in accordance with Articles 308a, 308b and 308c of Regulation (EEC) No 2454/93.

CHAPTER IV

FINAL PROVISIONS*Article 8***Repeal**

Regulation (EC) No 896/2001 is hereby repealed. However, Articles 21, 26 and 27 of and the annex to that Regulation shall remain applicable to imports under this Regulation.

*Article 9***Entry into force**

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

COMMISSION REGULATION (EC) No 220/2006**of 8 February 2006****fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs ⁽¹⁾, and in particular Article 8(3) thereof,

Whereas:

(1) Article 8(1) of Regulation (EEC) No 2771/75 provides that the difference between prices in international trade for the products listed in Article 1(1) of that Regulation and prices within the Community may be covered by an export refund where these goods are exported in the form of goods listed in the Annex to that Regulation.

(2) Commission Regulation (EC) No 1043/2005 of 30 June 2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ⁽²⁾, specifies the products for which a rate of refund is to be fixed, to be applied where these products are exported in the form of goods listed in Annex I to Regulation (EEC) No 2771/75.

(3) In accordance with the second paragraph of Article 14 of Regulation (EC) No 1043/2005, the rate of the refund per 100 kilograms for each of the basic products in question is to be fixed for a period of the same duration as that for which refunds are fixed for the same products exported unprocessed.

(4) Article 11 of the Agreement on Agriculture concluded under the Uruguay Round lays down that the export refund for a product contained in a good may not exceed the refund applicable to that product when exported without further processing.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Poultrymeat and Eggs,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex I to Regulation (EC) No 1043/2005 and in Article 1(1) of Regulation (EEC) No 2771/75, and exported in the form of goods listed in Annex I to Regulation (EEC) No 2771/75, shall be fixed as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission
Günter VERHEUGEN
Vice-President

⁽¹⁾ OJ L 282, 1.11.1975, p. 49. Regulation as last amended by Regulation (EC) No 1913/2005 (OJ L 307, 25.11.2005, p. 2).

⁽²⁾ OJ L 172, 5.7.2005, p. 24.

ANNEX

Rates of the refunds applicable from 9 February 2006 to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

| (EUR/100 kg) | | | |
|---------------|---|----------------------------|----------------|
| CN code | Description | Destination ⁽¹⁾ | Rate of refund |
| 0407 00 | Birds' eggs, in shell, fresh, preserved or cooked: | | |
| | – Of poultry: | | |
| 0407 00 30 | – – Other: | | |
| | (a) On exportation of ovalbumin of CN codes 3502 11 90 and 3502 19 90 | 02 | 6,00 |
| | | 03 | 20,00 |
| | | 04 | 3,00 |
| | (b) On exportation of other goods | 01 | 3,00 |
| 0408 | Birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or by boiling in water, moulded, frozen or otherwise preserved, whether or not containing added sugar or other sweetening matter: | | |
| | – Egg yolks: | | |
| 0408 11 | – – Dried: | | |
| ex 0408 11 80 | – – – Suitable for human consumption: not sweetened | 01 | 40,00 |
| 0408 19 | – – Other: | | |
| | – – – Suitable for human consumption: | | |
| ex 0408 19 81 | – – – – Liquid: not sweetened | 01 | 20,00 |
| ex 0408 19 89 | – – – – Frozen: not sweetened | 01 | 20,00 |
| | – Other: | | |
| 0408 91 | – – Dried: | | |
| ex 0408 91 80 | – – – Suitable for human consumption: not sweetened | 01 | 73,00 |
| 0408 99 | – – Other: | | |
| ex 0408 99 80 | – – – Suitable for human consumption: not sweetened | 01 | 18,00 |

⁽¹⁾ The destinations are as follows:

01 Third countries except Bulgaria as from 1 October 2004 and Romania as from 1 December 2005. For Switzerland and Liechtenstein these rates are not applicable to the goods listed in Tables I and II to Protocol No 2 to the Agreement between the European Community and the Swiss Confederation of 22 July 1972 exported with effect from 1 February 2005,

02 Kuwait, Bahrain, Oman, Qatar, United Arab Emirates, Yemen, Turkey, Hong Kong SAR and Russia,

03 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines,

04 all destinations except Switzerland, Bulgaria with effect from 1 October 2004, Romania with effect from 1 December 2005 and those of 02 and 03.

COMMISSION REGULATION (EC) No 221/2006**of 8 February 2006****laying down the reduction coefficient to be applied in the context of subquota III for common wheat of a quality other than high quality provided for in Regulation (EC) No 2375/2002, pursuant to Regulation (EC) No 169/2006**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1784/2003 of 29 September 2003 on the common organisation of the market in cereals ⁽¹⁾,Having regard to Commission Regulation (EC) No 2375/2002 of 27 December 2002 opening and providing for the administration of Community tariff quotas for common wheat of a quality other than high quality from third countries and derogating from Council Regulation (EEC) No 1766/92 ⁽²⁾, and in particular Article 5(3) thereof,

Whereas:

- (1) Regulation (EC) No 2375/2002 opened an annual tariff quota of 2 981 600 tonnes of common wheat of a quality other than high quality. That quota is divided into three subquotas.
- (2) Article 1 of Commission Regulation (EC) No 169/2006 of 31 January 2006 derogating from Regulation (EC) No 2375/2002 as regards the issue of import licences under tranche No 1 of subquota III for common wheat of a

quality other than high quality ⁽³⁾ fixed at 464 879,874 tonnes the quantity under subquota III still available for the period from 1 January to 31 March 2006.

- (3) The quantities applied for on 6 February 2006, in accordance with Article 5(1) of Regulation (EC) No 2375/2002, exceed the quantities available. The extent to which licences may be issued should therefore be determined and the reduction coefficient for the quantities applied for laid down,

HAS ADOPTED THIS REGULATION:

Article 1

Each application for an import licence under subquota III for common wheat of a quality other than high quality lodged and forwarded to the Commission on 6 February 2006 in accordance with Article 5(1) and (2) of Regulation (EC) No 2375/2002 shall be accepted at a rate of 80,56049 % of the quantity applied for.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 270, 21.10.2003, p. 78. Regulation as amended by Commission Regulation (EC) No 1154/2005 (OJ L 187, 19.7.2005, p. 11).

⁽²⁾ OJ L 358, 31.12.2002, p. 88. Regulation as last amended by Regulation (EC) No 777/2004 (OJ L 123, 27.4.2004, p. 50).

⁽³⁾ OJ L 27, 1.2.2006, p. 3.

COMMISSION REGULATION (EC) No 222/2006**of 8 February 2006****on granting of import licences for cane sugar for the purposes of certain tariff quotas and preferential agreements**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector ⁽¹⁾,

Having regard to Council Regulation (EC) No 1095/96 of 18 June 1996 on the implementation of the concessions set out in Schedule CXL drawn up in the wake of the conclusion of the GATT XXIV.6 negotiations ⁽²⁾,

Having regard to Commission Regulation (EC) No 1159/2003 of 30 June 2003 laying down detailed rules of application for the 2003/04, 2004/05 and 2005/06 marketing years for the import of cane sugar under certain tariff quotas and preferential agreements and amending Regulations (EC) No 1464/95 and (EC) No 779/96 ⁽³⁾, and in particular Article 5(4) thereof,

Whereas:

- (1) Article 9 of Regulation (EC) No 1159/2003 lays down detailed rules on determining the delivery obligations at zero duty for products falling within CN code 1701 expressed as white sugar equivalent for imports origi-

nating in countries which are parties to the ACP Protocol and the India Agreement.

- (2) Commission Regulation (EC) No 180/2006 of 1 February 2006 fixing the quantities of the delivery obligations for sugar cane to be imported under the ACP Protocol and the India Agreement for the 2005/06 delivery period ⁽⁴⁾ fixed a delivery obligation for Congo, India, Mozambique, Tanzania and Zimbabwe higher than all the import licence applications submitted to date for the 2005/06 delivery period.
- (3) Under these circumstances, and in the interests of clarity, it should be indicated that the limits concerned have not been reached,

HAS ADOPTED THIS REGULATION:

Article 1

In the case of import licence applications presented from 30 January to 3 February 2006 in line with Article 5(1) of Regulation (EC) No 1159/2003 licences shall be issued for the quantities indicated in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 987/2005 (OJ L 167, 29.6.2005, p. 12).

⁽²⁾ OJ L 146, 20.6.1996, p. 1.

⁽³⁾ OJ L 162, 1.7.2003, p. 25. Regulation as last amended by Regulation (EC) No 568/2005 (OJ L 97, 15.4.2005, p. 9).

⁽⁴⁾ OJ L 29, 2.2.2006, p. 28.

ANNEX

ACP-INDIA preferential sugar
Title II of Regulation (EC) No 1159/2003
2005/06 marketing year

| Country | Week of 30.1.2006-3.2.2006: percentage of requested quantity to be granted | Limit |
|-----------------------|--|---------|
| Barbados | 100 | |
| Belize | 100 | |
| Congo | 100 | |
| Fiji | 100 | |
| Guyana | 100 | |
| India | 100 | |
| Côte d'Ivoire | 100 | |
| Jamaica | 100 | |
| Kenya | 100 | |
| Madagascar | 100 | |
| Malawi | 100 | |
| Mauritius | 100 | |
| Mozambique | 100 | |
| Saint Kitts and Nevis | 100 | |
| Swaziland | 0 | reached |
| Tanzania | 100 | |
| Trinidad and Tobago | 100 | |
| Zambia | 100 | |
| Zimbabwe | 100 | |

Special preferential sugar
Title III of Regulation (EC) No 1159/2003
2005/06 marketing year

| Country | Week of 30.1.2006-3.2.2006: percentage of requested quantity to be granted | Limit |
|---------|--|---------|
| India | 0 | reached |
| ACP | 0 | reached |

CXL concessions sugar
Title IV of Regulation (EC) No 1159/2003
2005/06 marketing year

| Country | Week of 30.1.2006-3.2.2006: percentage of requested quantity to be granted | Limit |
|-----------------------|--|---------|
| Brazil | 0 | reached |
| Cuba | 100 | |
| Other third countries | 0 | reached |

COMMISSION REGULATION (EC) No 223/2006
of 8 February 2006
fixing the export refunds on eggs applicable from 9 February 2006

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs ⁽¹⁾, and in particular the third subparagraph of Article 8(3) thereof,

Whereas:

- (1) Article 8 of Regulation (EEC) No 2771/75 provides that the difference between prices on the world market for the products listed in Article 1(1) of that regulation and prices for those products on the Community market may be covered by an export refund.
- (2) It follows from applying these rules and criteria to the present situation on the market in eggs that the refund should be fixed at an amount which would permit Community participation in world trade and would also take account of the nature of these exports and their importance at the present time.
- (3) The present market situation in certain third countries and that regarding competition makes it necessary to fix a refund differentiated by destination for certain products in the egg sector.
- (4) Article 21 of Commission Regulation (EC) No 800/1999 of 15 April 1999 laying down detailed rules for the application of the system of export refunds on agricultural products ⁽²⁾, stipulates that no refund is granted if the products are not of sound and fair marketable

quality on the date on which the export declaration is accepted. In order to ensure uniform application of the rules in force, it should be stated that, in order to qualify for the refund, the egg products listed in Article 1 of Regulation (EEC) No 2771/75 must bear the health mark laid down in Council Directive 89/437/EEC of 20 June 1989 on hygiene and health problems affecting the production and the placing on the market of egg products ⁽³⁾.

- (5) The negotiations within the framework of the Europe Agreements between the European Community and Romania and Bulgaria aim in particular to liberalise trade in products covered by the common organisation of the market concerned. For these two countries export refunds should therefore be abolished. That abolition should not, however, lead to a differentiated refund for exports to other countries.
- (6) The Management Committee for Poultrymeat and Eggs has not delivered an opinion within the time limit set by its chairman,

HAS ADOPTED THIS REGULATION:

Article 1

The codes of products for which, when they are exported, the export refund referred to in Article 8 of Regulation (EEC) No 2771/75 is granted and the amount of that refund shall be as shown in the Annex hereto.

However, in order to qualify for the refund, products falling within the scope of Chapter XI of the Annex to Directive 89/437/EEC must also satisfy the health marking conditions laid down in that Directive.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission
Mariann FISCHER BOEL
Member of the Commission

⁽¹⁾ OJ L 282, 1.11.1975, p. 49. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 102, 17.4.1999, p. 11. Regulation as last amended by Regulation (EC) No 671/2004 (OJ L 105, 14.4.2004, p. 5).

⁽³⁾ OJ L 212, 22.7.1989, p. 87. Directive as last amended by Regulation (EC) No 806/2003.

ANNEX

Export refunds on eggs applicable from 9 February 2006

| Product code | Destination | Unit of measurement | Amount of refund |
|-----------------|-------------|---------------------|------------------|
| 0407 00 11 9000 | E16 | EUR/100 pcs | 1,35 |
| 0407 00 19 9000 | E16 | EUR/100 pcs | 0,70 |
| 0407 00 30 9000 | E09 | EUR/100 kg | 6,00 |
| | E10 | EUR/100 kg | 20,00 |
| | E17 | EUR/100 kg | 3,00 |
| 0408 11 80 9100 | E18 | EUR/100 kg | 40,00 |
| 0408 19 81 9100 | E18 | EUR/100 kg | 20,00 |
| 0408 19 89 9100 | E18 | EUR/100 kg | 20,00 |
| 0408 91 80 9100 | E18 | EUR/100 kg | 73,00 |
| 0408 99 80 9100 | E18 | EUR/100 kg | 18,00 |

NB: The product codes and the 'A' series destination codes are set out in Commission Regulation (EEC) No 3846/87 (OJ L 366, 24.12.1987, p. 1), as amended.

The numeric destination codes are set out in Commission Regulation (EC) No 750/2005 (OJ L 126, 19.05.2005, p. 12).

The other destinations are defined as follows:

E09 Kuwait, Bahrain, Oman, Qatar, the United Arab Emirates, Yemen, Hong Kong SAR, Russia and Turkey.

E10 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines.

E16 all destinations except the United States of America, Romania and Bulgaria.

E17 all destinations except Switzerland, Romania, Bulgaria and those of E09 and E10.

E18 all destinations except Switzerland, Romania and Bulgaria.

COMMISSION REGULATION (EC) No 224/2006**of 8 February 2006****fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2771/75 of 29 October 1975 on the common organisation of the market in eggs ⁽¹⁾, and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2777/75 of 29 October 1975 on the common organisation of the market in poultrymeat ⁽²⁾, and in particular Article 5(4) thereof,

Having regard to Council Regulation (EEC) No 2783/75 of 29 October 1975 on the common system of trade for ovalbumin and lactalbumin ⁽³⁾, and in particular Article 3(4) thereof,

Whereas:

- (1) Commission Regulation (EC) No 1484/95 ⁽⁴⁾, fixes detailed rules for implementing the system of additional import duties and fixes representative prices in the poultrymeat and egg sectors and for egg albumin.

(2) It results from regular monitoring of the information providing the basis for the verification of the import prices in the poultrymeat and egg sectors and for egg albumin that the representative prices for imports of certain products should be amended taking into account variations of prices according to origin. Therefore, representative prices should be published.

(3) It is necessary to apply this amendment as soon as possible, given the situation on the market.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for Poultrymeat and Eggs,

HAS ADOPTED THIS REGULATION:

Article 1

Annex I to Regulation (EC) No 1484/95 is hereby replaced by the Annex hereto.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 282, 1.11.1975, p. 49. Regulation as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 282, 1.11.1975, p. 77. Regulation as last amended by Regulation (EC) No 806/2003.

⁽³⁾ OJ L 282, 1.11.1975, p. 104. Regulation as last amended by Commission Regulation (EC) No 2916/95 (OJ L 305, 19.12.1995, p. 49).

⁽⁴⁾ OJ L 145, 29.6.1995, p. 47. Regulation as last amended by Regulation (EC) No 82/2006 (OJ L 14, 19.1.2006, p. 10).

ANNEX

to the Commission Regulation of 8 February 2006 fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending Regulation (EC) No 1484/95

'ANNEX I

| CN code | Description | Representative price (EUR/100 kg) | Security referred to in Article 3(3) (EUR/100 kg) | Origin ⁽¹⁾ |
|------------|--|-----------------------------------|---|-----------------------|
| 0207 12 90 | Chickens, plucked and drawn, without heads and feet and without necks, hearts, livers and gizzards, known as "65 % chickens", or otherwise presented, frozen | 111,7 | 2 | 01 |
| | | 96,5 | 6 | 02 |
| 0207 14 10 | Boneless cuts of fowl of the species Gallus domesticus, frozen | 195,3 | 32 | 01 |
| | | 229,4 | 21 | 02 |
| | | 279,7 | 6 | 03 |
| 0207 25 10 | Turkey carcasses, known as 80 % turkeys, frozen | 120,6 | 12 | 01 |
| 0207 27 10 | Boneless cuts of turkey, frozen | 236,2 | 18 | 01 |
| | | 276,7 | 6 | 03 |
| 1602 32 11 | Preparations of uncooked fowl of the species Gallus domesticus | 206,6 | 24 | 01 |
| | | 264,0 | 7 | 02 |
| | | 199,2 | 26 | 03 |

⁽¹⁾ Origin of imports:

- 01 Brazil
- 02 Argentina
- 03 Chile.

COMMISSION REGULATION (EC) No 225/2006**of 8 February 2006****amending the representative prices and additional duties for the import of certain products in the sugar sector fixed by Regulation (EC) No 1011/2005 for the 2005/2006 marketing year**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1260/2001 of 19 June 2001 on the common organisation of the markets in the sugar sector ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1423/95 of 23 June 1995 laying down detailed implementing rules for the import of products in the sugar sector other than molasses ⁽²⁾, and in particular the second sentence of the second subparagraph of Article 1(2), and Article 3(1) thereof,

Whereas:

- (1) The representative prices and additional duties applicable to imports of white sugar, raw sugar and certain syrups for the 2005/2006 marketing year are fixed by

Commission Regulation (EC) No 1011/2005 ⁽³⁾. These prices and duties were last amended by Commission Regulation (EC) No 200/2006 ⁽⁴⁾.

- (2) The data currently available to the Commission indicate that the said amounts should be changed in accordance with the rules and procedures laid down in Regulation (EC) No 1423/95,

HAS ADOPTED THIS REGULATION:

Article 1

The representative prices and additional duties on imports of the products referred to in Article 1 of Regulation (EC) No 1423/95, as fixed by Regulation (EC) No 1011/2005 for the 2005/2006 marketing year are hereby amended as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 9 February 2006.

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

Done at Brussels, 8 February 2006.

For the Commission

J. L. DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 178, 30.6.2001, p. 1. Regulation as last amended by Commission Regulation (EC) No 39/2004 (OJ L 6, 10.1.2004, p. 16).

⁽²⁾ OJ L 141, 24.6.1995, p. 16. Regulation as last amended by Regulation (EC) No 624/98 (OJ L 85, 20.3.1998, p. 5).

⁽³⁾ OJ L 170, 1.7.2005, p. 35.

⁽⁴⁾ OJ L 32, 4.2.2006, p. 39.

ANNEX

Amended representative prices and additional duties applicable to imports of white sugar, raw sugar and products covered by CN code 1702 90 99 applicable from 9 February 2006

(EUR)

| CN code | Representative price per 100 kg of the product concerned | Additional duty per 100 kg of the product concerned |
|---------------------------|--|---|
| 1701 11 10 ⁽¹⁾ | 36,67 | 0,28 |
| 1701 11 90 ⁽¹⁾ | 36,67 | 3,90 |
| 1701 12 10 ⁽¹⁾ | 36,67 | 0,15 |
| 1701 12 90 ⁽¹⁾ | 36,67 | 3,61 |
| 1701 91 00 ⁽²⁾ | 35,79 | 7,34 |
| 1701 99 10 ⁽²⁾ | 35,79 | 3,60 |
| 1701 99 90 ⁽²⁾ | 35,79 | 3,60 |
| 1702 90 99 ⁽³⁾ | 0,36 | 0,31 |

⁽¹⁾ Fixed for the standard quality defined in Annex I.II to Council Regulation (EC) No 1260/2001 (OJ L 178, 30.6.2001, p. 1).

⁽²⁾ Fixed for the standard quality defined in Annex I.I to Regulation (EC) No 1260/2001.

⁽³⁾ Fixed per 1 % sucrose content.

COMMISSION DIRECTIVE 2006/15/EC**of 7 February 2006****establishing a second list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Directives 91/322/EEC and 2000/39/EC****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Community limit value, but may determine its nature in accordance with national legislation and practice.

Having regard to the Treaty establishing the European Community,

(5) Indicative occupational exposure limit values should be regarded as an important part of the overall approach to ensuring the protection of the health of workers at the workplace against the risks arising from hazardous chemicals.

Having regard to Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work ⁽¹⁾, and in particular Article 3(2) thereof,

(6) Results of the risk assessments and risk reduction strategies developed in the framework of Council Regulation (EEC) No 793/93 ⁽²⁾ on the evaluation and control of the risks of existing substances provide for the establishment or revision of OELs for a number of substances.

Having regard to the opinion of the Advisory Committee on Safety, Hygiene and Health Protection at Work,

Whereas:

(1) Pursuant to Directive 98/24/EC, the Commission is to propose European objectives in the form of indicative occupational exposure limit values (IOELVs) for the protection of workers from chemical risks, to be set at Community level.

(7) A first and a second list of indicative occupational exposure limit values were established by Commission Directives 91/322/EEC ⁽⁴⁾ and 96/94/EC ⁽⁵⁾ under Council Directive 80/1107/EEC of 27 November 1980 on the protection of workers from the risks related to exposure to chemical, physical and biological agents at work ⁽⁶⁾.

(2) In carrying out this task, the Commission is assisted by the Scientific Committee for Occupational Exposure Limits to Chemical Agents (SCOEL) set up by Commission Decision 95/320/EC ⁽²⁾.

(8) Directive 80/1107/EEC was repealed with effect from 5 May 2001 by Directive 98/24/EC.

(3) Indicative occupational exposure limit values are health-based, non-binding values, derived from the most recent scientific data available and taking into account the availability of measurement techniques. They set threshold levels of exposure below which no detrimental effects are expected for any given substance. They are necessary for the determination and assessment of risks by the employer in accordance with Article 4 of Directive 98/24/EC.

(9) Directive 98/24/EC established that Directives 91/322/EEC and 96/94/EEC were to remain in force.

(4) For any chemical agent for which indicative occupational exposure limit values are established at Community level, Member States are required to establish a national occupational exposure limit value taking into account the

(10) Directive 96/94/EC was repealed with effect from 31 December 2001 by Commission Directive 2000/39/EC of 8 June 2000 establishing a first list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work ⁽⁷⁾.

⁽¹⁾ OJ L 131, 5.5.1998, p. 11.

⁽²⁾ OJ L 188, 9.8.1995, p. 14.

⁽³⁾ OJ L 84, 5.4.1993, p. 1. Regulation as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽⁴⁾ OJ L 177, 5.7.1991, p. 22.

⁽⁵⁾ OJ L 338, 28.12.1996, p. 86.

⁽⁶⁾ OJ L 327, 3.12.1980, p. 8.

⁽⁷⁾ OJ L 142, 16.6.2000, p. 47.

- (11) In the light of the evaluation of the latest available scientific data, it is appropriate to review the indicative occupational exposure limit values established by Directive 91/322/EEC.
- (12) In accordance with Article 3 of Directive 98/24/EC, SCOEL has assessed a total of 33 substances, which are listed in the Annex to the present Directive. Of these 33 substances, 17 were already listed in the Annex to Directive 91/322/EEC. For 4 of these substances, the SCOEL recommends the establishment of new indicative limit values and, for 13 substances, the maintenance of the previous limit values. Therefore those 17 substances now listed in the Annex to the present Directive should be deleted from the Annex to Directive 91/322/EEC, whereas the other 10 substances will remain in the Annex to Directive 91/322/EEC.
- (13) Ten substances should remain in the Annex to Directive 91/322/EEC. As to 9 of these substances the SCOEL has not yet recommended an indicative occupational exposure limit value, while for one remaining substance it is anticipated that additional scientific data will be available in the near future and that it will be submitted to SCOEL for consideration.
- (14) The list in the Annex to this Directive also incorporates 16 other substances for which indicative occupational exposure limit values have been recommended by SCOEL, following evaluation of the latest available scientific data on occupational health effects and taking into account the availability of measurement techniques in accordance with Article 3 of Directive 98/24/EC.
- (15) One of those 16 substances, monochlorobenzene, was included in the Annex of Directive 2000/39/EC. SCOEL has reviewed the IOELV in the light of the recent scientific data and recommended the establishment of a new IOELV. Therefore, this substance, now listed in the Annex of the present Directive, should be deleted from the Annex to Directive 2000/39/EC.
- (16) It is also necessary to establish short-term exposure limit values for certain substances to take account of effects arising from short-term exposure.
- (17) For some substances, it is necessary to take into account the possibility of penetration through the skin in order to ensure the best possible level of protection.
- (18) This Directive should constitute a practical step towards the achievement of the social dimension of the internal market.
- (19) The measures provided for in this Directive are in accordance with the opinion of the Committee instituted by Article 17 of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work ⁽¹⁾.
- (20) Directive 91/322/EEC should therefore be amended accordingly,

HAS ADOPTED THIS DIRECTIVE:

Article 1

In implementation of Directive 98/24/EC, a second list of Community indicative occupational exposure limit values is hereby established for the chemical agents listed in the Annex.

Article 2

Member States shall establish national occupational exposure limit values for the chemical agents listed in the Annex, taking into account the Community values.

Article 3

In the Annex to Directive 91/322/EEC the references to the substances nicotine, formic acid, methanol, acetonitrile, nitrobenzene, resorcinol, diethylamine, carbon dioxide, oxalic acid, cyanamide, diphosphorus pentaoxide, diphosphorus pentasulphide, bromine, phosphorus pentachloride, pyrethrum, barium (soluble compounds as Ba), silver (soluble compounds as Ag) and their indicative limit values are deleted.

In the Annex to Directive 2000/39/EC, the reference to the substance chlorobenzene is deleted.

⁽¹⁾ OJ L 183, 29.6.1989, p. 1.

Article 4

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 18 months after the entry into force at the latest.

They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 5

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

Article 6

This Directive is addressed to the Member States.

Done at Brussels, 7 February 2006.

For the Commission
Vladimír ŠPIDLA
Member of the Commission

ANNEX

INDICATIVE OCCUPATIONAL EXPOSURE LIMIT VALUES

| EINECS ⁽¹⁾ | CAS ⁽²⁾ | Name of agent | Limit values | | | | Notation ⁽³⁾ |
|-----------------------|--------------------|--|----------------------------------|--------------------|----------------------------------|--------------------|-------------------------|
| | | | 8 hours ⁽⁴⁾ | | Short term ⁽⁵⁾ | | |
| | | | mg/m ³ ⁽⁶⁾ | ppm ⁽⁷⁾ | mg/m ³ ⁽⁶⁾ | ppm ⁽⁷⁾ | |
| 200-193-3 | 54-11-5 | Nicotine | 0,5 | — | — | — | skin |
| 200-579-1 | 64-18-6 | Formic acid | 9 | 5 | — | — | — |
| 200-659-6 | 67-56-1 | Methanol | 260 | 200 | — | — | skin |
| 200-830-5 | 75-00-3 | Chloroethane | 268 | 100 | — | — | — |
| 200-835-2 | 75-05-8 | Acetonitrile | 70 | 40 | — | — | skin |
| 201-142-8 | 78-78-4 | Isopentane | 3 000 | 1 000 | — | — | — |
| 202-716-0 | 98-95-3 | Nitrobenzene | 1 | 0,2 | — | — | skin |
| 203-585-2 | 108-46-3 | Resorcinol | 45 | 10 | — | — | skin |
| 203-625-9 | 108-88-3 | Toluene | 192 | 50 | 384 | 100 | skin |
| 203-628-5 | 108-90-7 | Monochlorobenzene | 23 | 5 | 70 | 15 | — |
| 203-692-4 | 109-66-0 | Pentane | 3 000 | 1 000 | — | — | — |
| 203-716-3 | 109-89-7 | Diethylamine | 15 | 5 | 30 | 10 | — |
| 203-777-6 | 110-54-3 | n-Hexane | 72 | 20 | — | — | — |
| 203-806-2 | 110-82-7 | Cyclohexane | 700 | 200 | — | — | — |
| 203-815-1 | 110-91-8 | Morpholine | 36 | 10 | 72 | 20 | — |
| 203-906-6 | 111-77-3 | 2-(2-Methoxyethoxy)ethanol | 50,1 | 10 | — | — | skin |
| 203-961-6 | 112-34-5 | 2-(2-Butoxyethoxy)ethanol | 67,5 | 10 | 101,2 | 15 | — |
| 204-696-9 | 124-38-9 | Carbon dioxide | 9 000 | 5 000 | — | — | — |
| 205-483-3 | 141-43-5 | 2-Aminoethanol | 2,5 | 1 | 7,6 | 3 | skin |
| 205-634-3 | 144-62-7 | Oxalic acid | 1 | — | — | — | — |
| 206-992-3 | 420-04-2 | Cyanamide | 1 | 0,58 | — | — | skin |
| 207-343-7 | 463-82-1 | Neopentane | 3 000 | 1 000 | — | — | — |
| 215-236-1 | 1314-56-3 | Diphosphorus pentaoxide | 1 | — | — | — | — |
| 215-242-4 | 1314-80-3 | Diphosphorus pentasulphide | 1 | — | — | — | — |
| 231-131-3 | | Silver (soluble compounds as Ag) | 0,01 | — | — | — | — |
| | | Barium (soluble compounds as Ba) | 0,5 | — | — | — | — |
| | | Chromium Metal, Inorganic Chromium (II) Compounds and Inorganic Chromium (III) Compounds (insoluble) | 2 | — | — | — | — |
| 231-714-2 | 7697-37-2 | Nitric acid | — | — | 2,6 | 1 | — |
| 231-778-1 | 7726-95-6 | Bromine | 0,7 | 0,1 | — | — | — |
| 231-959-5 | 7782-50-5 | Chlorine | — | — | 1,5 | 0,5 | — |
| 232-260-8 | 7803-51-2 | Phosphine | 0,14 | 0,1 | 0,28 | 0,2 | — |
| | 8003-34-7 | Pyrethrum (purified of sensitising lactones) | 1 | — | — | — | — |
| 233-060-3 | 10026-13-8 | Phosphorus pentachloride | 1 | — | — | — | — |

⁽¹⁾ EINECS: European Inventory of Existing Chemical Substances.

⁽²⁾ CAS: Chemical Abstract Service Registry Number.

⁽³⁾ A skin notation assigned to the occupational exposure limit value indicates the possibility of significant uptake through the skin.

⁽⁴⁾ Measured or calculated in relation to a reference period of eight hours as a time-weighted average.

⁽⁵⁾ A limit value above which exposure should not occur and which is related to a 15-minute period unless otherwise specified.

⁽⁶⁾ mg/m³: milligrams per cubic metre of air at 20 °C and 101,3 kPa.

⁽⁷⁾ ppm: parts per million by volume in air (ml/m³).

COMMISSION DIRECTIVE 2006/17/EC

of 8 February 2006

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards certain technical requirements for the donation, procurement and testing of human tissues and cells

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

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

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells⁽¹⁾, and in particular points (b), (d), (e), (f), and (i) of Article 28 thereof,

Whereas:

- (1) Directive 2004/23/EC lays down standards of quality and safety for the donation, procurement and testing of all human tissues and cells intended for human applications, and of manufactured products derived from human tissues and cells intended for human applications, so as to ensure a high level of human health protection.
- (2) In order to prevent the transmission of diseases by human tissues and cells for human applications and to ensure an equivalent level of quality and safety, Directive 2004/23/EC calls for the establishment of specific technical requirements for each one of the steps in the human tissue and cell application process.
- (3) The use of tissues and cells for application in the human body carries a risk of disease transmission and other potential adverse effects in recipients. That risk can be reduced by careful donor selection, testing of each donation and the application of procedures to procure tissues and cells in accordance with rules and processes established and updated according to the best available scientific advice. Therefore, all tissues and cells, including those used as starting material for the manufacture of medicinal products, to be used in the Community should meet the quality and safety requirements laid down in this Directive.
- (4) Reproductive cells have, due to the specific nature of their application, specific quality and safety characteristics that are taken into account in this Directive.
- (5) For the donation of reproductive cells between partners that have an intimate physical relationship, it is justified to require less stringent biological testing, given that in this case the risk for the recipient is considered less than for donation from third parties. In order to minimise the

risk of cross-contamination, biological testing of the donor will be necessary only when the donated cells will be processed, cultured or stored.

- (6) This Directive is based on international experience drawn upon through an extensive consultation, the Council of Europe's Guide to safety and quality assurance for organs, tissues and cells, the European Convention on Human Rights, the Council of Europe's Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (Oviedo, 4.IV.1997), with its additional protocols, and recommendations from the World Health Organisation. In particular, with regard to further additional biological testing for donors originating from high-incidence areas of specific diseases or whose sexual partners or parents originate from high-incidence areas, Member States will refer to existing international scientific evidence. The Directive is consistent with the fundamental principles set out in the European Charter of Fundamental Rights.
- (7) The measures provided for in this Directive are in accordance with the opinion of the Committee set up by Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Definitions

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

- (a) 'reproductive cells' means all tissues and cells intended to be used for the purpose of assisted reproduction;
- (b) 'partner donation' means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;
- (c) 'direct use' means any procedure where cells are donated and used without any banking;
- (d) 'quality system' means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

⁽¹⁾ OJ L 102, 7.4.2004, p. 48.

- (e) 'standard operating procedures' (SOPs) means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;
- (f) 'validation' (or 'qualification' in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;
- (g) 'traceability' means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;
- (h) 'procurement organisation' means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment.

Article 2

Requirements for the procurement of human tissues and cells

1. With the exception of partner donation of reproductive cells for direct use, Member States shall ensure that the procurement of human tissues and cells is accredited, designated, authorised or licensed only when the requirements in paragraphs 2 to 12 are met.
 2. Procurement of human tissues and cells shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement.
 3. The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the same organisation or establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors set out in Annex I.
 4. The tissue establishment or procurement organisation shall have written agreements with the staff or clinical teams responsible for tissue/cell procurement, unless they are employed by the same establishment or organisation, specifying the type(s) of tissues and/or cells and/or test samples to be procured and the protocols to be followed.
 5. There shall be standard operating procedures (SOPs) for the verification of:
 - (a) donor identity;
 - (b) the details of donor or donor family consent or authorisation;
 - (c) the assessment of the selection criteria for donors as detailed in Article 3;
 - (d) the assessment of the laboratory tests required for donors as detailed in Article 4.
- There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the tissues and cells to the point of arrival at the tissue establishment or, in the case of direct distribution of tissues and cells, to the clinical team responsible for their application or, in the case of tissue/cell samples, to the laboratory for testing, in accordance with Article 5 of this Directive.
6. Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with Article 5.
 7. Procurement materials and equipment shall be managed in accordance with the standards and specifications laid down in Annex IV, section 1.3, and with due regard to relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for tissue and cell procurement.
 8. Procurement of tissues and cells from living donors shall take place in an environment that ensures their health, safety and privacy.
 9. Where appropriate, the staff and equipment necessary for body reconstruction of deceased donors shall be provided. Such reconstruction shall be completed effectively.
 10. The procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements specified in Article 5.

11. A unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose.

12. Donor documentation shall be maintained in accordance with section 1.4 of Annex IV.

Article 3

Selection criteria for donors of tissues and cells

The competent authority or authorities shall ensure that donors comply with the selection criteria set out in:

- (a) Annex I for donors of tissues and cells, except donors of reproductive cells;
- (b) Annex III for donors of reproductive cells.

Article 4

Laboratory tests required for donors

1. The competent authority or authorities shall ensure that:
 - (a) donors of tissues and cells, except donors of reproductive cells, undergo the biological tests set out in point 1 of Annex II;
 - (b) the tests referred to in point (a) are carried out in compliance with the general requirements set out in point 2 of Annex II.
2. The competent authority or authorities shall ensure that:
 - (a) donors of reproductive cells undergo the biological tests set out in points 1, 2 and 3 of Annex III;
 - (b) the tests referred to in point (a) above are carried out in compliance with the general requirements set out in point 4 of Annex III.

Article 5

Tissue and/or cell donation and procurement procedures and reception at the tissue establishment

The competent authority or authorities shall ensure that the tissue and/or cell donation and procurement procedures and the reception of tissues and/or cells at the tissue establishment comply with the requirements set out in Annex IV.

Article 6

Requirements for direct distribution to the recipient of specific tissues and cells

The competent authority or authorities may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a health care establishment for immediate transplantation.

Article 7

Transposition

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 November 2006, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

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

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

Article 8

Entry into force

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

Article 9

Addressees

This Directive is addressed to the Member States.

Done at Brussels, 8 February 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission

ANNEX I

SELECTION CRITERIA FOR DONORS OF TISSUES AND/OR CELLS (EXCEPT DONORS OF REPRODUCTIVE CELLS) AS REFERRED TO IN ARTICLE 3(a)

Selection criteria for donors are based on an analysis of the risks related to the application of the specific cells/tissues. Indicators of these risks must be identified by physical examination, review of the medical and behavioural history, biological testing, post-mortem examination (for deceased donors) and any other appropriate investigation. Unless justified on the basis of a documented risk assessment approved by the responsible person as defined in Article 17 of Directive 2004/23/EC, donors must be excluded from donation if any of the following criteria applies:

1. Deceased Donors**1.1. General criteria for exclusion**

1.1.1. Cause of death unknown, unless autopsy provides information on the cause of death after procurement and none of the general criteria for exclusion set out in the present section applies.

1.1.2. History of a disease of unknown aetiology.

1.1.3. Presence, or previous history, of malignant disease, except for primary basal cell carcinoma, carcinoma *in situ* of the uterine cervix, and some primary tumours of the central nervous system that have to be evaluated according to scientific evidence. Donors with malignant diseases can be evaluated and considered for cornea donation, except for those with retinoblastoma, haematological neoplasm, and malignant tumours of the anterior segment of the eye.

1.1.4. Risk of transmission of diseases caused by prions. This risk applies, for example, to:

- (a) people diagnosed with Creutzfeldt-Jakob disease, or variant Creutzfeldt-Jacob disease, or having a family history of non-iatrogenic Creutzfeldt-Jakob disease;
- (b) people with a history of rapid progressive dementia or degenerative neurological disease, including those of unknown origin;
- (c) recipients of hormones derived from the human pituitary gland (such as growth hormones) and recipients of grafts of cornea, sclera and dura mater, and persons that have undergone undocumented neurosurgery (where dura mater may have been used).

For variant Creutzfeldt-Jakob disease, further precautionary measures may be recommended.

1.1.5. Systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated. Donors with bacterial septicaemia may be evaluated and considered for eye donation but only where the corneas are to be stored by organ culture to allow detection of any bacterial contamination of the tissue.

1.1.6. History, clinical evidence, or laboratory evidence of HIV, acute or chronic hepatitis B (except in the case of persons with a proven immune status), hepatitis C and HTLV I/II, transmission risk or evidence of risk factors for these infections.

1.1.7. History of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the tissue to be retrieved.

1.1.8. Indications that test results of donor blood samples will be invalid due to:

- (a) the occurrence of haemodilution, according to the specifications in Annex II, section 2, where a pre-transfusion sample is not available; or
- (b) treatment with immunosuppressive agents.

- 1.1.9. Evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration donor travel and exposure history and local infectious disease prevalence.
- 1.1.10. Presence on the donor's body of physical signs implying a risk of transmissible disease(s) as described in Annex IV, point 1.2.3.
- 1.1.11. Ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.
- 1.1.12. Recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist.
- 1.1.13. Transplantation with xenografts.
- 1.2. *Additional exclusion criteria for deceased child donors*
 - 1.2.1. Any children born from mothers with HIV infection or that meet any of the exclusion criteria described in section 1.1 must be excluded as donors until the risk of transmission of infection can be definitely ruled out.
 - (a) Children aged less than 18 months born from mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have been breastfed by their mothers during the previous 12 months, cannot be considered as donors regardless of the results of the analytical tests.
 - (b) Children of mothers with HIV, hepatitis B, hepatitis C or HTLV infection, or at risk of such infection, and who have not been breastfed by their mothers during the previous 12 months and for whom analytical tests, physical examinations, and reviews of medical records do not provide evidence of HIV, hepatitis B, hepatitis C or HTLV infection, can be accepted as donors.
2. **Living donors**
 - 2.1. *Autologous living donor*
 - 2.1.1. If the removed tissues and cells are to be stored or cultured, the same minimum set of biological testing requirements must apply as for an allogeneic living donor. Positive test results will not necessarily prevent the tissues or cells or any product derived from them being stored, processed and reimplanted, if appropriate isolated storage facilities are available to ensure no risk of cross-contamination with other grafts and/or no risk of contamination with adventitious agents and/or mix-ups.
 - 2.2. *Allogeneic living donor*
 - 2.2.1. Allogeneic living donors must be selected on the basis of their health and medical history, provided on a questionnaire and through an interview performed by a qualified and trained healthcare professional with the donor, in compliance with point 2.2.2. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases or health risks to themselves. For any donation, the collection process must not interfere with or compromise the health or care of the donor. In the case of cord blood or amniotic membrane donation, this applies to both mother and baby.
 - 2.2.2. Selection criteria for allogeneic living donors must be established and documented by the tissue establishment (and the transplanting clinician in the case of direct distribution to the recipient), based on the specific tissue or cells to be donated, together with the donor's physical status and medical and behavioural history and the results of clinical investigations and laboratory tests establishing the donor's state of health.
 - 2.2.3. The same exclusion criteria must be applied as for deceased donors with the exception of point 1.1.1. Depending on the tissue or cell to be donated, other specific exclusion criteria may need to be added, such as:
 - (a) pregnancy (except for donors of umbilical cord blood cells and amniotic membrane and sibling donors of haematopoietic progenitors);
 - (b) breastfeeding;
 - (c) in the case of haematopoietic progenitor cells, the potential for transmission of inherited conditions.

ANNEX II

LABORATORY TESTS REQUIRED FOR DONORS (EXCEPT DONORS OF REPRODUCTIVE CELLS) AS REFERRED TO IN ARTICLE 4(1)**1. Biological tests required for donors**

1.1. The following biological tests must be performed for all donors as a minimum requirement:

| | |
|-------------|-------------------|
| HIV 1 and 2 | Anti-HIV-1,2 |
| Hepatitis B | HBsAg Anti HBc |
| Hepatitis C | Anti-HCV-Ab |
| Syphilis | See 1.4 (below) |

1.2. HTLV-I antibody testing must be performed for donors living in, or originating from, high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas.

1.3. When anti-HBc is positive and HBsAg is negative, further investigations are necessary with a risk assessment to determine eligibility for clinical use.

1.4. A validated testing algorithm must be applied to exclude the presence of active infection with *Treponema pallidum*. A non-reactive test, specific or non-specific, can allow tissues and cells to be released. When a non-specific test is performed, a reactive result will not prevent procurement or release if a specific *Treponema* confirmatory test is non-reactive. A donor whose specimen tests reactive on a *Treponema*-specific test will require a thorough risk assessment to determine eligibility for clinical use.

1.5. In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, HLA, malaria, CMV, toxoplasma, EBV, *Trypanosoma cruzi*).

1.6. For autologous donors, Annex I, point 2.1.1, applies.

2. General requirements to be met for determining biological markers

2.1. The tests must be carried out by a qualified laboratory, authorised as a testing centre by the competent authority in the Member State, using EC-marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.

2.2. The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.

2.3. When potential donors have lost blood and have recently received donated blood, blood components, colloids or crystalloids, blood testing may not be valid due to haemodilution of the sample. An algorithm must be applied to assess the degree of haemodilution in the following circumstances:

(a) **ante-mortem blood sampling:** if blood, blood components and/or colloids were infused in the 48 hours preceding blood sampling or if crystalloids were infused in the hour preceding blood sampling;

(b) **post-mortem blood sampling:** if blood, blood components and/or colloids were infused in the 48 hours preceding death or if crystalloids were infused in the hour preceding death.

Tissue establishments may accept tissues and cells from donors with plasma dilution of more than 50 % only if the testing procedures used are validated for such plasma or if a pre-transfusion sample is available.

- 2.4. In the case of a deceased donor, blood samples must have been obtained just prior to death or, if not possible, the time of sampling must be as soon as possible after death and in any case within 24 hours after death.
 - 2.5.
 - (a) In the case of living donors (except allogeneic bone marrow stem-cell and peripheral blood stem-cell donors, for practical reasons), blood samples must be obtained at the time of donation or, if not possible, within seven days post donation (this is the 'donation sample').
 - (b) Where tissues and cells of allogeneic living donors can be stored for long periods, repeat sampling and testing is required after an interval of 180 days. In these circumstances of repeat testing, the donation sample can be taken up to 30 days prior to and 7 days post donation.
 - (c) Where tissues and cells of allogeneic living donors cannot be stored for long periods and repeat sampling is therefore not possible, point 2(5)(a) above applies.
 - 2.6. If in a living donor (except bone marrow stem-cell and peripheral blood stem-cell donors) the 'donation sample', as defined in point 2(5)(a) above, is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.
 - 2.7. In the case of bone marrow and peripheral blood stem-cell collection, blood samples must be taken for testing within 30 days prior to donation.
 - 2.8. In the case of neonatal donors, the biological tests may be carried out on the donor's mother to avoid medically unnecessary procedures upon the infant.
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ANNEX III

SELECTION CRITERIA AND LABORATORY TESTS REQUIRED FOR DONORS OF REPRODUCTIVE CELLS AS REFERRED TO IN ARTICLE 3(b) AND ARTICLE 4(2)**1. Partner donation for direct use**

Donor selection criteria and laboratory testing do not need to be applied in the case of partner donation of reproductive cells for direct use.

2. Partner donation (not direct use)

Reproductive cells that are processed and/or stored and reproductive cells that will result in the cryopreservation of embryos must meet the following criteria:

- 2.1. the clinician responsible for the donor must determine and document, based on the patient's medical history and therapeutic indications, the justification for the donation and its safety for the recipient and any child(ren) that might result;
- 2.2. the following biological tests must be carried out to assess the risk of cross-contamination:

| | |
|-------------|-------------------|
| HIV 1 and 2 | Anti-HIV-1,2 |
| Hepatitis B | HBsAg Anti-HBc |
| Hepatitis C | Anti-HCV-Ab |

In case of sperm processed for intrauterine insemination and not to be stored, if the tissue establishment can demonstrate that the risk of cross contamination and staff exposure has been addressed through the use of validated processes, biological testing may not be required;

- 2.3. where HIV 1 and 2, hepatitis B or hepatitis C test results are positive or unavailable, or where the donor is known to be a source of infection risk, a system of separate storage must be devised;
- 2.4. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;
- 2.5. in certain circumstances, additional testing may be required depending on the donor's travel and exposure history and the characteristics of the tissue or cells donated (e.g. Rh D, malaria, CMV, *T. cruzi*);
- 2.6. positive results will not necessarily prevent partner donation in accordance with national rules.

3. Donations other than by partners

The use of reproductive cells other than for partner donation must meet the following criteria:

- 3.1. donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or the psychological consequences of being a donor);
- 3.2. the donors must be negative for HIV 1 and 2, HCV, HBV and syphilis on a serum or plasma sample, tested in accordance with Annex II, point 1.1, and sperm donors must additionally be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT);
- 3.3. HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas;

- 3.4. in certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the tissue or cells donated (e.g. RhD, malaria, CMV, *T. cruzi*).
- 3.5. for autologous donors, Annex I, point 2.1.1 applies;
- 3.6. genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information must be provided, in accordance with the requirements in force in Member States. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.

4. General requirements to be met for determining biological markers

- 4.1. The tests must be carried out in accordance with Annex II, points 2.1 and 2.2.
 - 4.2. Blood samples must be obtained at the time of donation.
 - 4.3. Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.
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ANNEX IV

CELL AND/OR TISSUE DONATION AND PROCUREMENT PROCEDURES AND RECEPTION AT THE TISSUE ESTABLISHMENT AS REFERRED TO IN ARTICLE 5**1. Donation and procurement procedures****1.1. Consent and donor identification**

1.1.1. Before the procurement of tissues and cells proceeds, an authorised person must confirm and record:

(a) that consent for the procurement has been obtained in accordance with Article 13 of Directive 2004/23/EC;
and

(b) how and by whom the donor has been reliably identified.

1.1.2. In the case of living donors, the health professional responsible for obtaining the health history must ensure that the donor has:

(a) understood the information provided;

(b) had an opportunity to ask questions and been provided with satisfactory responses;

(c) confirmed that all the information provided is true to the best of his/her knowledge.

1.2. Donor evaluation (this section does not apply to partner donation of reproductive cells or to autologous donors)

1.2.1. An authorised person must collect and record the donor's relevant medical and behavioural information according to the requirements described in section 1.4.

1.2.2. In order to acquire the appropriate information, different relevant sources must be used, including at least an interview with the donor, for living donors, and the following when appropriate:

(a) the medical records of the donor;

(b) an interview with a person who knew the donor well, for deceased donors;

(c) an interview with the treating physician;

(d) an interview with the general practitioner;

(e) the autopsy report.

1.2.3. In addition, in the case of a deceased donor, and in the case of a living donor when justified, a physical examination of the body must be performed to detect any signs that may be sufficient in themselves to exclude the donor or which must be assessed in the light of the donor's medical and personal history.

1.2.4. The complete donor records must be reviewed and assessed for suitability and signed by a qualified health professional.

1.3. Procurement procedures for tissues and cells

1.3.1. The procurement procedures must be appropriate for the type of donor and the type of tissue/cells donated. There must be procedures in place to protect the safety of the living donor.

1.3.2. The procurement procedures must protect those properties of the tissue/cells that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process, particularly when tissues and cells cannot subsequently be sterilised.

1.3.3. For deceased donation, the area of access must be restricted. A local sterile field using sterile drapes must be used. Staff conducting procurement must be clothed appropriately for the type of procurement. Usually, this will extend to being scrubbed, gowned in sterile clothing and wearing sterile gloves, face shields and protective masks.

- 1.3.4. In the case of a deceased donor, the place of procurement must be recorded and the time interval from death to procurement must be specified so as to ensure that the required biological and/or physical properties of the tissues/cells are retained.
- 1.3.5. Once the tissues and cells have been retrieved from a deceased donor body, it must be reconstructed so that it is as similar as possible to its original anatomical appearance.
- 1.3.6. Any adverse event occurring during procurement that has or may have resulted in harm to a living donor and the outcome of any investigation to determine the cause must be recorded and reviewed.
- 1.3.7. Policies and procedures must be in place to minimise the risk of tissue or cell contamination by staff who might be infected with transmissible diseases.
- 1.3.8. Sterile instruments and devices must be used for tissue and cell procurement. Instruments or devices must be of good quality, validated or specifically certified and regularly maintained for the procurement of tissues and cells.
- 1.3.9. When reusable instruments must be used, a validated cleaning and sterilisation procedure for removal of infectious agents has to be in place.
- 1.3.10. Wherever possible, only CE marked medical devices must be used and all concerned staff must have received appropriate training on the use of such devices.
- 1.4. *Donor documentation*
 - 1.4.1. For each donor, there must be a record containing:
 - (a) the donor identification (first name, family name and date of birth — if a mother and child are involved in the donation, both the name and date of birth of the mother and the name, if known, and date of birth of the child);
 - (b) age, sex, medical and behavioural history (the information collected must be sufficient to allow application of the exclusion criteria, where required);
 - (c) outcome of body examination, where applicable;
 - (d) haemodilution formula, where applicable;
 - (e) the consent/authorisation form, where applicable;
 - (f) clinical data, laboratory test results, and the results of other tests carried out;
 - (g) if an autopsy was performed, the results must be included in the record (for tissues and cells that cannot be stored for extended periods, a preliminary verbal report of the autopsy must be recorded);
 - (h) for haematopoietic progenitor cell donors, the donor's suitability for the chosen recipient must be documented. For unrelated donations, when the organisation responsible for procurement has limited access to recipient data, the transplanting organisation must be provided with donor data relevant for confirming suitability.
 - 1.4.2. The organisation performing the procurement must produce a procurement report, which is passed on to the tissue establishment. This report must contain at least:
 - (a) the identification, name and address of the tissue establishment to receive the cells/tissues;
 - (b) donor identification data (including how and by whom the donor was identified);
 - (c) description and identification of procured tissues and cells (including samples for testing);
 - (d) identification of the person who is responsible for the procurement session, including signing;
 - (e) date, time (where relevant, start and end) and location of procurement and procedure (SOP) used, including any incidents that occurred; where relevant, environmental conditions at the procurement facility (description of the physical area where procurement took place);

(f) for deceased donors, conditions under which the cadaver is kept: refrigerated (or not), time of start and end of refrigeration;

(g) ID/batch numbers of reagents and transport solutions used.

The report must also contain the date and time of death where possible.

Where sperm is procured at home, the procurement report must state this and must contain only:

(a) the name and address of the tissue establishment to receive the cells/tissues;

(b) the donor identification.

The date and time of procurement may be included, where possible.

1.4.3. All the records must be clear and readable, protected from unauthorised amendment and retained and readily retrieved in this condition throughout their specified retention period in compliance with data protection legislation.

1.4.4. Donor records required for full traceability must be kept for a minimum of 30 years after clinical use, or the expiry date, in an appropriate archive acceptable to the competent authority.

1.5. *Packaging*

1.5.1. Following procurement, all recovered tissues and cells must be packaged in a manner which minimises the risk of contamination and must be stored at temperatures that preserve the required characteristics and biological function of the cells/tissues. The packaging must also prevent contamination of those responsible for packaging and transportation of the tissues and cells.

1.5.2. The packaged cells/tissues must be shipped in a container which is suitable for the transport of biological materials and which maintains the safety and quality of the contained tissue or cells.

1.5.3. Any accompanying tissue or blood samples for testing must be accurately labelled to ensure identification with the donor, and must include a record of the time and place the specimen was taken.

1.6. *Labelling of the procured tissues/cells*

At the time of procurement, every package containing tissues and cells must be labelled. The primary tissue/cell container must indicate the donation identification or code and the type of tissues and cells. Where the size of the package permits, the following information must also be provided:

(a) date (and time where possible) of donation;

(b) hazard warnings;

(c) nature of any additives (if used);

(d) in the case of autologous donations, the label must state 'for autologous use only';

(e) in the case of directed donations, the label must identify the intended recipient.

If any of the information under points (a) to (e) above cannot be included on the primary package label, it must be provided on a separate sheet accompanying the primary package.

1.7. *Labelling of the shipping container*

When tissues/cells are shipped by an intermediary, every shipping container must be labelled at least with:

(a) TISSUES AND CELLS and HANDLE WITH CARE;

(b) the identification of the establishment from which the package is being transported (address and phone number) and a contact person in the event of problems;

(c) the identification of the tissue establishment of destination (address and phone number) and the person to be contacted to take delivery of the container;

- (d) the date and time of the start of transportation;
- (e) specifications concerning conditions of transport relevant to the quality and safety of the tissues and cells;
- (f) in the case of all cellular products, the following indication: DO NOT IRRADIATE;
- (g) when a product is known to be positive for a relevant infectious disease marker, the following indication: BIOLOGICAL HAZARD;
- (h) in the case of autologous donors, the following indication: 'FOR AUTOLOGOUS USE ONLY';
- (i) specifications concerning storage conditions (such as DO NOT FREEZE).

2. Reception of the tissue/cells at the tissue establishment

- 2.1. When the retrieved tissues/cells arrive at the tissue establishment, there must be documented verification that the consignment, including the transport conditions, packaging, labelling and associated documentation and samples, meet the requirements of this Annex and the specifications of the receiving establishment.
 - 2.2. Each establishment must ensure that the tissue and cells received are quarantined until they, along with the associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant donor/procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons.
 - 2.3. Each tissue establishment must have a documented policy and specifications against which each consignment of tissues and cells, including samples, are verified. These must include the technical requirements and other criteria considered by the tissue establishment to be essential for the maintenance of acceptable quality. The tissue establishment must have documented procedures for the management and segregation of non-conforming consignments, or those with incomplete test results, to ensure that there is no risk of contamination of other tissues and cells being processed, preserved or stored.
 - 2.4. The data that must be registered at the tissue establishment (except for donors of reproductive cells intended for partner donation) include:
 - (a) consent/authorisation; including the purpose(s) for which the tissues and cells may be used (i.e. therapeutic or research, or both therapeutic use and research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;
 - (b) all required records relating to the procurement and the taking of the donor history, as described in the donor documentation section;
 - (c) results of physical examination, of laboratory tests and of other tests (such as the autopsy report, if used in accordance with point 1.2.2.);
 - (d) for allogeneic donors, a properly documented review of the complete donor evaluation against the selection criteria by an authorised and trained person;
 - (e) in the case of cell cultures intended for autologous use, documentation of the possibility of medicinal allergies (such as to antibiotics) of the recipient.
 - 2.5. In the case of reproductive cells intended for partner donation, the data to be registered at the tissue establishment include:
 - (a) consent; including the purpose(s) for which the tissues and cells may be used (such as reproductive only and/or for research) and any specific instructions for disposal if the tissue or cells are not used for the purpose for which consent was obtained;
 - (b) donor identification and characteristics: type of donor, age, sex, presence of risk factors and, in the case of a deceased donor, the cause of death;
 - (c) partner identification;
 - (d) place of procurement;
 - (e) tissues and cells obtained and relevant characteristics.
-