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I

(Acts whose publication is obligatory)

**COMMISSION REGULATION (EC) No 727/2004
of 19 April 2004
establishing the standard import values for determining the entry price of certain fruit and
vegetables**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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

Whereas:

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

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

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

This Regulation shall enter into force on 20 April 2004.

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

Done at Brussels, 19 April 2004.

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

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

ANNEX

to the Commission Regulation of 19 April 2004 establishing the standard import values for determining the entry price of certain fruit and vegetables

(EUR/100 kg)

CN code	Third country code ⁽¹⁾	Standard import value
0702 00 00	052	80,0
	204	27,3
	212	120,5
	999	75,9
0707 00 05	052	110,9
	068	128,2
	096	93,3
	220	147,3
	999	119,9
0709 90 70	052	106,6
	204	64,2
	999	85,4
0805 10 10, 0805 10 30, 0805 10 50	052	55,5
	204	40,8
	212	87,1
	220	55,9
	400	43,8
	600	36,6
	624	60,7
	999	54,3
0805 50 10	052	41,0
	400	48,3
	999	44,7
0808 10 20, 0808 10 50, 0808 10 90	060	34,7
	388	85,0
	400	104,4
	404	104,7
	508	59,4
	512	74,6
	524	54,3
	528	73,5
	720	82,6
	804	118,2
	999	79,1
0808 20 50	388	76,2
	512	79,2
	524	80,8
	528	74,9
	999	77,8

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

COMMISSION REGULATION (EC) No 728/2004
of 15 April 2004
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) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific Community provisions, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column 1 of the table set out in the Annex should be classified under the CN-code indicated in column 2, by virtue of the reasons set out in column 3.
- (4) It is appropriate to provide that, subject to the measures in force in the Community relating to double checking systems and to prior and retrospective Community surveillance of textile products on importation into the Community, binding tariff information issued by the customs authorities of Member States in respect of the

classification of goods in the Combined Nomenclature and which is not in accordance with this Regulation, can continue to be invoked for a period of 60 days by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code⁽²⁾.

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

HAS ADOPTED THIS REGULATION:

Article 1

The good described in column 1 of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN-code indicated in column 2.

Article 2

Subject to the measures in force in the Community relating to double checking systems and to prior and retrospective Community surveillance of textile products on importation into the Community, binding tariff information issued by the customs authorities of Member States which is not in accordance with this Regulation, can continue to be invoked for a period of 60 days, under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

This Regulation shall enter into force on the 20th day following that of 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, 15 April 2004.

For the Commission

Frederik BOLKESTEIN

Member of the Commission

⁽¹⁾ OJ L 256, 7.9.1987, p. 1. Regulation as last amended by Commission Regulation (EC) No 2344/2003 (OJ L 346, 31.12.2003, p. 38).

⁽²⁾ OJ L 302, 19.10.1992, p. 1. Regulation as last amended by the Act of Accession of 2003.



COMMISSION REGULATION (EC) No 729/2004
of 15 April 2004
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) In order to ensure uniform application of the Combined Nomenclature annexed to Regulation (EEC) No 2658/87, it is necessary to adopt measures concerning the classification of the goods referred to in the Annex to this Regulation.
- (2) Regulation (EEC) No 2658/87 has laid down the general rules for the interpretation of the Combined Nomenclature. Those rules apply also to any other nomenclature which is wholly or partly based on it or which adds any additional subdivision to it and which is established by specific Community provisions, with a view to the application of tariff and other measures relating to trade in goods.
- (3) Pursuant to those general rules, the goods described in column 1 of the table set out in the Annex should be classified under the CN codes indicated in column 2, by virtue of the reasons set out in column 3.
- (4) It is appropriate to provide that binding tariff information which has been issued by the customs authorities of Member States in respect of the classification of goods in

the Combined Nomenclature but which is not in accordance with this Regulation can, for a period of three months, continue to be invoked by the holder, under Article 12(6) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽²⁾.

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

HAS ADOPTED THIS REGULATION:

Article 1

The goods described in column 1 of the table set out in the Annex shall be classified within the Combined Nomenclature under the CN codes indicated in column 2.

Article 2

Binding tariff information issued by the customs authorities of Member States, which is not in accordance with this Regulation, can continue to be invoked for a period of three months under Article 12(6) of Regulation (EEC) No 2913/92.

Article 3

This Regulation shall enter into force on the 20th day following that of 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, 15 April 2004.

For the Commission
Frederik BOLKESTEIN
Member of the Commission

⁽¹⁾ OJ L 256, 7.9.1987, p. 1. Regulation as last amended by Commission Regulation (EC) No 2344/2003 (OJ L 346, 31.12.2003, p. 38).

⁽²⁾ OJ L 302, 19.10.1992, p. 1. Regulation as last amended by the Act of Accession of 2003.

ANNEX

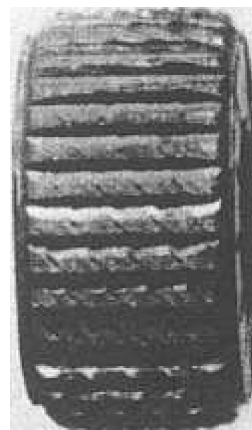
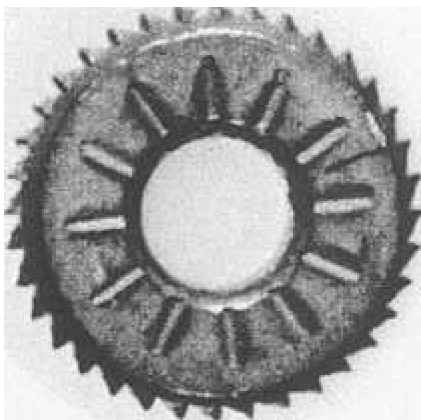
Description of the goods	Classification (CN code)	Reasons
(1)	(2)	(3)
1. A connector for an optical fibre cable, unassembled, consisting of the following components: — 1 connector part of base metal with a plastic interior and a ceramic ferrule, provided with a steel spring; — 1 tube of base metal with a shaped edge; — 1 plastic cylinder with a crimp-sleeve of aluminium; — 2 plastic holders. The connector part can be assembled with the other parts and one of the holders to form a connector. One individually sheathed optical fibre is passed through the ferrule and secured to it. The connector will be used as a connecting element for optical fibre cables.	6909 19 00	Classification is determined by General Rules 1, 2(a), 3(b) and 6 for the interpretation of the Combined Nomenclature, and by the wording of CN codes 6909 and 6909 19 00. The connector is not considered to be a part or an accessory of an optical fibre cable. The connector is to be classified according to the constituent material. Its essential character is conferred by the ferrule.
2. Apparatus consisting of: — an axial fan with an electrical motor and an electronic assembly for adjusting the speed of the fan; and — an aluminium heat sink. The function of the apparatus is to remove the excess heat of a central processing unit of an automatic data processing machine.	8414 59 30	Classification is determined by the provisions of General Rules 1, 3(b) and 6 for the interpretation of the Combined Nomenclature, and by the wording of CN codes 8414, 8414 59 and 8414 59 30. The fan gives the product its essential character. It is the primary component for removing excess heat.
3. An article ('snowshoe') measuring 65 cm in length and 23 cm at its widest consisting of an aluminium frame with a plastic covering, tapered at one end and rounded at the other. This frame has a plastic attachment 1 mm thick which has cutouts for metal blades on the underside to ensure better footing in the snow. A rigid metal plate is secured to the frame on the upper side by a plastic strap. Rubber pieces are attached to the plate to go round a shoe when worn and these in turn have rubber/fabric straps to attach the article to the shoe. The article is used to assist walking on the snow. See photograph (A) (*)	9506 99 90	Classification is determined by the provisions of General Rules 1 and 6 for the interpretation of the Combined Nomenclature, and by the wording of CN codes 9506, 9506 99 and 9506 99 90. It is not snow-ski equipment as it is not used for skiing. It is not equipment for general physical exercise. The product is considered to be an article for outdoor sport.
4. A base metal wheel, with a diameter of 6,74 mm, a centre hole size of 3 mm and a thickness of 3,54 mm, provided with teeth. The product is a component for incorporating into the ignition mechanism of a cigarette lighter. See photographs (B) (*)	9613 90 00	Classification is determined by the provisions of General Rules 1 and 6 for the interpretation of the Combined Nomenclature, and by the wording of CN- codes 9613 and 9613 90 00. The wheel is suitable for use principally in the manufacture of spark devices for cigarette lighters of heading 9613.

(*) The photographs are purely for information.

(A)



(B)



**COMMISSION REGULATION (EC) No 730/2004
of 19 April 2004**

adapting Regulation (EEC) No 1859/82 concerning the selection of returning holdings for the purpose of determining incomes of agricultural holdings by reason of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia to the European Union

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

HAS ADOPTED THIS REGULATION:

Having regard to the Treaty establishing the European Community,

Article 1

Regulation (EEC) No 1859/82 is amended as follows:

1. Article 2 is replaced by the following:

Having regard to the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 2(3) thereof,

'Article 2

For the 2004 accounting year (a period of 12 consecutive months beginning between 1 January 2004 and 1 July 2004) and for subsequent accounting years, the threshold as referred to in Article 4 of Regulation No 79/65/EEC in ESU shall be as follows:

Having regard to the Act of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia, and in particular Article 57(2) thereof,

Whereas:

- (1) Article 2 of Commission Regulation (EEC) No 1859/82 ⁽¹⁾ fixes per Member State the threshold of economic size of returning holdings falling within the field of survey of the farm accountancy data network.
- (2) The number of returning holdings per Member State to be selected by division is fixed in Annex I to Regulation (EEC) No 1859/82.
- (3) In view of the accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia (hereinafter 'the new Member States') the threshold for the new Member States, as well as the number of returning holdings by division for the new Member States should be fixed.
- (4) The deadline for the delivery of the first approved selection plan concerning the new Member States should be fixed.
- (5) Regulation (EEC) No 1859/82 should therefore be amended accordingly,

— Belgium:	16 ESU
— Czech Republic:	4 ESU
— Denmark:	8 ESU
— Germany:	8 ESU
— Estonia:	2 ESU
— Greece:	2 ESU
— Spain:	2 ESU
— France:	8 ESU
— Ireland:	2 ESU
— Italy:	4 ESU
— Cyprus:	1 ESU
— Latvia:	2 ESU
— Lithuania:	2 ESU
— Luxembourg:	8 ESU
— Hungary:	2 ESU
— Malta:	8 ESU
— Netherlands:	16 ESU
— Austria:	8 ESU
— Poland:	2 ESU
— Portugal:	2 ESU
— Slovenia:	2 ESU
— Slovakia:	6 ESU
— Finland:	8 ESU
— Sweden:	8 ESU
— United Kingdom (with the exception of Northern Ireland):	16 ESU
— United Kingdom (only Northern Ireland):	8 ESU.'

⁽¹⁾ OJ L 205, 13.7.1982, p. 5. Regulation as last amended by Regulation (EC) No 659/2004 (OJ L 104, 8.4.2004, p. 95).

2. In Article 5, the following subparagraph is added:

'The Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia shall forward to the Commission their selection plan for the accounting year 2004 before 30 November 2004.'

3. Annex I is replaced by the text in the Annex to this Regulation.

Article 2

This Regulation shall enter into force subject to and on the date of the entry into force of the Treaty of Accession of the Czech Republic, Estonia, Cyprus, Latvia, Lithuania, Hungary, Malta, Poland, Slovenia and Slovakia.

It shall apply from the 2004 accounting year.

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

Done at Brussels, 19 April 2004.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

'ANNEX I

Reference number	Name of division	Number of returning holdings
	BELGIUM	
341	Flanders	600
342	Brussels	—
343	Walloon Region	400
Total Belgium		1 000
745	CZECH REPUBLIC	1 300
370	DENMARK	2 000
	GERMANY	
010	Schleswig-Holstein	500
020	Hamburg	40
030	Lower Saxony	800
040	Bremen	—
050	North Rhine-Westphalia	660
060	Hessen	370
070	Rheinland-Pfalz	480
080	Baden-Württemberg	620
090	Bavaria	960
100	Saarland	70
110	Berlin	—
112	Brandenburg	180
113	Mecklenburg-Western Pomerania	130
114	Saxony	220
115	Saxony-Anhalt	140
116	Thuringia	130
Total Germany		5 300
755	ESTONIA	500
	GREECE	
450	Macedonia-Thrace	2 000
460	Epirus-Peloponnese-Ionian Islands	1 350
470	Thessaly	700
480	Continental Greece, Aegean Islands, Crete	1 450
Total Greece		5 500
	SPAIN	
500	Galicia	800
505	Asturias	350
510	Cantabria	230
515	Basque Country	310
520	Navarre	430
525	Rioja	290

Reference number	Name of division	Number of returning holdings
530	Aragon	640
535	Catalonia	870
540	Balearic Islands	270
545	Castile-Leon	1 230
550	Madrid	270
555	Castille-La Mancha	870
560	Valencia	700
565	Murcia	530
570	Extremadura	590
575	Andalusia	1 470
580	Canary Islands	250
Total Spain		10 100
FRANCE		
121	Île-de-France	95
131	Champagne-Ardenne	260
132	Picardy	230
133	Upper Normandy	145
134	Centre	350
135	Lower Normandy	215
136	Burgundy	285
141	Nord/Pas-de-Calais	305
151	Lorraine	215
152	Alsace	160
153	Franche-Comté	200
162	Region Loire	440
163	Brittany	475
164	Poitou-Charentes	325
182	Aquitaine	425
183	Midi-Pyrénées	430
184	Limousin	195
192	Rhône-Alpes	360
193	Auvergne	320
201	Languedoc-Roussillon	340
203	Provence-Alpes-Côte d'Azur	270
204	Corsica	60
Total France		6 100
380	IRELAND	1 300
ITALY		
221	Valle d'Aosta	367
222	Piedmont	1 110
230	Lombardy	917
241	Trentino	404
242	Alto Adige	404

Reference number	Name of division	Number of returning holdings
243	Veneto	1 589
244	Friuli-Venezia Giulia	795
250	Liguria	590
260	Emilia-Romagna	914
270	Tuscany	620
281	Marche	951
282	Umbria	668
291	Lazio	931
292	Abruzzi	882
301	Molise	445
302	Campania	748
303	Calabria	911
311	Apulia	1 013
312	Basilicata	1 138
320	Sicily	1 350
330	Sardinia	1 253
Total Italy		18 000
740	CYPRUS	500
770	LATVIA	1 000
775	LITHUANIA	1 000
350	LUXEMBOURG	300
HUNGARY		
760	Közép-Magyarország	160
761	Közép-Dunántúl	190
762	Nyugat-Dunántúl	230
763	Dél-Dunántúl	260
764	Észak- Magyarország	210
765	Észak-Alföld	380
766	Dél-Alföld	470
Total Hungary		1 900
780	MALTA	500
360	NETHERLANDS	1 500
660	AUSTRIA	2 000
POLAND		
785	Pomorze and Mazury	1 640
790	Wielkopolska and Śląsk	3 980
795	Mazowsze and Podlasie	5 060
800	Małopolska and Pogórze	1 420
Total Poland		12 100

Reference number	Name of division	Number of returning holdings
	PORTUGAL	
610	Between Douro e Minho and Beira Litoral	980
620	Trás-os-Montes and Beira Interior	560
630	Ribatejo and the West	650
640	Alentejo and Algarve	460
650	Azores and Madeira	350
Total Portugal		3 000
820	SLOVENIA	900
810	SLOVAKIA	600
	FINLAND	
670	Etelä-Suomi	581
680	Sisä-Suomi	272
690	Pohjanmaa	277
700	Pohjois-Suomi	170
Total Finland		1 300
	SWEDEN	
710	Plains of South and Central Sweden	600
720	Forest and mixed agricultural and forest areas of South and Central Sweden	295
730	Areas of North Sweden	105
Total Sweden		1 000
	UNITED KINGDOM	
411	England — North Region	420
412	England — East Region	650
413	England — West Region	430
421	Wales	300
431	Scotland	380
441	Northern Ireland	320
Total United Kingdom		2 500'

COMMISSION DIRECTIVE 2004/43/EC
of 13 April 2004

amending Directive 98/53/EC and Directive 2002/26/EC as regards sampling methods and methods of analysis for the official control of the levels of aflatoxin and ochratoxin A in food for infants and young children

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption⁽¹⁾, and in particular Article 1 thereof,

Whereas:

- (1) Commission Regulation (EC) No 466/2001 of 8 March 2001 setting maximum levels for certain contaminants in foodstuffs⁽²⁾ fixes maximum limits for aflatoxin B1, aflatoxin M1 and ochratoxin A in food for infants and young children.
- (2) Sampling plays a crucial part in the precision of the determination of the levels of aflatoxins and ochratoxin A. Commission Directive 98/53/EC of 16 July 1998 laying down the sampling methods and the methods of analysis for the official control of the levels of certain contaminants in foodstuffs⁽³⁾ and Commission Directive 2002/26/EC of 13 March 2002 laying down the sampling methods and methods of analysis for the official control of the levels of ochratoxin A in foodstuffs⁽⁴⁾ should be amended to include provisions related to food for infants and young children.
- (3) It is of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the European Union. These interpretation rules are of application for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.
- (4) Directives 98/53/EC and 2002/26/EC should therefore be amended accordingly.

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

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annexes I and II to Directive 98/53/EC are amended as set out in Annex I to this Directive.

Article 2

Annexes I and II to Directive 2002/26/EC are amended as set out in Annex II to this Directive.

Article 3

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 12 months after its 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 texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 4

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

⁽¹⁾ OJ L 372, 31.12.1985, p. 50. Directive as amended by Regulation (EC) No 1882/2003 (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 455/2004 (OJ L 74, 12.3.2004, p. 11).

⁽³⁾ OJ L 201, 17.7.1998, p. 93. Directive as last amended by Directive 2003/121/EC (OJ L 332, 19.12.2003, p. 38).

⁽⁴⁾ OJ L 75, 16.3.2002, p. 38.

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

Annexes I and II to Directive 98/53/EC are amended as follows:

1. In Annex I to Directive 98/53/EC the following point 5.7 is inserted after point 5.6:

‘5.7. *Foods intended for infants and young children*

5.7.1. Sampling procedure

The sampling procedure as mentioned for milk and derived products as well as for compound food in points 5.4, 5.5 and 5.6 applies.

5.7.2. Acceptance of a lot

- Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,
- Rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt, taking into account the measurement uncertainty and correction for recovery.’

2. In Annex II, point 2 shall read as follows

‘2. **Treatment of the sample as received in the laboratory**

Finely grind and thoroughly mix each laboratory sample using a process that has been demonstrated to achieve complete homogenisation.

In case the maximum level applies to the dry matter, the dry matter content shall be determined on a part of the homogenised sample, using a procedure that has been demonstrated to determine accurately the dry matter content.’

ANNEX II

Annexes I and II to Directive 2002/26/EC are amended as follows:

1. Annex I is amended as follows:

(a) point 4.6 shall read as follows:

'4.6. Sampling procedure for foods intended for infants and young children

The sampling procedure as mentioned for cereals and cereal products in point 4.5 of this Annex applies. This means that the number of incremental samples to be taken depends on the weight of the lot, with a minimum of 10 and a maximum of 100, in accordance with Table 2 at point 4.5.

— The weight of the incremental sample should be about 100 grams. In case of lots in retail packing, the weight of the incremental sample depends on the weight of the retail packing.

— Weight of aggregate sampling = 1 to 10 kg sufficiently mixed.'

(b) the following point 4.7 is inserted:

'4.7. Sampling at retail stage

Sampling of foodstuffs at the retail stage should be done where possible in accordance with the above sampling provisions. Where this is not possible, other effective sampling procedures at retail stage can be used, provided that they ensure sufficient representativeness for the sampled lot.'

(c) point 5 shall read as follows:

'5. Acceptance of a lot or subplot

— Acceptance if the aggregate sample conforms to the maximum limit, taking into account the measurement uncertainty and correction for recovery,

— Rejection if the aggregate sample exceeds the maximum limit beyond reasonable doubt, taking into account the measurement uncertainty and correction for recovery.'

2. Annex II is amended as follows:

(a) point 2 shall read as follows

'2. Treatment of the sample as received in the laboratory

Finely grind and thoroughly mix each laboratory sample using a process that has been demonstrated to achieve complete homogenisation.

In case the maximum level applies to the dry matter, the dry matter content shall be determined on a part of the homogenised sample, using a procedure that has been demonstrated to determine accurately the dry matter content.'

(b) point 4.4 shall read as follows:

'4.4. Recovery calculation and reporting of results

The analytical result is to be reported corrected or uncorrected for recovery. The manner of reporting and the level of recovery must be reported. The analytical result corrected for recovery shall be used for checking compliance (see Annex I, point 5)

The analytical result has to be reported as $x \pm U$, whereby x is the analytical result and U is the expanded measurement uncertainty.

U is the expanded uncertainty, using a coverage factor of 2 which gives a level of confidence of approximately 95 %.'

**COMMISSION DIRECTIVE 2004/44/EC
of 13 April 2004**

**amending Directive 2002/69/EC laying down the sampling methods and the methods of analysis
for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs**

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 85/591/EEC of 20 December 1985 concerning the introduction of Community methods of sampling and analysis for the monitoring of foodstuffs intended for human consumption ⁽¹⁾, and in particular Article 1 thereof,

Whereas:

- (1) Commission Directive 2002/69/EC of 30 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in foodstuffs ⁽²⁾ establishes specific provisions concerning the sampling procedure and the methods of analysis to be applied for official control.
- (2) For the sampling of very large fish, it is necessary that the sampling is specified in order to ensure a harmonised approach throughout the Community.
- (3) It is of major importance that analytical results are reported and interpreted in a uniform way in order to ensure a harmonised enforcement approach across the Union.
- (4) Directive 2002/69/EC should therefore be amended accordingly.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Annex I to Directive 2002/69/EC is amended as set out in Annex I to this Directive.

Annex II to Directive 2002/69/EC is amended as set out in Annex II to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive 12 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 texts of the provisions of national law which they adopt in the field covered by this Directive.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 372, 31.12.1985, p. 50. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 209, 6.8.2002, p. 5.

ANNEX I

Annex I to Directive 2002/69/EC is amended as follows:

1. In point 4 'Sampling plans', the following point 4.1 'Specific provisions for the sampling of lots containing whole fishes' is inserted after Table 2:

'4.1. Specific provisions for the sampling of lots containing whole fishes

The number of incremental samples to be taken from the lot is defined in Table 1. The aggregate sample uniting all incremental samples shall be at least 1 kg (see point 3.5).

- In case the lot to be sampled contains small fish (individual fish weighing < 1 kg), the whole fish is taken as incremental sample to form the aggregate sample. In case the resulting aggregate sample weighs more than 3 kg, the incremental samples can consist of the middle part, weighing each at least 100 grams, of the fish forming the aggregate sample. The whole part to which the maximum level is applicable is used for homogenisation of the sample.
- In case the lot to be sampled contains larger fish (individual fish weighing more than 1 kg), the incremental sample consists of the middle part of the fish. Each incremental sample weighs at least 100 grams. In case the lot to be sampled consist of very large fish (e.g. > 6 kg) and taking a piece of the middle part of the fish would result in significant economic damage, taking three incremental samples of at least 350 grams each can be considered sufficient, independently of the size of the lot.'

2. Point 5 'Compliance of the lot or subplot with the specification' is replaced by the following:

'5. Compliance of the lot or subplot with the specification

The lot is accepted if the analytical result of a single analysis does not exceed the respective maximum level as laid down in Regulation (EC) No 466/2001, taking into account the measurement uncertainty.

The lot is non-compliant with the maximum level as laid down in Regulation (EC) No 466/2001, if the analytical result confirmed by duplicate analysis and calculated as the mean of at least two separate determinations exceeds the maximum level beyond reasonable doubt, taking into account the measurement uncertainty.

The taking into account of the measurement uncertainty can be done according to one of the following approaches:

- by calculating the expanded uncertainty, using a coverage factor of 2, which gives a level of confidence of approximately 95 %,
- by establishing the decision limit (CCa) according to the provisions of Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results (*) (point 3.1.2.5 of the Annex — the case of substances with established permitted levels).

The present interpretation rules apply for the analytical result obtained on the sample for official control. In case of analysis for defence or referee purposes, the national rules apply.

(*) OJ L 221, 17.8.2002, p. 8. Decision as last amended by Decision 2004/25/EC (OJ L 6, 10.1.2004, p. 38).'

ANNEX II

Annex II to Directive 2002/69/EC is amended as follows:

The following subparagraph is added at the end of the point 2 'Background'

'For the purposes of this Directive only, the accepted specific limit of quantification of an individual congener is the concentration of an analyte in the extract of a sample which produces an instrumental response at two different ions, to be monitored with an S/N (signal/noise) ratio of 3:1 for the less sensitive signal and fulfilment of the basic requirements such as, e.g., retention time, isotope ratio according to the determination procedure as described in EPA method 1613 revision B.'

**COMMISSION DIRECTIVE 2004/45/EC
of 16 April 2004**

amending Directive 96/77/EC laying down specific purity criteria on food additives other than colours and sweeteners

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption ⁽¹⁾, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee on Food,

Whereas:

- (1) Commission Directive 96/77/EC ⁽²⁾ of 2 December 1996 laying down specific purity criteria on food additives other than colours and sweeteners sets out the purity criteria for the additives mentioned in Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners ⁽³⁾.
- (2) The Scientific Committee on Food concluded in its opinion of 5 March 2003 that the presence of low molecular weight carrageenan should be kept to a minimum. Consequently, the relevant criterion of the existing purity criteria for E 407 Carrageenan and E 407a (Processed Eucheuma Seaweed) set out in Directive 96/77/EC needs to be adapted.
- (3) It is necessary to adopt specifications for the new additives authorised through Directive 2003/114/EC of the European Parliament and of the Council of 22 December 2003 amending Directive 95/2/EC on food additives other than colours and sweeteners: E 907 Hydrogenated poly-1-decene, E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol.
- (4) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (5) Directive 96/77/EC should therefore be amended accordingly.
- (6) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 96/77/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 April 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such 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 3

Products put on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 339, 30.12.1996, p. 1. Directive as last amended by Directive 2003/95/EC (OJ L 283, 31.10.2003, p. 71).

⁽³⁾ OJ L 61, 18.3.1995, p. 1. Directive as last amended by Directive 2003/114/EC (OJ L 24, 29.1.2003, p. 58).

ANNEX

The Annex to Directive 96/77/EC is amended as follows:

1. The texts concerning E 407 Carrageenan and E 407a Processed Eucheuma Seaweed are replaced by the following:

E 407 CARRAGEENAN

Synonyms	Products of commerce are sold under different names such as: Irish moss gelose Eucheuman (from <i>Eucheuma</i> spp.) Iridophycan (from <i>Iridaea</i> spp.) Hypnean (from <i>Hypnea</i> spp.) Furcellaran or Danish agar (from <i>Furcellaria fastigiata</i>) Carrageenan (from <i>Chondrus</i> and <i>Gigartina</i> spp.)
Definition	Carrageenan is obtained by aqueous extraction of natural strains of seaweeds of <i>Gigartinaceae</i> , <i>Solieriaceae</i> , <i>Hypneaceae</i> and <i>Furcellariaceae</i> , families of the class <i>Rhodophyceae</i> (red seaweeds). No organic precipitant shall be used other than methanol, ethanol and propane-2-ol. Carrageenan consists chiefly of the potassium, sodium, magnesium and calcium salts of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Carrageenan shall not be hydrolysed or otherwise chemically degraded
EINECS	232-524-2
Description	Yellowish to colourless, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not more than 2 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g

E 407a PROCESSED EUCHEUMA SEAWEED

Synonyms	PES (acronym for processed eucheuma seaweed)
Definition	Processed eucheuma seaweed is obtained by aqueous alkaline (KOH) treatment of the natural strains of seaweeds <i>Eucheuma cottonii</i> and <i>Eucheuma spinosum</i> , of the class <i>Rhodophyceae</i> (red seaweeds) to remove impurities and by fresh water washing and drying to obtain the product. Further purification may be achieved by washing with methanol, ethanol or propane-2-ol and drying. The product consist chiefly of the potassium salt of polysaccharide sulphate esters which, on hydrolysis, yield galactose and 3,6-anhydrogalactose. Sodium, calcium and magnesium salts of the polysaccharide sulphate esters are present in lesser amounts. Up to 15 % algal cellulose is also present in the product. The carrageenan in processed eucheuma seaweed shall not be hydrolysed or otherwise chemically degraded
Description	Tan to yellowish, coarse to fine powder which is practically odourless
Identification	
A. Positive tests for galactose, for anhydrogalactose and for sulphate	
B. Solubility	Forms cloudy viscous suspensions in water. Insoluble in ethanol
Purity	
Methanol, ethanol, propane-2-ol content	Not more than 0,1 % singly or in combination
Viscosity of a 1,5 % solution at 75 °C	Not less than 5 mPa.s
Loss on drying	Not more than 12 % (105 °C, four hours)
Sulphate	Not less than 15 % and not more than 40 % on the dried basis (as SO ₄)
Ash	Not less than 15 % and not more than 40 % determined on the dried basis at 550 °C
Acid-insoluble ash	Not more than 1 % on the dried basis (insoluble in 10 % hydrochloric acid)
Acid-insoluble matter	Not less than 8 % and not more than 15 % on the dried basis (insoluble in 1 % v/v sulphuric acid)
Low molecular weight carrageenan (Molecular weight fraction below 50 kDa)	Not more than 5 %
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg
Mercury	Not more than 1 mg/kg
Cadmium	Not more than 1 mg/kg
Total plate count	Not more than 5 000 colonies per gram
Yeast and moulds	Not more than 300 colonies per gram
<i>E. coli</i>	Negative in 5 g
<i>Salmonella</i> spp.	Negative in 10 g'

2. The following text concerning E 907 Hydrogenated poly-1-decene is inserted after E 905 Microcrystalline wax:

'E 907 HYDROGENATED POLY-1-DECENE

Synonyms	Hydrogenated polydec-1-ene Hydrogenated poly-alpha-olefin
Definition	
Chemical formula	$C_{10n}H_{20n+2}$ where $n = 3 - 6$
Molecular weight	560 (average)
Assay	Not less than 98,5 % of hydrogenated poly-1-decene, having the following oligomer distribution: C ₃₀ : 13 — 37 % C ₄₀ : 35 — 70 % C ₅₀ : 9 — 25 % C ₆₀ : 1 — 7 %
Description	Colourless, odourless, viscous liquid
Identification	
A. Solubility	Insoluble in water; slightly soluble in ethanol; soluble in toluene
B. Burning	Burns with a bright flame and a paraffin-like characteristic smell
Purity	
Viscosity	Between $5,7 \times 10^{-6}$ and $6,1 \times 10^{-6} \text{ m}^2\text{s}^{-1}$ at 100 °C
Compounds with carbon number less than 30	Not more than 1,5 %
Readily carbonisable substances	After 10 minutes shaking in a boiling water bath, a tube of sulfuric acid with a 5 g sample of hydrogenated poly-1-decene is not darker than a very slight straw colour
Nickel	Not more than 1 mg/kg
Lead	Not more than 1 mg/kg'

3. The following text concerning E 1517 Glyceryl diacetate and E 1519 Benzyl alcohol is added:

'E 1517 GLYCERYL DIACETATE

Synonyms	Diacetin
Definition	Glyceryl diacetate consists predominantly of a mixture of the 1,2- and 1,3-diacetates of glycerol, with minor amounts of the mono- and tri-esters
Chemical names	Glyceryl diacetate 1,2,3-propanetriol diacetate
Chemical formula	$C_7H_{12}O_5$
Molecular weight	176,17
Assay	Not less than 94,0 %
Description	Clear, colourless, hygroscopic, somewhat oily liquid with a slight, fatty odour
Identification	
A. Solubility	Soluble in water. Miscible with ethanol
B. Positive tests for glycerol and acetate	
C. Specific gravity	d_{20}^{20} : 1,175 — 1,195
D. Boiling range	Between 259 and 261 °C
Purity	
Total ash	Not more than 0,02 %
Acidity	Not more than 0,4 % (as acetic acid)
Arsenic	Not more than 3 mg/kg
Lead	Not more than 5 mg/kg

E 1519 BENZYL ALCOHOL**Synonyms**

Phenylcarbinol
Phenylmethyl alcohol
Benzenemethanol
Alpha-hydroxytoluene

Definition

Chemical names

Benzyl alcohol
Phenylmethanol

Chemical formula

C_7H_8O

Molecular weight

108,14

Assay

Not less than 98,0 %

Description

Colourless, clear liquid with a faint, aromatic odour

Identification

A. Solubility

Soluble in water, ethanol and ether

B. Refractive index

$[n]_D^{20}$: 1,538 – 1,541

C. Specific gravity

d_{25}^{25} : 1,042 — 1,047

D. Positive test for peroxides

Purity

Distillation range

Not less than 95 % v/v distils between 202 and 208 °C

Acid value

Not more than 0,5

Aldehydes

Not more than 0,2 % v/v (as benzaldehyde)

Lead

Not more than 5 mg/kg'

COMMISSION DIRECTIVE 2004/47/EC**of 16 April 2004****amending Directive 95/45/EC as regards mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii))****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption⁽¹⁾, and in particular Article 3(3)(a) thereof,

After consulting the Scientific Committee for Food,

Whereas:

- (1) Commission Directive 95/45/EC of 26 July 1995 laying down specific purity criteria concerning colours for use in foodstuffs⁽²⁾ sets out the purity criteria for the colours mentioned in Directive 94/36/EC of the European Parliament and of the Council of 30 June 1994 on colours for use in foodstuffs⁽³⁾.
- (2) It is necessary, in the light of technical progress, to amend the purity criteria set out in Directive 95/45/EC for mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)).
- (3) It is necessary to take into account the specifications and analytical techniques for additives as set out in the Codex Alimentarius as drafted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).
- (4) Directive 95/45/EC should therefore be amended accordingly.
- (5) The measures provided for in this Directive are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DIRECTIVE:

Article 1

The Annex to Directive 95/45/EC is amended in accordance with the Annex to this Directive.

Article 2

1. Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 April 2005 at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

When Member States adopt those provisions, they shall contain a reference to this Directive or shall be accompanied by such 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 3

Products on the market or labelled before 1 April 2005 which do not comply with this Directive may be marketed until stocks are exhausted.

Article 4

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

Article 5

This Directive is addressed to the Member States.

Done at Brussels, 16 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

⁽²⁾ OJ L 226, 22.9.1995, p. 1. Directive as last amended by Directive 2001/50/EC (OJ L 190, 12.7.2001, p. 14).

⁽³⁾ OJ L 237, 10.9.1994, p. 13. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

ANNEX

In the Annex, the text concerning mixed carotenes (E 160 a (i)) and beta-carotene (E 160 a (ii)) is replaced by the following:

E 160 a (i) MIXED CAROTENES**1. Plant carotenes****Synonyms**

CI Food Orange 5

Definition

Mixed carotenes are obtained by solvent extraction of natural strains of edible plants, carrots, vegetable oils, grass, alfalfa (lucerne) and nettle.

The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha, gamma-carotene and other pigments may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.

Only the following solvents may be used in the extraction: acetone, methyl ethyl ketone, methanol, ethanol, propan-2-ol, hexane (*), dichloromethane and carbon dioxide.

Class

Carotenoid

Colour index No

75130

EINECS

230-636-6

Chemical formulaBeta-carotene: $C_{40}H_{56}$ **Molecular weight**

Beta-carotene: 536,88

Assay

Content of carotenes (calculated as beta-carotene) is not less than 5 %. For products obtained by extraction of vegetable oils: not less than 0,2 % in edible fats

$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Identification**A. Spectrometry**

Maximum in cyclohexane at 440 nm to 457 nm and 470 nm to 486 nm

Purity**Solvent residues**

Acetone

Methyl ethyl ketone

Methanol

Propan-2-ol

Hexane

Ethanol

} Not more than 50 mg/kg, singly or in combination

Dichloromethane

} Not more than 10 mg/kg

Lead

Not more than 5 mg/kg

(*) Benzene not more than 0,05 % v/v.

2. Algal carotenes

Synonyms	CI Food Orange 5
Definition	Mixed carotenes may also be produced from natural strains of the algae <i>Dunaliella salina</i> , grown in large saline lakes located in Whyalla, South Australia. Beta-carotene is extracted using an essential oil. The preparation is a 20 to 30 % suspension in edible oil. The ratio of trans-cis isomers is in the range of 50/50 to 71/29. The main colouring principle consists of carotenoids of which beta-carotene accounts for the major part. Alpha-carotene, lutein, zeaxanthin and beta-cryptoxanthin may be present. Besides the colour pigments, this substance may contain oils, fats and waxes naturally occurring in the source material.
Class	Carotenoid
Colour index No	75130
Chemical formula	Beta-carotene: $C_{40}H_{56}$
Molecular weight	Beta-carotene: 536,88
Assay	Content of carotenes (calculated as beta-carotene) is not less than 20 %. $E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane
Identification	
A. Spectrometry	Maximum in cyclohexane at 440 nm to 457 nm and 474 nm to 486 nm
Purity	
Natural tocopherols in edible oil	Not more than 0,3 %
Lead	Not more than 5 mg/kg

E 160 a (ii) BETA-CAROTENE**1. Beta-carotene**

Synonyms	CI Food Orange 5
Definition	These specifications apply predominantly to all trans isomers of beta-carotene together with minor amounts of other carotenoids. Diluted and stabilised preparations may have different trans-cis isomer ratios.
Class	Carotenoid
Colour index No	40800
EINECS	230-636-6
Chemical names	Beta-carotene, beta,beta-carotene
Chemical formula	$C_{40}H_{56}$
Molecular weight	536,88
Assay	Not less than 96 % total colouring matters (expressed as beta-carotene) $E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane
Description	Red to brownish-red crystals or crystalline powder
Identification	
A. Spectrometry	Maximum in cyclohexane at 453 to 456 nm
Purity	
Sulfated ash	Not more than 0,2 %
Subsidiary colouring matters	Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters
Lead	Not more than 2 mg/kg

2. Beta-carotene from *Blakeslea trispora*

Synonyms

CI Food Orange 5

Definition

Obtained by a fermentation process using a mixed culture of the two sexual mating types (+) and (-) of natural strains of the fungus *Blakeslea trispora*. The beta-carotene is extracted from the biomass with ethyl acetate, or isobutyl acetate followed by isopropyl alcohol, and crystallised. The crystallised product consists mainly of trans beta-carotene. Because of the natural process, approximately 3 % of the product consists of mixed carotenoids, which is specific for the product.

Class

Carotenoid

Colour index No

40800

EINECS

230-636-6

Chemical names

Beta-carotene, beta,beta-carotene

Chemical formula

$C_{40}H_{56}$

Molecular weight

536,88

Assay

Not less than 96 % total colouring matters (expressed as beta-carotene)

$E_{1\text{ cm}}^{1\%}$ 2 500 at approximately 440 nm to 457 nm in cyclohexane

Description

Red, brownish-red or purple-violet crystals or crystalline powder (colour varies according to extraction solvent used and conditions of crystallisation)

Identification

A. Spectrometry

Maximum in cyclohexane at 453 nm to 456 nm

Purity

Solvent residues

Ethyl acetate

Ethanol

} Not more than 0,8 %, singly or in combination

Isobutyl acetate: Not more than 1,0 %

Isopropyl alcohol: Not more than 0,1 %

Sulfated ash

Not more than 0,2 %

Subsidiary colouring matters

Carotenoids other than beta-carotene: not more than 3,0 % of total colouring matters

Lead

Not more than 2 mg/kg

Mycotoxins:

Aflatoxin B1

Absent

Trichothecene (T2)

Absent

Ochratoxin

Absent

Zearalenone

Absent

Microbiology:

Moulds

Not more than 100/g

Yeasts

Not more than 100/g

Salmonella

Absent in 25 g

Escherichia coli

Absent in 5 g'

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 7 April 2004

amending Decision 1999/217/EC as regards the register of flavouring substances

(notified under document number C(2004) 1273)

(Text with EEA relevance)

(2004/357/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 laying down a Community procedure for flavouring substances used or intended for use in or on foodstuffs ⁽¹⁾, as amended by Regulation (EC) No 1882/2003 ⁽²⁾, and in particular Article 3(2) thereof,

Whereas:

(1) Regulation (EC) No 2232/96 lays down the procedure for the establishment of rules in respect of flavouring substances used or intended to be used in foodstuffs. That Regulation provides for the adoption of a register of flavouring substances ('the register') following notification by the Member States of a list of the flavouring substances which may be used in or on foodstuffs marketed in their territory and on the basis of scrutiny by the Commission of that notification.

(2) In addition, Regulation (EC) No 2232/96 provides for a programme of evaluation of the flavouring substances contained in the register ('the evaluation programme') in order to check if those substances comply within the general criteria for their use set out in the Annex to that Regulation. Regulation (EC) No 2232/96 provides that the persons responsible for placing the flavouring substances on the market are to forward data necessary

for their evaluation to the Commission. That Regulation also provides that following completion of the evaluation programme, the list of flavouring substances the use of which is to be authorised to the exclusion of others, is to be adopted.

(3) Pursuant to Regulation (EC) No 2232/96, Commission Decision 1999/217/EC of 23 February 1999 adopting a register of flavouring substances used in or on foodstuffs drawn up in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council of 28 October 1996 ⁽³⁾, as last amended by Decision 2002/113/EC ⁽⁴⁾, adopted a register of flavouring substances used in or on foodstuffs.

(4) Commission Regulation (EC) No 1565/2000 of 18 July 2000 laying down the measures necessary for the adoption of an evaluation programme in application of Regulation (EC) No 2232/96 of the European Parliament and of the Council ⁽⁵⁾, provides for certain information to be submitted by the person responsible for placing certain flavouring substances contained in the register on the market in order to enable the evaluation of the substance to be carried out.

(5) Commission Regulation (EC) No 622/2002 of 11 April 2002 establishing deadlines for the submission of information for the evaluation of chemically defined flavouring substances used in or on foodstuffs ⁽⁶⁾, established time limits for the submission of information for the evaluation of flavouring substances as required

⁽¹⁾ OJ L 299, 23.11.1996, p. 1.

⁽²⁾ OJ L 284, 31.10.2003, p. 1.

⁽³⁾ OJ L 84, 27.3.1999, p. 1.

⁽⁴⁾ OJ L 49, 20.2.2002, p. 1.

⁽⁵⁾ OJ L 180, 19.7.2000, p. 8.

⁽⁶⁾ OJ L 95, 12.4.2002, p. 10.

pursuant to Regulation (EC) No 1565/2000. However, for a number of substances for which the deadline of 31 December 2002 had been established, no information has been submitted nor has the Commission been informed about any intention to still submit information. Therefore, these substances cannot be evaluated in respect of their compliance with the general criteria for the use of flavouring substances set out in Regulation (EC) No 2232/96 before the completion of the evaluation programme. Accordingly, it is appropriate to delete these substances from the register.

(6) Scrutiny of the flavouring substances listed in the register revealed inconsistencies concerning the names of certain substances (FL No 06.100, and FL No 06.131) and also concerning certain chemical numbers (FL No 02.027, FL No 07.033, FL No 07.153, and FL No 09.578). In addition, cases were identified where the same substance appeared under different chemical names in the register (FL No 02.228 and FL No 02.027; FL No 07.221 and FL No 07.033). Those inconsistencies should be rectified.

(7) Scrutiny by the Commission also revealed that of the different forms of quinine only quinine hydrochloride (FL No 14.011), quinine monohydrochloride dihydrate (FL No 14.155) and quinine sulphate (FL No 14.152) are used as flavouring substances. The other forms of quinine (FL No 14.146 and FL No 14.154) should therefore be deleted from the register.

(8) The Scientific Committee on Food concluded in its opinion of 26 February 2002 that N-(4-hydroxy-3-methoxybenzyl)-8-methylnon-6-enamide (capsaicin, FL No 16.014) is genotoxic. Capsaicin is naturally present in *Capsicum* species (e.g. chilli, cayenne pepper, red pepper). High consumption of chillies has been reported to be a risk factor for cancer. Although the maximum daily intake in the European Union is much lower than the intake levels associated with cancer, the addition of capsaicin as such to food should be avoided, as it does not comply with the general criteria for the use of flavouring substances set out in the Annex to Regulation (EC) No 2232/96. Accordingly, that substance should be deleted from the register.

(9) For two substances listed in the register (CN060 and CN061), the notifying Member State has withdrawn its notification. Those substances should therefore be deleted from the register.

(10) It is not appropriate to maintain the confidential code of substances that otherwise have been notified with their full name and were on the market at the moment the register was elaborated.

(11) The industry has now provided information concerning certain substances which are indicated with the number 4 in the column 'comments' of part A of the Annex to Decision 1999/217/EC and for which additional information was required under that Decision. In particular, evidence was provided that those substances are flavouring substances. Accordingly, that Annex should be amended to delete the reference to number 4.

(12) It is appropriate to make a correction to the register by giving a Flavis number to some substances that were on the market at the moment the register was elaborated to ensure that they are correctly taken up in the evaluation programme.

(13) Member States have notified new flavouring substances to be included in the evaluation programme and they should therefore be incorporated into the register.

(14) For some newly notified substances, in application of Regulation (EC) No 2232/96 and Commission Recommendation 98/282/EC of 21 April 1998 on the ways in which the Member States and signatory States to the Agreement on the European Economic Area should protect intellectual property in connection with the development and manufacture of flavouring substances referred to in Regulation (EC) No 2232/96 of the European Parliament and of the Council⁽¹⁾, the notifying Member State requested designation in such a way as to protect the intellectual property rights of their manufacturer. Those substances should therefore be listed in part B of the Annex to Decision 1999/217/EC.

(15) Decision 1999/217/EC should therefore be amended accordingly.

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

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 1999/217/EC is amended in accordance with the Annex to this Decision.

⁽¹⁾ OJ L 127, 29.4.1998, p. 32.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 7 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX

The Annex to Decision 1999/217/EC is amended as follows:

1. in the list in the third paragraph of the introductory part of the Annex which precedes part A, the following point 6 is added:

'6. Substance which may not be used in and on food, unless lawfully placed on the market in the Member State(s) concerned.';

2. part A is amended as follows:

- (a) the entries for the substances attributed with the FL-Nos referred to in points (i) to (vi) are amended as follows:
 - (i) for FL No 02.027, the entry '141-25-3' in the column 'CAS' is replaced by the entry '6812-78-8' and the entry '205-473-9' in the column 'Einecs' shall be replaced by '229-887-4';
 - (ii) for FL No 06.100, the entry 'Acetaldehyde dipentyl acetal' in the column 'Name' is replaced by the entry '1,1-dipentyloxyethane';
 - (iii) for FL No 06.131, the entry '1-Ethoxy-3-methyl-1-isopentyloxybutane' in the column 'Name' is replaced by the entry '1-ethoxy-1-(3-methylbutoxy)-3-methylbutane';
 - (iv) for FL No 07.033, the entry '95-41-0' in the column 'CAS' is replaced by the entry '11050-62-7';
 - (v) for FL No 07.153, the entry '1803-39-0' in the column 'CAS' is replaced by the entry '20489-53-6';
 - (vi) for FL No 09.578, the entry '19089-92-0' in the column 'CAS' is replaced by the entry '1617-25-0';
 - (vii) for FL No 12.201, the entry '57074-34-7' in the column 'CAS' is replaced by the entry '94293-57-9';
- (b) the rows set out in the table for the substances attributed with the following FL-numbers are deleted:

'02.046	02.143	02.158	02.161	02.169	02.179	02.220	02.225
02.228	02.241	05.086	05.138	05.145	05.151	05.161	05.162
05.163	05.165	05.168	05.181	05.206	06.056	06.093	06.110
06.112	07.006	07.037	07.073	07.155	07.166	07.186	07.197
07.209	07.218	07.221	07.222	07.227	08.077	08.084	08.091
08.105	08.106	08.118	08.122	08.124	08.125	09.172	09.175
09.190	09.224	09.226	09.320	09.322	09.336	09.338	09.343
09.344	09.359	09.361	09.366	09.373	09.376	09.378	09.393
09.497	09.577	09.591	09.597	09.610	09.622	09.627	09.628
09.630	09.653	09.828	09.849	09.856	09.863	09.868	09.883
09.889	09.890	12.011	12.090	12.091	12.105	12.119	12.131
12.133	12.140	12.144	12.160	12.184	12.185	12.190	12.204
12.213	12.215	12.219	12.220	12.225	12.229	14.146	14.154
16.014	16.077	17.004	17.011	17.016	17.030'		

- (c) for the substances attributed with the following FL-Nos, the number '4' in the column 'comments' in the table is deleted:

'02.004	02.121	02.216	02.217	09.016	09.034	09.367	09.712
16.009	16.017'						

(d) the following rows are inserted in the table:

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
'02.243	04	56805-23-3	(E)-3-(Z)-6-Nonadien-1-ol	3884	278-518-3		6
04.095	25	527-60-6	2,4,6-Trimethyl phenol		208-419-2		6
04.096	18	579-60-2	2-Methoxy-6-(2-propenyl)phenol		209-444-1		6
05.207	04	105683-99-6	6-Decenal, cis				6
05.208	04	169054-69-7	Z-8-Tetradecenal				6
05.209	04	147159-48-6	6-Decenal, trans				6
06.132	23	63253-24-7	Vanillin butan-2,3-diol acetal (mixture of stereo isomers)	4023		Vanillin erythro and threo-butan-2,3-diol acetal	6
05.217	04	21662-08-8	5-Decenal				
05.218	04	56554-87-1	16-Octadecenal				
07.239	05	2278-53-7	[R-(E)]-5-Isopropyl-8-methylnona-6,8-dien-2-one		218-907-7		6
07.240	05	13019-20-0	2-Methylheptan-3-one	4000	235-877-0		6
07.241	05	1635-02-5	3,4-Dimethylhex-3-en-2-one		216-656-8		6
07.242	21	5355-63-5	3-Hydroxy-4-phenylbutane-2-one				6
07.243	21	99-93-4	4-Hydroxy acetophenone		202-802-8		6
07.244	05	20859-10-3	Trans-6-Methyl-3-hepten-2-one	4001			6
07.245	08	71048-82-3	Trans-delta-damascone		275-156-8	(1alpha(E),2beta) - 1-(2,6,6-trimethyl-cyclohex-3-en-1-yl)but-2-en-1-one	6
07.246	08	25304-14-7	Dimethyl cyclohexyl methyl ketone		246-799-1		6
07.247	05	30086-02-3	Octadien-2-one/3,5- (E,E)	4008			6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
07.248	10	585-25-1	Octan-2,3-dione		209-552-9		6
07.249	05	927-49-1	Undecan-6-one	4022	213-150-9		6
07.253	05	30086-02-3	3,5-Octadiene-2-one				
09.917	04	1576-85-8	4-Pentenyl acetate	4011	216-413-6		6
09.918	04	67452-27-1	Cis-4-decenyl acetate	3967			6
09.919	09	139564-43-5	Ethyl 3-acetoxy-2-methylbutyrate				6
09.920	08	156324-82-2	2-Isopropyl-5-methylcyclohexyl oxycarbo- nyloxy-2-hydroxypropane	3992	417-420-9		6
09.921	04	54653-25-7	Ethyl 5-hexenoate	3976			6
09.922	04	39924-27-1	Ethyl cis-4-heptenoate	3975	254-702-9		6
09.923	05	39026-94-3	Hept-2-yl butyrate	3981			6
09.924	05	5921-83-5	(+/-)-3-Heptyl acetate	3980	203-932-8		6
09.925	05	60826-15-5	Nonan-3-yl acetate	4007	262-444-3		6
09.926	05	84434-65-1	Octan-3-yl formate	4009	282-866-1		6
09.927	04	141-15-1	Rhodinyl butyrate	2982	205-462-9		6
09.928	04	3681-82-1	Trans-3-hexenyl acetate		222-962-2		6
10.069	09	67663-01-8	3-Methyl gamma-decalactone	3999			6
10.070	09	1073-11-6	4-Methyl-5-hexen-1,4-olide		214-024-6		6
12.238	20	227456-27-1	3-Mercapto-2-methylpentan-1-ol	3996			6
12.239	20	227456-28-2	3-Mercapto-2-methylpentanal	3994			6
12.240	20	6540-86-9	2,4,6-Trithiaheptane				6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
12.241	20	258823-39-1	2-Mercapto-2-methylpentan-1-ol	3995			6
12.242	20	29414-47-9	Methylthiomethylmercaptan				
12.243	20	6725-64-0	Dimercaptomethane				6
12.244	20	14109-72-9	1-Methylthio-2-propanone	3882			6
12.245	20	7529-06-8	1,3-Dimercapto-2-thiapropane				6
12.246	20		1-(Methylthio) hexan-3-one				6
12.247	20	61837-77-2	1-(Methylthio) octan-3-one				6
12.248	20	5862-47-5	2-(Methylthio) ethyl acetate				6
12.249	20	227456-27-1	3-Mercapto-2-methylpentanol (mixture of stereo isomers)	3996			6
12.250	20	51755-72-7	3-Mercaptohexanal				6
12.251	20	136954-22-8	3-Mercaptohexyl hexanoate	3853			6
12.252	20	31539-84-1	4-Mercapto-4-methyl-2-pentanol				6
12.253	20	72437-68-4	Amyl methyl disulfide				6
12.254	20	63986-03-8	Butyl ethyl disulfide				6
12.255	20	156472-94-5	Ethyl 3-mercaptopbutyrate	3977			6
12.256	20	31499-70-4	Ethyl propyl trisulfide				6
12.257	20	104228-51-5	Ethyl 4-(acetylthio) butyrate	3974			6
12.259	20	29725-66-4	p-menthan-3-one, 1 mercapto				6
13.191	14	376595-42-5	O-Ethyl S-(2-furylmethyl)thiocarbonate				6
13.192	14	109537-55-5	Furfuryl 2-methyl-3-furyldisulfide				6

FL No	Chemical group	CAS	Name	FEMA	Einecs	Synonyms	Comments
13.193	14	26486-21-5	2,5-Dimethyltetrahydro-3-furanthiol	3971			6
13.194	14	252736-39-3	2,5-Dimethyltetrahydro-3-furyl thio acetate	3972			6
13.195	30	26131-91-9	2-Isobutyl-4,5-dimethyl oxazole				6
13.196	14	180031-78-1	4-(Furfurylthio) pentan-2-one	3840			6
13.197	14	252736-36-0	Furyl propyldisulfide	3979			6
14.162	28	98-79-3	L-2-Pyrrolidone-5-carboxylic acid				6
14.163	28	1192-58-1	1-Methylpyrrole-2-carboxaldehyde		214-755-0		6
14.164	28	622-39-9	2-Propylpyridine		210-732-4		6
14.165	28	2168-14-8	N-ethyl-2-formylpyrrole				6
15.123	20	53897-58-5	2,4,6-Triethyl-1,3,5-trithiane				6
16.082	30	21018-84-8	Amarogentin				6'

3. the table of part B is replaced by the following:

'Flavouring substances notified in application of Article 3(2) of Regulation (EC) No 2232/96, for which the protection of the intellectual property rights of the manufacturer has been requested

Code	Date of receipt of the notification by the Commission	Comments
CN003	17.10.1998	
CN004	17.10.1998	
CN009	17.10.1998	
CN010	17.10.1998	
CN012	17.10.1998	
CN013	17.10.1998	
CN014	17.10.1998	
CN016	17.10.1998	
CN019	17.10.1998	
CN022	17.10.1998	
CN023	17.10.1998	
CN030	17.10.1998	
CN033	17.10.1998	
CN035	17.10.1998	
CN036	17.10.1998	
CN037	17.10.1998	
CN042	17.10.1998	
CN045	17.10.1998	
CN048	17.10.1998	
CN049	17.10.1998	
CN050	17.10.1998	
CN052	17.10.1998	
CN053	17.10.1998	
CN054	17.10.1998	
CN057	17.10.1998	
CN058	30.10.1998	
CN059	18.9.1998	
CN064	3.2.1999	
CN065	26.1.2001	
CN074	18.4.2003	6
CN075	18.4.2003	6
CN076	18.4.2003	6'

COMMISSION RECOMMENDATION

of 7 April 2004

on the use of a common European format for licence documents issued in accordance with Council Directive 95/18/EC on the licensing of railway undertakings

(notified under document number C(2004) 1279)

(2004/358/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 211, second indent, thereof,

Whereas:

(1) Article 4 of Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings⁽¹⁾, as amended by Directive 2001/13/EC of the European Parliament and of the Council of 26 February 2001⁽²⁾, states that a licence shall be valid throughout the territory of the Community and Article 11(8) obliges Member States to inform the Commission of licences that have been issued, suspended, revoked or amended and the Commission to inform the other Member States forthwith. A common format for the licence document and communications on licences would therefore facilitate the work of the Member States and of the Commission and would provide easier access to information on licences by all interested parties, in particular the licensing authorities and the infrastructure managers.

(2) Directive 2001/13/EC extends the obligation on Member States to grant railway licences from railway undertakings providing services according to Article 10 of Council Directive 91/440/EEC of 29 July 1991 on the development of the Community's railways⁽³⁾, as amended by Directive 2001/12/EC of the European Parliament and Council⁽⁴⁾, to all relevant railway undertakings. The railway licence will hereafter consequently become more widely recognised and used within the Community.

(3) Directive 2001/12/EC provides access for licensed railway undertakings to the Trans-European Rail Freight Network for the purpose of operating international freight services as from 15 March 2003 and to the entire rail network as from 15 March 2008. Member States will increasingly exchange information on licences and carry out checks that railway undertakings exercising these access rights have a valid licence and there is therefore a need to standardise the licence document and information on licences and make them more easily available.

(4) The railway licences issued by the provisions of Directives 95/18/EC and 2001/13/EC are valid also in the European Economic Area through Decision No 118/2001 of the EEA Joint Committee of 28 September 2001 amending Annex XIII to the EEA Agreement⁽⁵⁾. Licences issued in the European Economic Area are equally valid in the Community through the same Decision.

(5) All necessary information that confirms that an identified railway undertaking has been duly licensed for a certain type of rail transport services can be contained within a one-page standardised document. The standard format for the licence document would facilitate publication of all relevant information on licences on the website of the Commission. The standard format could be modified in the future depending on experience of its use and the development of the needs for further information on licences.

(6) However, the requirements of Article 9 of Directive 95/18/EC on insurance, or equivalent arrangements for cover for liability, can vary between Member States depending on national law and therefore proof that the railway undertaking meets these national requirements should be provided for by an annex to the licence document. In case the legal requirements on financial cover for liability make it necessary a separate annex should be added for each of the Member States where access rights are exercised by the licensed railway undertaking.

(7) In addition to the requirements of Directive 95/18/EC a Member State may impose national legal and regulatory provisions on railway undertakings, as described in Article 12 of Directive 95/18/EC. These provisions may be referred to in the licensing document, but should not be required to be communicated to the Commission in connection with the standard licence document. It should, however, be noticed in that document that they exist and they should be available on request by the Commission.

⁽¹⁾ OJ L 143, 27.6.1995, p. 70.

⁽²⁾ OJ L 75, 15.3.2001, p. 26.

⁽³⁾ OJ L 237, 24.8.1991, p. 25.

⁽⁴⁾ OJ L 75, 15.3.2001, p. 1.

⁽⁵⁾ OJ L 322, 6.12.2001, p. 32.

- (8) The provisions of this recommendation have been submitted to The Developing European Railways Committee established by Article 11a of Directive 91/440/EEC and by Article 35 of Directive 2001/14/EC of the European Parliament and of the Council of 26 February 2001 on the allocation of railway infrastructure capacity and the levying of charges for the use of railway infrastructure and safety certification ⁽¹⁾, as amended by Commission Decision 2002/844/EC ⁽²⁾. The Committee has given a positive opinion on the recommendation.
- (9) Where Member States, in applying the requirements of Directive 95/18/EC, establish rules on the format of railway licences, this should be based on the standard format
- (10) The licensing authority of the Member State communicates information on the issuing, suspension, revocation and amendment of rail licences to the railway undertaking concerned and the European Commission using the standard format for the licence document.

HEREBY RECOMMENDS:

1. Licence documents issued in accordance with Directive 95/18/EC should use the standard format set out in Annex I to this Recommendation.

A document should be issued in the case a particular licence is amended, suspended, revoked or replaced by a temporary licence and should be presented in the standard format.

2. The proof that a licensed railway undertaking complies with national requirements concerning insurance or has made equivalent arrangements for cover for its liabilities should be set out in an annex to the licence document, using the standard format laid down in Annex II to this Recommendation.
3. This Recommendation is addressed to the Member States.

Done at Brussels, 7 April 2004.

For the Commission
Loyola DE PALACIO
Vice-President

⁽¹⁾ OJ L 75, 15.3.2001, p. 29.

⁽²⁾ OJ L 289, 26.10.2002, p. 30.

*ANNEX I***Standard format for railway licence**

The standard format for the railway licence document and the explanations and instructions that are necessary for the user of the form are laid out on the following pages.



LICENCE FOR THE PERFORMANCE OF RAIL TRANSPORT SERVICES

Within the European Union and the European Economic Area according to Directive 95/18/EC, as amended by Directive 2001/13/EC and the relevant national legislation.

1. Licence issuing State

Issuing State	☐ New licence ☐ Amended licence
National licence No	Decision identification
Applicable legislation	
Licensing authority	Phone No
Postal address	Facsimile No
Post Code and city	E-mail

2. Licence holder

Railway undertaking	Phone No
Postal address	Facsimile No
Post code and city	E-mail
Registration No	VAT No

3. Validity

Valid from	Temporary licence: ☐ YES ☐ NO If yes: valid until
Type of services: ☐ freight ☐ passenger	
Suspended on	Revoked on

4. Amendments

Amended on
Description of amendment

5. Conditions and obligations

Conditions according to Articles 10(2) and/or 12 of Directive 95/18/EC should be mentioned here, or reference should be given to where documentation is available

Date

Signature

Name

EC licence-notification No

Explanations and instructions for use

The relevant EU legislation is laid down in Council Directive 95/18/EC of 19 June 1995 on the licensing of railway undertakings (OJ L 143, 27.6.1995, p. 70) and Directive 2001/13/EC of the European Parliament and of the Council of 26 February 2001 amending Council Directive 95/18/EC on the licensing of railway undertakings (OJ L 75, 15.3.2001, p. 26).

The railway licences issued by the provisions of Directives 95/18/EC and 2001/13/EC are valid also in the European Economic Area through Decision No 118/2001 of the EEA Joint Committee of 28 September 2001 amending Annex XIII (Transport) to the EEA Agreement (OJ L 322, 6.12.2001, p. 32). Licences issued in the European Economic Area are equally valid in the Community through the same Decision.

Each time a decision concerning a particular licensed railway undertaking is taken, i.e. by amending, suspending, revoking or replacing a permanent licence by a temporary one, a new document shall be submitted.

A licence document shall always be accompanied by the annex on financial cover for liability.

The detailed explanations below refer to the numbered fields of the form. References are made to Articles in Directive 95/18/EC.

1. **Licence issuing State.** It shall always be indicated if a document concerns a new licence or any kind of amendment to an existing licence. The legislation applicable in the issuing state shall be identified by reference to law or other legal provisions. The licence identification number used in the issuing State shall be entered and, where applicable, the identification of the authority decision through a reference number or other relevant reference. The licensing authority is designated by Member States according to Article 3. It shall be identified in a way that makes it possible for interested parties to get in contact with the body in question. Telephone numbers should indicate the number to the switchboard, where applicable, and not to the person in charge of licensing issues. Telephone and fax numbers should indicate the country code. The e-mail address should be the general mail box of the authority.
2. **Licence holder.** The contact details of the licence holder should, in a similar way as the details of the authority, indicate the general addresses of the railway undertaking, avoiding giving reference to a certain person. If several registration numbers are attributed to the holder under national law there are possibilities in the form to enter both the VAT number and a second registration number. Telephone and fax numbers should indicate the country code.
3. **Validity.** According to Article 10 a licence is valid as long as the railway undertaking fulfils the obligations of the Directive. The reviews that are allowed according to Article 10(1) do not require that the licence document as such is amended. If the review leads to suspension, revocation or amendment, it shall be indicated in the relevant fields and a new document shall be submitted.

The issuing authority shall indicate the first date of validity and the type(s) of services that the licence is valid for. In the case of a temporary licence, issued according to the provisions of Article 11(3), an end date must be entered. The maximum validity of a temporary licence is six months. In the case of suspension or revocation the dates shall be entered in the form. Dates shall be entered in a common format (ddmmyy).

4. **Amendments.** If the licensed railway undertaking significantly changes or extends its activities the licence shall be resubmitted for review (Article 11.6). Such a review might cause that the licence is amended and if so, the date of the amendment shall be entered in the field together with a short description. Dates shall be entered in a common format (ddmmyy).
 5. **Conditions and obligations.** Article 10(2) states that specific provisions governing the suspension or revocation of a licence may be incorporated in the licence itself. If that is the case, the provisions shall be indicated in this field. Article 12 provides for additional requirements on a railway undertaking imposed by a Member State by national law and regulatory provisions. A reference to these additional requirements or to the authority decision should be made in the field, if they have relevance for the licence.
 6. **Signature.** A person authorised to decide on licences shall sign the licence document delivered to the railway undertaking. A copy of the signed document shall be sent to the Commission and an electronic version of the document shall be transmitted to the Commission. The name of the signing person shall be spelled out. The Commission will attribute an EC licence notification number to the licence before publication and communicate the attributed number to the licensing authority.
-

*ANNEX II***Standard format for insurance annex to railway licence**

The standard format for the annex to the railway licence document and the explanations and instructions that are necessary for the user of the form are laid out on the following pages.



LICENCE

Insurance Annex No

Financial cover for liability

Concerning licence to perform rail transport services within the European Union and the European Economic Area according to directive 95/18/EC, as amended by directive 2001/13/EC and the relevant national legislation

1. Licence issuing State

Issuing state	Licensing authority
National licence No	Decision identification
Applicable legislation	

2. Licence holder

Railway undertaking	
Registration No	VAT No

3. Licensing authority approving financial cover (if other than licensing authority in 1)

Licensing authority	Phone No
Postal address	Facsimile No
Post code and city	E-mail
State	Applicable legislation

4. Financial cover for liability

Financial cover, amount	Equivalent arrangements (short description)
Geographical coverage	
Valid from	Valid until

5. Conditions and obligations

National conditions according to Articles 10(2) and/or 12 of Directive 95/18/EC should be mentioned here, or reference should be given to where documentation is available

Date

Signature

Name

EC licence-notification No

Explanations and instructions for use

According to Article 9 of Directive 95/18/EC a railway undertaking shall be adequately insured or make equivalent arrangements for cover, in accordance with national and international law, of its liabilities in the event of accidents. The maximum insurance amount that is requested by Member States to fulfil this requirement varies in accordance with national legislation and other regulatory requirements. Thus an insurance taken by a railway undertaking in one Member State may not be sufficient in another Member State. The body issuing the licence shall therefore attach an annex to the licence, using the format provided for by Annex II to this Recommendation. This first insurance annex should be given the number one (1) and should be submitted by the licensing authority.

Through the information provided for by the insurance annex the licensing authority in a particular Member State is able to check whether the insurance originally taken by the railway undertaking and approved in the licensing state is sufficient in the other Member State. If that is not the case the concerned licensing authority may request an additional insurance policy to be taken out by the railway undertaking and can thereafter submit a new insurance annex to the licence, using the standard format of this Annex II and giving it a new number (2, 3, 4 etc.). It shall be noted that the railway undertaking is obliged by Article 5 of Directive 95/18/EC to demonstrate to the licensing authorities that it will be able to meet the requirements.

The detailed explanations below refer to the numbered fields of the form. References are made to Articles in Directive 95/18/EC:

1. **Licence issuing State.** The information given in the licence shall be repeated here to enable a correct identification of the licence. The licensing authority is designated by Member States according to Article 3. Since the annex is linked to a licence document according to Annex I of this Recommendation it is not necessary to repeat all information given on the licensing authority. The name is sufficient.
 2. **Licence holder.** Since the annex is linked to a licence it is not necessary to repeat all information given on the licence holder. The name and possible registration numbers are sufficient.
 3. **Licensing body responsible for validation of financial cover.** If the insurance annex is submitted by the body granting the licence to the railway undertaking this field should not be filled in. In case a licensing authority in another Member State has required and approved additional insurance cover, the relevant contact details of that licensing authority should be entered in this field. Telephone and fax numbers should indicate the country code.
 4. **Financial cover for liability.** The maximum insurance amount that is required and approved shall be entered in this field, stating the currency in which it is noted. If the railway undertaking has not taken out an insurance policy but demonstrated its cover by equivalent arrangements (e.g. a financial guarantee), the nature of this cover shall be described. If the geographical coverage is limited to a specific country or to a region or if certain countries or regions are specifically excluded it shall be described. The first date of validity of the insurance policy shall be entered. The railway undertaking has an obligation to maintain its cover for liability. The licence is not valid if the railway undertaking does not fulfil this requirement (Article 5). However, in exceptional cases an insurance might be taken for a limited time. In such a case an end date of the validity may be introduced. Dates shall be entered in a common format (ddmmyy). The licensing authority may check that the railway undertaking complies with the requirements (Article 11). If the financial cover for liability is changed and resubmitted to the licensing authority a new annex shall be issued to replace the old one.
 5. **Conditions and obligations.** The cover for liability may be linked to national conditions or obligations imposed on the railway undertaking by the provisions of Article 12. In such case it should be indicated in this field.
 6. **Signature.** A person authorised to approve insurance arrangements shall sign the document delivered to the railway undertaking. A copy of the signed document shall be sent to the Commission. An electronic version of the document shall be transmitted to the Commission. The name of the signing person shall be spelled out.
 7. **EC licence notification-number.** To enable a positive identification of the licence holder the EC licence notification number shall be introduced in the annex by the authority approving the insurance cover. In the case where a new licence is issued the Commission will attribute an EC licence notification number and communicate the attributed number to the licensing authority.
-

COMMISSION DECISION

of 13 April 2004

amending Decision 97/296/EC drawing up the list of third countries from which the import of fishery products is authorised for human consumption, with respect to Romania and Zimbabwe*(notified under document number C(2004) 1304)***(Text with EEA relevance)**

(2004/359/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Decision 95/408/EC of 22 of June 1995 on the conditions for drawing up, for an interim period, provisional lists of third country establishments from which Member States are authorised to import certain products of animal origin, fishery products or live bivalve molluscs ⁽¹⁾, and in particular Article 2(2) thereof,

Whereas:

- (1) Commission Decision 97/296/EC of 22 April 1997 drawing up the list of third countries from which the import of fishery products is authorised for human consumption ⁽²⁾ lists the countries and territories from which imports of fishery products for human consumption is authorised. Part I of the Annex to that Decision lists the countries and territories covered by a specific Decision under Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products ⁽³⁾, and part II of that Annex lists the countries and territories meeting the conditions set out in Article 2(2) of Decision 95/408/EC.
- (2) Commission Decisions 2004/361/EC ⁽⁴⁾ and 2004/360/EC ⁽⁵⁾ provide for specific import conditions for fishery products originating in Romania and Zimbabwe. Those countries should therefore be included in the list in part I of the Annex to Decision 97/296/EC. In the interests of clarity the lists concerned should be replaced in their entirety.

(3) Decision 97/296/EC should therefore be amended accordingly.

(4) This Decision should apply from the same day as Decisions 2004/361/EC, and 2004/360/EC as regards the import of fishery products from Romania and Zimbabwe.

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

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Decision 97/296/EC is replaced by the text in the Annex to this Decision.

Article 2

This Decision shall apply from 4 June 2004.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission

⁽¹⁾ OJ L 243, 11.10.1995, p. 17. Decision as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 122, 14.5.1997, p. 21. Decision as last amended by Decision 2004/36/EC (OJ L 8, 14.1.2004, p. 8).

⁽³⁾ OJ L 268, 24.9.1991, p. 15. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽⁴⁾ See page 54 of this Official Journal.

⁽⁵⁾ See page 48 of this Official Journal.

ANNEX

‘ANNEX

LIST OF COUNTRIES AND TERRITORIES FROM WHICH IMPORTATION OF FISHERY PRODUCTS IN ANY FORM INTENDED FOR HUMAN CONSUMPTION IS AUTHORISED

I. Countries and territories covered by a specific decision under Council Directive 91/493/EEC

AE — UNITED ARAB EMIRATES	KR — SOUTH KOREA
AL — ALBANIA	KZ — KAZAKHSTAN
AN — NETHERLANDS ANTILLES	LK — SRI LANKA
AR — ARGENTINA	LT — LITHUANIA
AU — AUSTRALIA	LV — LATVIA
BD — BANGLADESH	MA — MOROCCO
BG — BULGARIA	MG — MADAGASCAR
BR — BRAZIL	MR — MAURITANIA
BZ — BELIZE	MU — MAURITIUS
CA — CANADA	MV — MALDIVES
CH — SWITZERLAND	MX — MEXICO
CI — IVORY COAST	MY — MALAYSIA
CL — CHILE	MZ — MOZAMBIQUE
CN — CHINA	NA — NAMIBIA
CO — COLOMBIA	NC — NEW CALEDONIA
CR — COSTA RICA	NG — NIGERIA
CS — SERBIA AND MONTENEGRO ⁽¹⁾	NI — NICARAGUA
CU — CUBA	NZ — NEW ZEALAND
CV — CAPE VERDE	OM — OMAN
CZ — CZECH REPUBLIC	PA — PANAMA
EC — ECUADOR	PE — PERU
EE — ESTONIA	PG — PAPUA NEW GUINEA
EG — EGYPT	PH — PHILIPPINES
FK — FALKLAND ISLANDS	PF — FRENCH POLYNESIA
GA — GABON	PM — ST PIERRE AND MIQUELON
GH — GHANA	PK — PAKISTAN
GL — GREENLAND	PL — POLAND
GM — GAMBIA	RO — ROMANIA
GN — GUINEA CONAKRY	RU — RUSSIA
GT — GUATEMALA	SC — SEYCHELLES
GY — GUYANA	SG — SINGAPORE
HN — HONDURAS	SI — SLOVENIA
HR — CROATIA	SK — SLOVAKIA
ID — INDONESIA	SN — SENEGAL
IN — INDIA	SR — SURINAME
IR — IRAN	TH — THAILAND
JM — JAMAICA	TN — TUNISIA
JP — JAPAN	TR — TURKEY
KE — KENYA	

⁽¹⁾ Not including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999.

TW	—	TAIWAN	VN	—	VIETNAM
TZ	—	TANZANIA	YE	—	YEMEN
UG	—	UGANDA	YT	—	MAYOTTE
UY	—	URUGUAY	ZA	—	SOUTH AFRICA
VE	—	VENEZUELA	ZW	—	ZIMBABWE

II. Countries and territories meeting the terms of Article 2(2) of Council Decision 95/408/EC

AM	—	ARMENIA ⁽¹⁾	FJ	—	FIJI
AO	—	ANGOLA	GD	—	GRENADA
AG	—	ANTIGUA AND BARBUDA ⁽²⁾	HK	—	HONG KONG
AZ	—	AZERBAIJAN ⁽³⁾	HU	—	HUNGARY ⁽⁵⁾
BJ	—	BENIN	IL	—	ISRAEL
BS	—	BAHAMAS	MM	—	MYANMAR
BY	—	BELARUS	MT	—	MALTA
CG	—	REPUBLIC OF CONGO ⁽⁴⁾	SB	—	SOLOMON ISLANDS
CM	—	CAMEROON	SH	—	ST HELENA
CY	—	CYPRUS	SV	—	EL SALVADOR
DZ	—	ALGERIA	TG	—	TOGO
ER	—	ERITREA	US	—	UNITED STATES OF AMERICA

⁽¹⁾ Authorised only for imports of live crayfish (*Astacus leptodactylus*) intended for direct human consumption.

⁽²⁾ Authorised only for imports of fresh fish.

⁽³⁾ Authorised only for imports of caviar.

⁽⁴⁾ Authorised only for imports of fishery products caught, frozen and packed in their final packaging at sea.

⁽⁵⁾ Authorised only for import of live animals intended for direct human consumption.'

COMMISSION DECISION
of 13 April 2004
laying down special conditions for imports of fishery products from Zimbabwe

(notified under document number C(2004) 1328)

(Text with EEA relevance)

(2004/360/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products ⁽¹⁾, and in particular Article 11(1) thereof,

Whereas:

- (1) An inspection has been carried out on behalf of the Commission in Zimbabwe to verify the conditions under which fishery products are produced, stored and dispatched to the Community.
- (2) The requirements in the legislation of Zimbabwe on health inspection and monitoring of fishery products may be considered equivalent to those laid down in Directive 91/493/EEC.
- (3) In particular, the 'Department of Livestock and Veterinary Services (DLVS)', is capable of effectively verifying the implementation of the rules in force.
- (4) The DLVS has provided official assurances on compliance with the standards for health controls and monitoring of fishery products as set out in Chapter V of the Annex to Directive 91/493/EEC and on the fulfilment of hygienic requirements equivalent to those laid down by that Directive.
- (5) It is appropriate to lay down detailed provisions concerning fishery products imported into the Community from Zimbabwe, in accordance with Directive 91/493/EEC.
- (6) It is also necessary to draw up a list of approved establishments, factory vessels, or cold stores, and a list of freezer vessels equipped in accordance with the requirements of Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC ⁽²⁾. Those lists should be drawn up on the basis of a communication from the DLVS to the Commission.

(7) It is appropriate for this Decision to be applied 45 days after its publication providing for the necessary transitional period.

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

HAS ADOPTED THIS DECISION:

Article 1

The 'Department of Livestock and Veterinary Services (DLVS)', shall be the competent authority in Zimbabwe identified for the purposes of verifying and certifying compliance of fishery products with the requirements of Directive 91/493/EEC.

Article 2

Fishery products imported into the Community from Zimbabwe shall meet the requirements set out in Articles 3, 4 and 5.

Article 3

1. Each consignment shall be accompanied by a numbered original health certificate in accordance with the model set out in Annex I and comprising a single sheet, duly completed, signed and dated.

2. The health certificate shall be drawn up in at least one official language of the Member State where the checks are carried out.

3. The health certificate shall bear the name, capacity and signature of the representative of the DLVS, and the latter's official stamp in a colour different from that of the endorsements.

Article 4

The fishery products shall come from approved establishments, factory vessels, or cold stores, or from registered freezer vessels listed in Annex II.

⁽¹⁾ OJ L 268, 24.9.1991, p. 15. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 187, 7.7.1992, p. 41.

Article 5

All packages shall bear the word 'ZIMBABWE' and the approval/registration number of the establishment, factory vessel, cold store or freezer vessel of origin in indelible letters, except in the case of frozen fishery products in bulk and intended for the manufacture of preserved foods.

Article 6

This Decision shall apply from 4 June 2004.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

HEALTH CERTIFICATE

for fishery products from Zimbabwe and intended for export to the European Community, excluding bivalve molluscs, echinoderms, tunicates and marine gastropods in whatever form

Reference No:

Country of dispatch: ZIMBABWE

Competent authority: 'Department of Livestock and Veterinary Services (DLVS)'

I. *Details identifying the fishery products*

— Description of fishery/aquaculture ⁽¹⁾ products:

— Species (scientific name):

— Presentation of product and type of treatment ⁽²⁾:

— Code number (where available):

— Type of packaging:

— Number of packages:

— Net weight:

— Requisite storage and transport temperature:

II. *Origin of products*

Name(s) and official approval/registration number(s) of establishment(s), factory vessel(s), or cold store(s) approved or freezer vessel(s) registered by DLVS for export to the EC:

.....

III. *Destination of products*

The products are dispatched

to:

(place of dispatch)

from:

(country and place of destination)

by the following means of transport:

Name and address of dispatcher:

.....

Name of consignee and address at place of destination:

.....

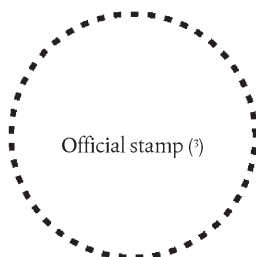
⁽¹⁾ Delete where applicable.

⁽²⁾ Live, refrigerated, frozen, salted, smoked, preserved, etc.

IV. *Health attestation*

- The official inspector hereby certifies that the fishery products specified above:
1. were caught and handled on board vessels in accordance with the health rules laid down by Directive 92/48/EEC;
 2. were landed, handled and where appropriate packaged, prepared, processed, frozen, thawed and stored hygienically in compliance with the requirements laid down in Chapters II, III and IV of the Annex to Directive 91/493/EEC;
 3. have undergone health controls in accordance with Chapter V of the Annex to Directive 91/493/EEC;
 4. are packaged, marked, stored and transported in accordance with Chapters VI, VII and VIII of the Annex to Directive 91/493/EEC;
 5. do not come from toxic species or species containing biotoxins;
 6. have satisfactorily undergone the organoleptic, parasitological, chemical and microbiological checks laid down for certain categories of fishery products by Directive 91/493/EEC and in the implementing decisions thereto.
- The undersigned official inspector hereby declares that he is aware of the provisions of Directives 91/493/EEC and 92/48/EEC and Decision 2004/360/EC.

Done at , on
(Place) (Date)



.....
Signature of official inspector (3)
(Name in capital letters, capacity and qualifications of person signing)

(3) The color of the stamp and signature must be different from that of the other particulars in the certificate.

ANNEX II

LIST OF ESTABLISHMENTS AND VESSELS

N° d'agrément/ Approval No.	Nom/Name	Ville/City Région/Region	Date limite d'agrément/ Approval limit	Catégorie/ Category
18/FO2PP	Lake Harvest Aquaculture Pvt Ltd	PO Box 322 — Kariba		PP

Categorie Legend:

PP: Processing plant/Etablissement

COMMISSION DECISION
of 13 April 2004
laying down special conditions for imports of fishery products from Romania

(notified under document number C(2004) 1330)

(Text with EEA relevance)

(2004/361/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/493/EEC of 22 July 1991 laying down the health conditions for the production and the placing on the market of fishery products ⁽¹⁾, and in particular Article 11(1) thereof,

Whereas:

- (1) An inspection has been carried out on behalf of the Commission in Romania to verify the conditions under which fishery products are produced, stored and dispatched to the Community.
- (2) The requirements in the legislation of Romania on health inspection and monitoring of fishery products may be considered equivalent to those laid down in Directive 91/493/EEC.
- (3) In particular, the 'National Sanitary Veterinary Agency (NSVA)', is capable of effectively verifying the implementation of the (legislation) rules in force.
- (4) The NSVA has provided official assurances on compliance with the standards for health controls and monitoring of fishery products as set out in Chapter V of the Annex to Directive 91/493/EEC and on the fulfilment of hygienic requirements equivalent to those laid down by that Directive.
- (5) It is appropriate to lay down detailed provisions concerning fishery products imported into the Community from Romania, in accordance with Directive 91/493/EEC.
- (6) It is also necessary to draw up a list of approved establishments, factory vessels, or cold stores, and a list of freezer vessels equipped in accordance with the requirements of Council Directive 92/48/EEC of 16 June 1992 laying down the minimum hygiene rules applicable to fishery products caught on board certain vessels in accordance with Article 3(1)(a)(i) of Directive 91/493/EEC ⁽²⁾. Those lists should be drawn up on the basis of a communication from the NSVA to the Commission.

(7) It is appropriate for this Decision to be applied 45 days after its publication providing for the necessary transitional period.

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

HAS ADOPTED THIS DECISION:

Article 1

The 'National Sanitary Veterinary Agency (NSVA)', shall be the competent authority in Romania identified for the purposes of verifying and certifying compliance of fishery products with the requirements of Directive 91/493/EEC.

Article 2

Fishery products imported into the Community from Romania shall meet the requirements set out in Articles 3, 4 and 5.

Article 3

1. Each consignment shall be accompanied by a numbered original health certificate in accordance with the model set out in Annex I and comprising a single sheet, duly completed, signed and dated.

2. The health certificate shall be drawn up in at least one official language of the Member State where the checks are carried out.

3. The health certificate shall bear the name, capacity and signature of the representative of the NSVA, and the latter's official stamp in a colour different from that of the endorsements.

Article 4

The fishery products shall come from approved establishments, factory vessels, or cold stores, or from registered freezer vessels listed in Annex II.

⁽¹⁾ OJ L 268, 24.9.1991, p. 15. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

⁽²⁾ OJ L 187, 7.7.1992, p. 41.

Article 5

All packages shall bear the word 'ROMANIA' and the approval/registration number of the establishment, factory vessel, cold store or freezer vessel of origin in indelible letters, except in the case of frozen fishery products in bulk and intended for the manufacture of preserved foods.

Article 6

This Decision shall apply from 4 June 2004.

Article 7

This Decision is addressed to the Member States.

Done at Brussels, 13 April 2004.

For the Commission

David BYRNE

Member of the Commission

ANNEX I

HEALTH CERTIFICATE

for fishery products from Romania and intended for export to the European Community, excluding bivalve molluscs, echinoderms, tunicates and marine gastropods in whatever form

Reference No:

Country of dispatch: ROMANIA

Competent authority: 'National Sanitary Veterinary Agency (NSVA)

I. *Details identifying the fishery products*

— Description of fishery/aquaculture ⁽¹⁾ products:

— Species (scientific name):

— Presentation of product and type of treatment ⁽²⁾:

— Code number (where available):

— Type of packaging:

— Number of packages:

— Net weight:

— Requisite storage and transport temperature:

II. *Origin of products*

Name(s) and official approval/registration number(s) of establishment(s), factory vessel(s), or cold store(s) approved or freezer vessel(s) registered by NSVA for export to the EC:

.....

III. *Destination of products*

The products are dispatched

from:

(place and dispatch)

to:

(country and place of destination)

by the following means of transport:

Name and address of dispatcher:

.....

Name of consignee and address at place of destination:

.....

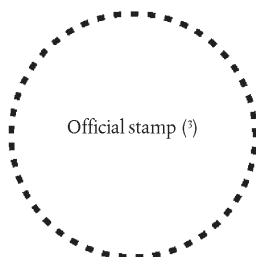
⁽¹⁾ Delete where applicable.

⁽²⁾ Live, refrigerated, frozen, salted, smoked, preserved, etc.

IV. *Health attestation*

- The official inspector hereby certifies that the fishery products specified above:
1. were caught and handled on board vessels in accordance with the health rules laid down by Directive 92/48/EEC;
 2. were landed, handled and where appropriate packaged, prepared, processed, frozen, thawed and stored hygienically in compliance with the requirements laid down in Chapters II, III and IV of the Annex to Directive 91/493/EEC;
 3. have undergone health controls in accordance with Chapter V of the Annex to Directive 91/493/EEC;
 4. are packaged, marked, stored and transported in accordance with Chapters VI, VII and VIII of the Annex to Directive 91/493/EEC;
 5. do not come from toxic species or species containing biotoxins;
 6. have satisfactorily undergone the organoleptic, parasitological, chemical and microbiological checks laid down for certain categories of fishery products by Directive 91/493/EEC and in the implementing decisions thereto.
- The undersigned official inspector hereby declares that he is aware of the provisions of Directives 91/493/EEC and 92/48/EEC and Decision 2004/361/EC.

Done at , on
(Place) (Date)



.....
Signature of official inspector (³)
(Name in capital letters, capacity and qualifications of person signing)

(³) The color of the stamp and signature must be different from that of the other particulars in the certificate.

ANNEX II

LIST OF ESTABLISHMENTS AND VESSELS

N° d'agrément/ Approval No	Nom/Name	Ville/City Région/Region	Date limite d'agrément/ Approval limit	Catégorie/ Category
F-303	Condemar SA	Constanta		PP
F-320	Europesca SRL	Timis		PP
F-322	Black Sea Stuger SRL	Tulcea		PP
F-324	Kaviar House SRL	Bucuresti		PP
F-330	MF Import Export SRL	Bucuresti		PP
F-331	Blapis Prod SA	Brasov		PP
F-332	Conectii International SA	Galati		PP

Categorie legend:

PP: Processing plant/Etablissement.

**DECISION No 1/2004 OF THE EUROPEAN UNION-MEXICO JOINT COMMITTEE
of 22 March 2004**

**relating to Annex III to Decision No 2/2000 of the EU-Mexico Joint Council of 23 March 2000,
concerning the definition of the concept of 'originating products' and methods of administrative
cooperation**

(2004/362/EC)

THE JOINT COMMITTEE,

Having regard to Decision No 2/2000 of the EU-Mexico Joint Council of 23 March 2000 (hereinafter Decision No 2/2000), and in particular Notes 2 and 3 of Appendix II(a) to Annex III and Joint Declaration V thereto;

Whereas:

- (1) Annex III to Decision No 2/2000, concerning the definition of the concept of 'originating products' and methods of administrative cooperation sets out the rules of origin for the products originating in the territory of the Parties to the Agreement.
- (2) According to Joint Declaration V, the Joint Committee shall review the necessity to extend beyond 30 June 2003 the rules of origin established in Notes 2 and 3 of Appendix II(a) to Annex III, where the economic conditions which formed the basis for establishing the rule set out in those Notes continue.
- (3) In accordance with the analysis of the relevant economic conditions undertaken according to Joint Declaration V, it is considered appropriate to extend on a temporarily basis the application of the origin rules established in Notes 2 and 3 of Appendix II(a) to Annex III,

HAS DECIDED AS FOLLOWS:

Article 1

The origin rules set out in Notes 2 and 3 of Appendix II(a) to Annex III to Decision No 2/2000, shall be applied until 30 June 2006 instead of the origin rules set out in Appendix II to Annex III to Decision No 2/2000.

Article 2

This Decision shall enter into force on 1 July 2003.

Done at Brussels, 22 March 2004.

For the Joint Committee
Tomás DUPLÁ DEL MORAL
