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Price: EUR 22

⁽¹⁾ Text with EEA relevance

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EN

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⁽¹⁾ Text with EEA relevance

I

(Acts adopted under the EC Treaty/Euratom Treaty whose publication is obligatory)

REGULATIONS

COUNCIL REGULATION (EC) No 412/2009

of 18 May 2009

amending Regulation (EC) No 428/2005 imposing a definitive anti-dumping duty on imports of polyester staple fibres originating in the People's Republic of China and Saudi Arabia, amending Regulation (EC) No 2852/2000 imposing a definitive anti-dumping duty on imports of polyester staple fibres originating in the Republic of Korea and terminating the anti-dumping proceeding in respect of such imports originating in Taiwan

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 233 thereof,

Having regard to Council Regulation (EC) No 384/96 of 22 December 1995 on protection against dumped imports from countries not members of the European Community⁽¹⁾ (‘the basic Regulation’), and in particular Article 9(4) thereof,

Having regard to the proposal submitted by the Commission after having consulted the Advisory Committee,

Whereas:

A. PROCEDURE

(1) In October 1999, the Commission initiated an investigation⁽²⁾ with regards to imports of polyester staple fibres (‘PSF’) originating in the Republic of Korea (‘original investigation’). In July 2000 provisional anti-dumping duties were imposed by Commission Regulation (EC) No 1472/2000⁽³⁾ and in December 2000 definitive anti-dumping duties were imposed by Council Regulation (EC) No 2852/2000⁽⁴⁾.

(2) Pursuant to Article 11(3) of the basic Regulation, the Commission initiated⁽⁵⁾ an interim review (‘review investigation’) of the anti-dumping duties on imports of PSF originating, *inter alia*, in the Republic of Korea in December 2003. The duties on imports from the Republic of Korea were amended by Council Regulation (EC) No 428/2005⁽⁶⁾, hereinafter ‘Regulation 428/2005’.

(3) On 10 June 2005, Huvis Corporation (‘Huvis’) lodged a request⁽⁷⁾ before the Court of First Instance of the European Communities (‘CFI’) to annul Article 2 of Regulation 428/2005 as far as the anti-dumping duty rate with regard to Huvis was concerned.

(4) On 8 July 2008, the CFI⁽⁸⁾ annulled Article 2 of Regulation 428/2005 with regard to Huvis.

(5) The CFI found, *inter alia*, that the Institutions did not sufficiently justify the use of different methodologies applied in the original investigation on the one hand and the review investigation on the other hand when calculating Huvis’ individual duty rate. The findings of the Institutions in this regard were therefore considered inconsistent with Article 11(9) of the basic Regulation.

(6) Article 2 of Regulation 428/2005 was consequently annulled to the extent to which the anti-dumping duty imposed on exports into the European Community of goods produced and exported by Huvis exceeded that which would be applicable if the method applied in the original investigation had been used.

⁽¹⁾ OJ L 56, 6.3.1996, p. 1.

⁽²⁾ OJ C 285, 7.10.1999, p. 3.

⁽³⁾ OJ L 166, 6.7.2000, p. 1.

⁽⁴⁾ OJ L 332, 28.12.2000, p. 17.

⁽⁵⁾ OJ C 309, 19.12.2003, p. 2.

⁽⁶⁾ OJ L 71, 17.3.2005, p. 1.

⁽⁷⁾ OJ C 193, 6.8.2005, p. 38.

⁽⁸⁾ OJ C 209, 15.8.2008, p. 44.

(7) It is recognised by the Courts⁽¹⁾ that, in cases where a proceeding consists of several steps, the annulment of one of these steps does not annul the complete proceeding. The anti-dumping proceeding is an example of such a multi-step proceeding. Consequently, the annulment of parts of the definitive anti-dumping Regulation does not imply the annulment of the entire procedure prior to the adoption of the Regulation in question. On the other hand, according to Article 233 of the Treaty establishing the European Community, the Community institutions are obliged to comply with the Judgment of the Courts of the European Communities. Accordingly, the Community Institutions, in so complying with the Judgment, have the possibility to remedy the aspects of the contested Regulation which led to its annulment, while leaving unchanged the uncontested parts which are not affected by the Judgment⁽²⁾.

(8) This Regulation seeks to correct the aspects of the Regulation 428/2005 found to be inconsistent with the basic Regulation, and which thus led to the annulment of parts of that Regulation. It also draws, regarding exporters in the Republic of Korea that were willing to cooperate in the investigation that led to Regulation 428/2005, the consequences from Article 9(6) of the Basic Regulation. All other findings made in Regulation 428/2005, which were not contested within the time limits for a challenge and thus were not considered by the CFI and did not lead to the annulment of the contested Regulation, remain valid.

(9) Therefore, in accordance with Article 233 of the Treaty establishing the European Community, the anti-dumping duty rate for Huvis was re-calculated on the basis of the judgment of the CFI.

B. NEW ASSESSMENT OF THE FINDINGS BASED ON THE JUDGMENT OF THE CFI

(10) In this Regulation, the aspect of the judgment that is addressed is the calculation of the dumping margin, more specifically the calculation of the adjustment made to the normal value for differences between the export price and the normal value in import charges in accordance with Article 2(10)(b) of the basic Regulation.

(11) As outlined in recitals (127) and (128) of the Regulation 428/2005, different methodologies were used to calculate the adjustment on the normal value in the original investigation on the one hand and in the above mentioned interim review on the other hand.

(12) Without ruling on the legality as such of the method used in the interim review to calculate the abovementioned adjustment, the CFI in its Judgment found that the Community Institutions had not demonstrated the existence of a change in circumstances which could justify a use of a different method from the one used in the original investigation, as required by Article 11(9) of the basic Regulation. It therefore annulled Article 2 of Council Regulation 428/2005 to the extent to which the anti-dumping duty imposed on exports into the Community of goods produced and exported by Huvis exceeded that which would be applicable if the method, used in the initial investigation, had been used to calculate the adjustment to the normal value for import charges.

tioned adjustment, the CFI in its Judgment found that the Community Institutions had not demonstrated the existence of a change in circumstances which could justify a use of a different method from the one used in the original investigation, as required by Article 11(9) of the basic Regulation. It therefore annulled Article 2 of Council Regulation 428/2005 to the extent to which the anti-dumping duty imposed on exports into the Community of goods produced and exported by Huvis exceeded that which would be applicable if the method, used in the initial investigation, had been used to calculate the adjustment to the normal value for import charges.

(13) Therefore, the adjustment to the normal value for import duties was re-calculated on the basis of the method used in the original investigation.

(14) The comparison of the thus calculated weighted average normal value with the weighted average export price as found during the interim review by product type on an ex-factory basis showed the existence of dumping. The dumping margin established, expressed as a percentage of the CIF import price at the Community frontier, duty unpaid is 3,9 %.

(15) The individual rate calculated for Huvis had formed part of the basis for calculating the weighted average duty that should apply to non-sampled cooperating Korean exporters. Therefore the dumping margin for cooperating companies not included in the sample was recalculated. The new dumping margin for cooperating exporting producers not included in the sample established on the basis of a weighted average dumping margin is 4,4 %.

(16) One company, Woongjin Chemical Co., Ltd (formerly Saehan Industries Inc.), contacted the Commission and argued that its duty, too, should be adapted. However, since that company has not asked for annulment of its duty by the CFI its duty has become definitive.

C. DISCLOSURE

(17) All interested parties concerned by the implementation of the judgment were informed of the proposal to revise the rates of anti-dumping duty applicable to Huvis Corporation and the non-sampled cooperating companies. They were also granted a period within which they could make representations subsequent to this disclosure in accordance with the provisions of the basic Regulation. Comments were taken into consideration where sufficiently substantiated and justified.

⁽¹⁾ IPS v Council [1998] ECR II-3939.

⁽²⁾ Case C-458/98 P IPS v Council [2000] ECR I-08147.

D. CONCLUSION

- (18) On the basis of the above the duty rate applicable to Huvis and the cooperating exporting producers not included in the sample should be amended accordingly. The amended rates should apply retroactively from the date that Regulation (EC) No 428/2005 came into effect,

HAS ADOPTED THIS REGULATION:

Article 1

The table in Article 2 of Regulation (EC) No 428/2005 concerning the definitive anti-dumping duty rates applicable on imports of synthetic staple fibres of polyesters, not carded, combed or otherwise processed for spinning, falling within CN code 5503 20 00 originating in the Republic of Korea, shall be replaced by the following:

Company	Duty (%)	TARIC additional code
Huvis Corporation 151-7, Samsung-dong, Gangnam-gu, Seoul	3,9	A151
Woongjin Chemical Co., Ltd (formerly Saehen Industries Inc.) 254-8, Kongduk-dong, Mapo-ku, Seoul	10,6	A599
Sung Lim Co., Ltd RM 911, Dae-Young Bldg, 44-1; Youido-Dong Youngdungpo-ku, Seoul	0	A154
Dongwoo Industry Co. Ltd 729, Geochon-Ri, Bongwha-up, Bongwha-Kun, Kyongsangbuk-do	4,4	A608
East Young Co. Ltd Bongwan #202, Gumi Techno Business Center, 267 Gongdan-Dong, Gumi-si, Kyungbuk	4,4	A609

Company	Duty (%)	TARIC additional code
Estal Industrial Co. 845 Hokye-dong, Yangsan-City, Kyungnam	4,4	A610
Geum Poong Corporation 62-2, Gachun-Ri, Samnam-Myon, Ulju-Ku, Ulsan-shi	4,4	A611
Keon Baek Co. Ltd 1188-3, Shinsang-Ri, Jinryang-Eup, Kyungsan-si, Kyungbuk-do	4,4	A612
Samheung Co. Ltd 557-12, Dongkyu-Ri, Pochon-Eub Pochon-Kun, Kyungki-do	4,4	A613
All other companies	10,6	A999

Article 2

The amounts of duties paid or entered into the accounts pursuant to Article 2 of Regulation (EC) No 428/2005 in its initial version and which exceeds those as established on the basis of Article 2 of Regulation (EC) No 428/2005 as amended by this Regulation, shall be repaid or remitted.

Repayment and remission shall be requested from national customs authorities in accordance with applicable customs legislation. In duly justified cases, the time limit of three years provided in Article 236(2) of Council Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾ shall be extended for a period of two years.

Article 3

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

It shall apply from 18 March 2005.

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

Done at Brussels, 18 May 2009.

For the Council
The President
J. KOHOUT

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

COMMISSION REGULATION (EC) No 413/2009
of 20 May 2009
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 Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1580/2007 of 21 December 2007 laying down implementing rules for Council Regulations (EC) No 2200/96, (EC) No 2201/96 and (EC) No 1182/2007 in the fruit and vegetable sector ⁽²⁾, and in particular Article 138(1) thereof,

Whereas:

Regulation (EC) No 1580/2007 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 Annex XV, Part A thereto,

HAS ADOPTED THIS REGULATION:

Article 1

The standard import values referred to in Article 138 of Regulation (EC) No 1580/2007 are fixed in the Annex hereto.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 350, 31.12.2007, p. 1.

ANNEX

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	JO	73,9
	MA	43,0
	MK	66,2
	TN	101,3
	TR	82,0
	ZZ	73,3
0707 00 05	EG	127,4
	JO	156,8
	MA	32,7
	TR	135,3
	ZZ	113,1
0709 90 70	TR	122,5
	ZZ	122,5
0805 10 20	EG	38,8
	IL	57,0
	MA	46,7
	TN	49,2
	TR	107,8
	US	49,3
	ZA	56,7
	ZZ	57,9
0805 50 10	AR	67,3
	TR	49,6
	ZA	48,5
	ZZ	55,1
0808 10 80	AR	84,1
	BR	75,0
	CL	72,8
	CN	96,7
	NZ	96,3
	US	123,6
	UY	71,7
	ZA	83,9
	ZZ	88,0

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). Code 'ZZ' stands for 'of other origin'.

COMMISSION REGULATION (EC) No 414/2009**of 30 April 2009****amending Regulation (EEC) No 2454/93 laying down provisions for the implementation of Council Regulation (EEC) No 2913/92 establishing the Community Customs Code****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EEC) No 2913/92 of 12 October 1992 establishing the Community Customs Code ⁽¹⁾, and in particular Article 247 thereof,

Whereas:

(1) Regulation (EC) No 648/2005 of the European Parliament and of the Council ⁽²⁾ introduced in Regulation (EEC) No 2913/92 the obligation to lodge entry or exit summary declarations by electronic means. Starting from 1 July 2009, the lodgement of a paper-based export customs declaration is allowed only where the computerised system of the customs authorities is not functioning or where the electronic application of the person lodging the declaration is not functioning.

(2) An alternative version of the Transit Accompanying Document (the Transit/Security Accompanying Document) and the related list of items should be established to include the data required in Annex 30A to Commission Regulation (EEC) No 2454/93 ⁽³⁾ to enhance security.

(3) The Export Accompanying Document and the related list of items provided for in Article 796a of Regulation (EEC) 2454/93 should also be adapted to include the data set out in Annex 30A to Regulation (EEC) No 2454/93.

(4) Where the persons lodging the declaration cannot provide the customs authorities with export and exit

summary declarations data using the normal computerised procedures because the computerised system of the customs authorities or the electronic application of the person lodging the declaration is not functioning, they should be permitted to use an alternative paper procedure that enables them to provide the necessary information to the customs authorities. To this end, it is necessary to provide for the use of a form, the Export/Security Single Administrative Document, that can contain both export declaration and exit summary declaration data.

(5) For situations where the computerised system of the customs authorities is not functioning or where the electronic application of the person lodging the declaration is not functioning it is necessary to provide for a paper-based Security and Safety Document that should be used for entry summary declarations and for exit summary declarations. It should contain the data defined in Annex 30A to Regulation (EEC) No 2454/93 and it should be supplemented by a list of items where the consignment consists of more than one item of goods.

(6) In order to give economic operators the widest possible range of options to provide the required data where all customs and private computerised systems are not functioning, it is necessary to allow customs authorities to authorise them to communicate this data by commercial documents providing the documents produced to customs authorities contain the particulars laid down for entry or exit summary declarations in Annex 30A to Regulation (EEC) No 2454/93.

(7) Since the provisions of Commission Regulation (EC) No 1875/2006 ⁽⁴⁾ relating to safety and security apply from 1 July 2009, the corresponding provisions laid down in this Regulation should apply from the same date. Commission Regulation (EEC) No 2454/93 should therefore be amended accordingly.

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

⁽¹⁾ OJ L 302, 19.10.1992, p. 1.

⁽²⁾ OJ L 117, 4.5.2005, p. 13.

⁽³⁾ OJ L 253, 11.10.1993, p. 1.

⁽⁴⁾ OJ L 360, 19.12.2006, p. 64.

HAS ADOPTED THIS REGULATION:

Article 1

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

1. Article 183(2) is amended as follows:

(a) the second subparagraph is replaced by the following:

'In the cases referred to in points (a) and (b) of the first subparagraph, the paper-based entry summary declaration shall be made using the Security and Safety Document form, corresponding to the specimen set out in Annex 45i. Where the consignment for which an entry summary declaration is made consists of more than one item of goods, the Security and Safety Document shall be supplemented by a list of items corresponding to the specimen set out in Annex 45j. The list of items shall form an integral part of the Security and Safety Document.';

(b) the following subparagraph is added:

'In the cases referred to in points (a) and (b) of the first subparagraph, the customs authorities may allow the Security and Safety Document to be replaced by, or complemented by, commercial documents provided the documents submitted to the customs authorities contain the particulars laid down for entry summary declarations in Annex 30A.';

2. in Article 340b the following point 6a is added:

'6a. "Transit/security accompanying document": means the document printed by the computerised system to accompany the goods based on the data of the transit declaration and the entry or exit summary declaration.';

3. Article 358 is amended as follows:

(a) in paragraph 2, first subparagraph, the introductory phrase is replaced by the following:

'2. Following the release of goods, the Transit Accompanying Document or the Transit/Security Accompanying Document shall accompany the goods

placed under the Community transit procedure. It shall correspond to the specimen and particulars of the Transit Accompanying Document in Annex 45a or, in situations where data referred to in Annex 30A are provided in addition to transit data, to the specimen and particulars of the Transit/Security Accompanying Document set out in Annex 45e and the Transit/Security List of Items set out in Annex 45f. The document shall be made available to the operator in one of the following ways:';

(b) paragraph 3 is replaced by the following text:

'3. Where the declaration contains more than one item of goods, the Transit Accompanying Document referred to in paragraph 2 shall be supplemented by a list of items corresponding to the specimen set out in Annex 45b. The Transit/Security Accompanying Document referred to in paragraph 2 shall always be supplemented by the list of items set out in Annex 45f. The list of items shall form an integral part of the Transit Accompanying Document or the Transit/Security Accompanying Document.';

4. in Article 787, paragraph 2 is replaced by the following:

'2. Where the custom authorities' computerised system is not functioning or where the electronic application of the person lodging an export declaration is not functioning, the customs authorities shall accept a paper-based export declaration provided that it is made in one of the following ways:

(a) using a form corresponding to the specimen set out in Annexes 31 to 34 complemented by a Security and Safety Document corresponding to the specimen set out in Annex 45i and a Security and safety List of Items corresponding to the specimen set out in Annex 45j;

(b) using an Export/Security Single Administrative Document corresponding to the specimen set out in Annex 45k and an Export/Security List of Items corresponding to the specimen set out in Annex 45l.

The form shall contain the minimum list of data set out in Annex 37 and in Annex 30A for the export procedure.';

5. Articles 796a is amended as follows:

(a) in paragraph 1 the words 'Annex 45c' are replaced by 'Annex 45g';

(b) in paragraph 2 the words 'Annex 45d' are replaced by 'Annex 45h';

6. in Article 796c second paragraph, the words 'Annex 45c' are replaced by 'Annex 45g';

7. Article 842b(3) is amended as follows:

(a) the second subparagraph is replaced by the following:

'In the cases referred to in points (a) and (b) of the first subparagraph, the paper-based exit summary declaration shall be made using the Security and Safety Document corresponding to the specimen set out in Annex 45i. Where the consignment for which an exit summary declaration is made consists of more than one item, the Security and Safety Document shall be supplemented by a list of items corresponding to the specimen set out in Annex 45j. The list of items shall form an integral part of the Security and Safety Document.';

(b) the following third subparagraph is added:

'In the cases referred to in points (a) and (b) of the first subparagraph, customs authorities may allow the Security and Safety Document to be replaced by, or complemented by, commercial documents provided the documents submitted to customs authorities contain the particulars laid down for exit summary declarations in Annex 30A.';

8. in Articles 183, 359(1) and (4), 360(1) and (2), 361(3) and (4), 406(1) and (2), 408(1)(d), 454(4), 454b(2) and (4), 455(1) and 457b(2) and (3), the words 'Transit accompanying document' are replaced by 'Transit accompanying document — Transit/security accompanying document';

9. Annex 37d is amended as follows:

(a) in point 3.1, third indent, 'Transit accompanying document (TAD)' is replaced by 'Transit accompanying document (TAD) — Transit/security accompanying document (TSAD)';

(b) in points 3.2, 3.3, 4.1, 7, 8, 18 and 30.1, 'TAD' is replaced by 'TAD/TSAD';

(c) in point 3.2 the words 'Annex 37 and 45a' are replaced by 'Annex 37, 45a and 45e';

10. Annexes 45c and 45d are deleted;

11. Annex 45e set out in Annex I to this Regulation is inserted;

12. Annex 45f set out in Annex II to this Regulation is inserted;

13. Annex 45g set out in Annex III to this Regulation is inserted;

14. Annex 45h set out in Annex IV to this Regulation is inserted;

15. Annex 45i set out in Annex V to this Regulation is inserted;

16. Annex 45j set out in Annex VI to this Regulation is inserted;

17. Annex 45k set out in Annex VII to this Regulation is inserted;

18. Annex 45l set out in Annex VIII to this Regulation is inserted.

Article 2

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

It shall apply from 1 July 2009.

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

Done at Brussels, 30 April 2009.

For the Commission

László KOVÁCS

Member of the Commission

*ANNEX I**'ANNEX 45e*

(referred to in Article 358(2))

TRANSIT/SECURITY ACCOMPANYING DOCUMENT (TSAD)

CHAPTER I

Specimen of the Transit/Security Accompanying Document

EUROPEAN COMMUNITY

TRANSIT/SECURITY ACCOMPANYING DOCUMENT

TRANSIT/SECURITY ACCOMPANYING DOCUMENT	Consignor/Exporter (2) ☐ No		DECLARATION TYPE (1) Other SCI (S32)		MRN	
			Forms (3) 001			
			Sec. Decl. (S00)			
			Items (5)		Total packages (6)	Gross mass (kg) (35)
	Consignee (8) No		Reference numbers (7)			
			Return copy has to be sent to the office:			
	Date and time of arrival at first place of arrival in Customs territory (S12)		C. disp./exp. Code (15)		Country destin. Code (17)	
	Transport charges method of payment code (S29)		Other incidents during carriage Details and measures taken (S6)		CERTIFICATION BY COMPETENT AUTHORITIES (G)	
	Identity and nationality of means of transport at departure (18)					
	Identity and nationality of active means of transport crossing the border (21)					
Mode of transport at the border (25)						
Location of goods (30)						
Place of loading (S17)		Place of unloading (S18)		Country(ies) of routing codes (S13)		
Conveyance reference number (S10)						
Consignee (security) (S06) No		Consignor (security) (S04) No				
Carrier (S07) No		Seal Number (S28)				
Transshipments (55)	Place and country:		Place and country:			
	Ident. and nat. new means transp.:		Ident. and nat. new means transp.:			
	Ctr. ☐ (1) Identity of new container:		Ctr. ☐ (1) Identity of new container:			
	(1) Enter 1 if YES and 0 if NO.		(1) Enter 1 if YES and 0 if NO.			
CERTIFICATION BY COMPETENT AUTHORITIES (F)	New seals: Number: identity:		New seals: Number: identity:			
	Signature: Stamp:		Signature: Stamp:			
☐ Data already recorded into the system		☐ Data already recorded into the system				
Intended offices of transit (and country) (S1)	Principal/TIR Holder (50) No		OFFICE OF DEPARTURE (C)			
Guarantee		Code		Office of destination (and country) (53)		
not valid for (52)						

CONTROL BY OFFICE OF DEPARTURE (D)

Result:
Seals affixed: Number:
identity:
Time limit (date):

CONTROL BY OFFICE OF DESTINATION (I)

Date of arrival:
Examination of seals:
Remarks:

Return copy sent
on
after registration under
No
Signature: Stamp:

CHAPTER II

Explanatory notes and particulars (data) for the Transit/Security Accompanying Document

The acronym "BCP" (Business continuity plan) used in this Chapter refers to situations in which the fallback procedure defined in Article 340b(7) applies.

The Transit/Security Accompanying Document contains data valid for the whole of the declaration.

The information contained in the Transit/Security Accompanying Document shall be based on data derived from the transit declaration; where necessary, that information will be amended by the principal and/or verified by the office of departure.

The paper to be used for the Transit/Security Accompanying Document can be of green colour.

In addition to the provisions in the explanatory notes of Annexes 30A, 37 and 38, particulars have to be printed as follows:

1. MRN (MOVEMENT REFERENCE NUMBER):

The MRN is to be printed on the first page and on all lists of items except where these forms are used in the context of the BCP in which cases no MRN is allocated.

The information is alphanumerical and comprises 18 characters following the prescriptions below:

Field	Content	Field type	Examples
1	Last two digits of year of formal acceptance of the transit declaration (YY)	Numeric 2	06
2	Identifier of the country where the movement originates (alpha 2 country code)	Alphabetic 2	RO
3	Unique identifier for transit movement per year and country	Alphanumeric 13	9876AB8890123
4	Check digit	Alphanumeric 1	5

Fields 1 and 2 as explained above.

Field 3 shall be filled in with an identifier for the transit transaction. The way that field is used is under the responsibility of national administrations but each transit transaction handled during one year within the given country must have a unique number.

National administrations that want to have the office reference number of the customs authorities included in the MRN, could use up to the first 6 characters to insert the national number of the office.

Field 4 shall be filled with a value that is a check digit for the whole MRN. This field allows for detection of an error when capturing the whole MRN.

The "MRN" shall also be printed in bar code mode using the standard "code 128", character set "B".

2. BOX SEC. DECL. (S00):

Indicate code S where the Transit/Security Accompanying Document contains security information as well. Where this Document does not contain security information, the box shall be left blank.

3. BOX FORMS (3):

First subdivision: serial number of the current printed sheet,

Second subdivision: total number of sheets printed (including list of items)

4. BOX REFERENCE NUMBERS (7):

Indicate LRN or/and UCR.

LRN — a local reference number as defined in Annex 37a.

UCR — a Unique Consignment Reference Number as referred to in Annex 37, title II, box 7.

5. IN THE SPACE TO THE RIGHT OF BOX CONSIGNEE (8):

Name and address of the customs office to which the return copy of the Transit/Security Accompanying Document shall be returned.

6. BOX OTHER SCI (S32):

Enter other specific circumstance indicator.

7. BOX OFFICE OF DEPARTURE (C):

- Reference number of the office of departure,
- Acceptance date of the transit declaration,
- The name and the authorisation number of the authorised consignor (if any).

8. BOX CONTROL BY OFFICE OF DEPARTURE (D):

- Control results,
- Seals affixed or the indication “- -” identifying the “Waiver — 99201”,
- The indication “Binding itinerary”, where appropriate.

The Transit/Security Accompanying Document shall not be modified nor shall any addition or deletion be made thereto unless otherwise specified in this Regulation.

9. FORMALITIES EN ROUTE

Between the time when the goods leave the office of departure and the time they arrive at the office of destination, certain details may have to be added on the Transit/Security Accompanying Document accompanying the goods. The details relate to the transport operation and must be entered by the carrier responsible for the means of transport on which the goods are loaded as and when the corresponding activities are carried out. The particulars may be added legibly by hand, in which case the entries should be made in ink and in block letters.

Carriers are reminded that goods can be transhipped only under an authorisation of the customs authorities of the country in whose territory the transhipment is to be made.

Where those authorities consider that the Community transit operation concerned may continue in the normal way they shall, once they have taken any steps that may be necessary, endorse the Transit/Security Accompanying Documents.

The customs authorities at the office of transit or office of destination, as the case may be, have the obligation to incorporate into the system the added data on the Transit/Security Accompanying Document. The data can also be incorporated by the authorised consignee.

The boxes and activities involved are:

10. TRANSHIPMENT: USE BOX 55

Box Transhipment (55):

The carrier must complete the first three lines of this box when goods are transhipped from one means of transport to another or from one container to another in the course of the operation in question.

However where goods are carried in containers that are to be transported by road vehicles, customs authorities may authorise the principal to leave box 18 blank where the logistical pattern at the point of departure may prevent the identity and nationality of the means of transport from being provided at the time of establishment of the transit declaration, and where they can ensure that the proper information concerning the means of transport shall be subsequently entered in box 55.

11. OTHER INCIDENTS: USE BOX 56

Box Other incidents during carriage (56):

Box to be completed in accordance with current obligations regarding transit.

In addition, where goods have been loaded on a semi-trailer and the tractor is changed during the journey (without the goods being handled or transhipped), enter in this box the registration number and nationality of the new tractor. In this case, endorsement by the competent authorities is not necessary.’

*ANNEX II**'ANNEX 45f**(referred to in Article 358(3))***TRANSIT/SECURITY LIST OF ITEMS (TSLol)**

CHAPTER I

Specimen of the Transit/Security List of Items

TRANSIT/SECURITY LIST OF ITEMS

MRN

3)

[illegible]

CHAPTER II

Explanatory notes and particulars (data) for the Transit/Security List of Items

The acronym “BCP” (Business continuity plan) used in this Chapter refers to situations in which the fallback procedure defined in Article 340b(7) applies.

The Transit/Security List of Items shall contain the data specific to items of goods within the declaration.

The boxes of the list of items are vertically expandable. In addition to the provisions in the explanatory notes of Annexes 30A and 37, particulars have to be printed as follows, if appropriate using codes:

1. Box MRN — movement reference number as defined in Annex 45e. The MRN is to be printed on the first page and on all lists of items except where these forms are used in the context of the BCP in which cases no MRN is allocated.
 2. The particulars of the different boxes at item level have to be printed as follows:
 - (a) Box Item No (32) — serial number of the current item;
 - (b) Box Tpt.Ch.M.pay.code (S29) — enter transport charges method of payment code;
 - (c) UNDG (44/4) — UN Dangerous Goods code;
 - (d) Box Forms (3):
 - First subdivision: serial number of the current printed sheet,
 - Second subdivision: total number of sheets printed (Transit/Security List of Items).'
-

ANNEX III

'ANNEX 45g

(referred to in Article 796a)

EXPORT ACCOMPANYING DOCUMENT (EAD)

CHAPTER I

Specimen of the Export Accompanying Document

EUROPEAN COMMUNITY

EXPORT ACCOMPANYING DOCUMENT

Consignor/Exporter (2)

No



DECLARATION TYPE (1)

MRN

Other SCI (S32)

Forms (3)

Sec. Decl. (S00)

001

Items (5)

Total packages (6)

Issuing date:

Customs office:

Consignee (8)

No

Reference numbers (7)

Transport charges method of payment code (S29)

C. disp./exp. Code (15)

Country destin. Code (17)

a|

a|

Countr(ies) of routing codes (S13)

Declarant/Representative (14)

No

Representative of person lodging sum.decl. (14b) No

Identity of means of transport at departure (18)

Gross mass (kg) (35)

Mode of transport

Location of goods (30)

at the border (25)

Seal Number (S28)

Office of exit (29)

Packages and description of goods (31)

Marks and numbers - Container No(s) - Number and kind

32 Item No

Number and kind of packages, pieces, marks and numbers of packages (31/1)

Description of goods (31/2)

Consignor/Exporter (2)

Consignee (8)

Identity of means of transport at departure (18)

Commodity Code (33)

Unique consignment reference number (7)

Summary declaration/Previous document (40)

Produced documents / certificates (44/1)

Container numbers (31/3)

Seal Number (S28)

Special mentions (44/2)

Procedure (37)

C. Exp. (15a)

C. Dest. (17a)

Gross mass (kg) (35)

UNDG (44/4)

Transport charges method of payment code (S29)

Declaration type (1)

Statistical value (46)

Net mass (kg) (38)

CONTROL BY OFFICE OF DISPATCH/EXPORT (E)

Result:

Seals affixed: Number:

identity:

Time limit (date):

CONTROL BY OFFICE OF EXIT (K)

Date of arrival:

Examination of seals:

Remarks:

CHAPTER II

Explanatory notes and particulars (data) for the Export Accompanying Document

The acronym “BCP” (Business continuity plan) used in this Chapter refers to situations in which the fallback procedure defined in Article 787(2) applies.

The Export Accompanying Document contains data valid for the whole of the declaration and for one item of goods.

The information contained in the Export Accompanying Document shall be based on data derived from the export declaration; where necessary, that information will be amended by the declarant/representative and/or verified by the office of export.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, particulars have to be printed as follows:

1. BOX MRN (movement reference number):

The MRN is to be printed on the first page and on all lists of items except where these forms are used in the context of the BCP in which cases no MRN is allocated.

The information is alphanumerical and comprises 18 characters following the prescriptions below:

Field	Content	Field type	Examples
1	Last two digits of year of formal acceptance of the export declaration (YY)	Numeric 2	06
2	Identifier of the country of export. (alpha 2 code as provided for box 2 of the Single Administrative Document in Annex 38)	Alphabetic 2	RO
3	Unique identifier for export operation per year and country	Alphanumeric 13	9876AB8890123
4	Check digit	Alphanumeric 1	5

Fields 1 and 2 as explained above.

Field 3 shall be filled in with an identifier for the export control system transaction. The way that field is used is under the responsibility of national administrations but each export transaction handled during one year within the given country must have a unique number. National administrations that want to have the office reference number of the competent authorities included in the MRN, could use up to the first 6 characters to insert the national number of the office.

Field 4 shall be filled with a value that is a check digit for the whole MRN. This field allows for detection of an error when capturing the whole MRN.

The “MRN” shall also be printed in bar code mode using the standard “code 128”, character set “B”.

2. BOX SEC. DECL. (S00):

Indicate code S where the Export Accompanying Document contains security information as well. Where this Document does not contain security information, the box shall be left blank.

3. BOX CUSTOMS OFFICE:

Reference number of the office of export.

4. BOX REFERENCE NUMBER (7):

Indicate LRN or/and UCR:

LRN — a local reference number as defined in Annex 37a.

UCR — a Unique Consignment Reference Number as referred to in Annex 37, title II, box 7.

5. BOX OTHER SCI (S32):

Enter other specific circumstance indicator.

6. THE PARTICULARS OF THE DIFFERENT BOXES AT ITEM LEVEL HAVE TO BE PRINTED AS FOLLOWS:

(a) Box Item No (32) — serial number of the current item;

(b) Box UNDG (44/4) — UN Dangerous Goods code.

The Export Accompanying Document shall not be modified nor shall any addition or deletion be made thereto unless otherwise specified in this Regulation.'

*ANNEX IV**'ANNEX 45h*

(referred to in Article 796a)

EXPORT LIST OF ITEMS (ELoI)

CHAPTER I

Specimen of the Export List of Items

EUROPEAN COMMUNITY

EXPORT LIST OF ITEMS

MRN

Forms (3)

[illegible]

CHAPTER II

Explanatory notes and particulars (data) for the Export List of Items

The export List of Items contains the data specific to items of goods within the declaration.

The boxes of the export list of items are vertically expandable.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, the particulars have to be printed as follows, if appropriate using codes:

1. Box MRN — movement reference number as defined in Annex 45g. The MRN shall be printed on first page and on all lists of items.
2. The particulars of the different boxes at item level have to be printed as follows:
 - (a) Box Item No (32) — serial number of the current item;
 - (b) Box UNDG (44/4) — UN Dangerous Goods code.'

ANNEX V

'ANNEX 45i

(referred to in Articles 183(2), 787(2)(a) and 842b(3))

SECURITY AND SAFETY DOCUMENT (SSD)

CHAPTER I

Specimen of the Security and Safety Document

EUROPEAN COMMUNITY

SECURITY AND SAFETY DOCUMENT

Carrier (S07)	No

DECLARATION TYPE (1)		MRN
	Other SCI (S32)	
Forms (3)	Items (5)	Issuing date:
001		Customs office:
Reference number (7)		

Identity and nationality of active means of transport crossing the border (21)		
Mode of tpt	Conveyance reference number (S10)	Date/time arr.1st place cust.Terr. (S12)
(25)		
Office of exit (29)	Location of goods (30)	First place arr. cde (S11)
Offices of subsequent entry (S11/2)		

Countr(ies) of routing codes (S13)
Shipping marks (S22)

Consignee (security) (S06)	No

Notify party (S08)	No

Consignor (security) (S04)	No

Place of loading (S17)	Place of unloading (S18)
Unique consignment/transport reference Nr (S02-03)	

Container numbers (31/3)

Seal Number (S28)	Gross mass (kg) (35)
	T.C.M.paym.cde (S29)

Consignee (security) (S06)	No

Notify party (S08)	No

Consignor (security) (S04)	No

Place of loading (S17)	Place of unloading (S18)
Unique consignment/transport reference Nr (S02-03)	

Container numbers (31/3)

Seal Number (S28)	Gross mass (kg) (35)
	T.C.M.paym.cde (S29)

No/kind pack./pces, marks and numbers of packages (31/1)

Identity and nationality of active means of transport crossing the border (21)
Special mentions (44/2)

Description of goods (31/2)

Commodity Code (33)
UNDG (S27)
32 Item No 001

Person lodging the exit/entry sum. Dec. (S05)	No
Representative of Pers.lodging sum.Dec. (S05a)	No

Place and date:
Signature and name:

CHAPTER II

Explanatory notes and particulars (data) for the Security and Safety Document

The form contains header level information and the information for one item of goods.

The information contained in the Security and Safety Document shall be based on data provided for the entry or exit summary declaration; where necessary, that information will be amended by the person lodging the summary declaration and/or verified by the office of entry or exit respectively.

The Security and Safety Document shall be completed by the person lodging the summary declaration.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, particulars have to be printed as follows:

1. Box MRN — movement reference number as defined in Annex 45e or ad-hoc references issued by the customs office.
The MRN shall be printed on first page and on all lists of items;
2. Customs office:

Reference number of the office of entry/exit;
3. Box Declaration type (1):

Codes “IM” or “EX” according to whether the document contains Entry summary declaration or exit summary declaration data;
4. Box Reference number (7):

Enter LRN — LRN — a local reference number as defined in Annex 37a;
5. Box First place arr.cde (S11):

First place of arrival code;
6. Box Date/time arr. first place cust. Terr. (S12):

Enter date and time of arrival at first place of arrival in Customs territory;
7. Box T.C.M.paym.cde (S29):

Enter transport charges method of payment code;
8. Box UNDG (S27) — UN Dangerous Goods code;
9. Box Other SCI (S32):

Enter other specific circumstance indicator.

The Security and Safety Document shall not be modified nor shall any addition or deletion be made thereto unless otherwise specified in this Regulation.'

ANNEX VI

‘ANNEX 45j

(referred to in Articles 183(2), 787(2)(a) and 842b(3))

SECURITY AND SAFETY LIST OF ITEMS (SSLoI)

CHAPTER I

Specimen of the Security and Safety List of Items

EUROPEAN COMMUNITY

SECURITY AND SAFETY LIST OF ITEMS		DECLARATION TYPE (1)		MRN	
		Other SCI (S32)			
		Forms (3)		Issuing date: Customs office:	
Consignee (security) (S06) No		Notify party (S08) No			
Consignor (security) (S04) No		Place of loading (S17)		Place of unloading (S18)	
		Unique consignment/transport reference Nr (S02-03)			
Container numbers (31/3)		Seal Number (S28)		Gross mass (kg) (35)	
				T.C.M.paym.cde (S29)	
No/kind pack./pces, marks and numbers of packages (31/1)		Identity and nationality of active means of transport crossing the border (21)			
		Special mentions (44/2)			
Description of goods (31/2)				Commodity Code (33)	
				UNDG (S27)	
				32 Item No	
Consignee (security) (S06) No		Notify party (S08) No			
Consignor (security) (S04) No		Place of loading (S17)		Place of unloading (S18)	
		Unique consignment/transport reference Nr (S02-03)			
Container numbers (31/3)		Seal Number (S28)		Gross mass (kg) (35)	
				T.C.M.paym.cde (S29)	
No/kind pack./pces, marks and numbers of packages (31/1)		Identity and nationality of active means of transport crossing the border (21)			
		Special mentions (44/2)			
Description of goods (31/2)				Commodity Code (33)	
				UNDG (S27)	
				32 Item No	

CHAPTER II

Explanatory notes and particulars (data) for the Security and Safety List of Items

The boxes of the list of items are not vertically expandable.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, the particulars of the different boxes have to be printed as follows:

Box Item No (32) — serial number of the current item;

Box T.C.M.paym.cde (S29) — transport charges method of payment code;

Box UNDG (S27) — UN Dangerous Goods code.'

ANNEX VII

‘ANNEX 45k

(referred to in Article 787)

EXPORT/SECURITY SAD (ESS)

CHAPTER I

Specimen of the Export/Security SAD

EUROPEAN COMMUNITY - EXP-SAD/SEC

A OFFICE OF DISPATCH/EXPORT

2

2 Consignor/Exporter

No

☐

1 DECLARATION

Other SCI (S32)

3 Forms

4 Loading lists

5 Items

6 Total packages

7 Reference numbers

8 Consignee

No

Seal Number (S28)

14 Declarant/Representative

No

Transport charges method of payment code (S29)

15 C. disp./exp. Code

17 Country destin. Code

a|

b|

a|

Countr(ies) of routing codes (S13)

18 Identity and nationality of means of transport at departure

19 Ctr.

20 Delivery terms

21 Identity and nationality of active means of transport crossing the border

22 Currency and total amount invoiced

23 Exchange rate

24 Nature of

transaction

25 Mode of transport

26 Inland mode

at the border

of transport

2

29 Office of exit

30 Location of goods

31 Packages and description of goods

Marks and numbers - Container No(s) - Number and kind

32 Item

No

33 Commodity Code

34 Country origin Code

35 Gross mass (kg)

a|

b|

37 P R O C E D U R E

38 Net mass (kg)

40 Summary declaration/Previous document

41 Supplementary units

Seal Number (S28)

44 Additional information/ Documents produced/ Certificates and authorizations

A.I. Code

46 Statistical value

47 Calculation of taxes

Type

Tax base

Rate

Amount

MP

48 Deferred payment

49 Identification of warehouse

Total:

50 Principal

No

Signature:

represented by

Place and date:

CONTROL BY OFFICE OF EXIT (K)

Stamp:

Date of arrival:

Examination of seals:

Remarks:

CONTROL BY OFFICE OF DISPATCH/EXPORT (E)

Stamp:

54 Place and date:

Result:

Seals affixed: Number:

Signature and name of declarant/representative:

identity:

Time limit (date):

Signature:

EUROPEAN COMMUNITY - EXP-SAD/SEC

A OFFICE OF DISPATCH/EXPORT

3 Copy for the consignor/exporter	2 Consignor/Exporter No				1 DECLARATION		Other SCI (S32)	
					3 Forms		4 Loading lists	
					5 Items		6 Total packages	
					7 Reference numbers			
	8 Consignee No				Seal Number (S28)			
	14 Declarant/Representative No				Transport charges method of payment code (S29)		15 C. disp./exp. Code	
					a		b	
					17 Country destin. Code			
	18 Identity and nationality of means of transport at departure				19 Ctr.		20 Delivery terms	
	21 Identity and nationality of active means of transport crossing the border				22 Currency and total amount invoiced		23 Exchange rate	
25 Mode of transport				26 Inland mode		24 Nature of transaction		
at the border				of transport				
29 Office of exit				30 Location of goods				
31 Packages and description of goods				32 Item No		33 Commodity Code		
				a		b		
				34 Country origin Code		35 Gross mass (kg)		
				37 P R O C E D U R E		38 Net mass (kg)		
				40 Summary declaration/Previous document				
				41 Supplementary units		Seal Number (S28)		
44 Additional information/ Documents produced/ Certificates and authorizations				A.I. Code		46 Statistical value		
47 Calculation of taxes				48 Deferred payment		49 Identification of warehouse		
Type				Tax base		Rate		
Amount				MP				
Total:								
50 Principal No				Signature:				
represented by								
Place and date:								
CONTROL BY OFFICE OF EXIT (K)				Stamp:				
Date of arrival:								
Examination of seals:								
Remarks:								
CONTROL BY OFFICE OF DISPATCH/EXPORT (E)				Stamp:				
Result:				54 Place and date:				
Seals affixed: Number:				Signature and name of declarant/representative:				
identity:								
Time limit (date):								
Signature:								

CHAPTER II

Explanatory notes and particulars (data) for the Export/Security SAD

The acronym "BCP" (Business continuity plan) used in this Chapter refers to situations in which the fallback procedure defined in Article 787(2) applies.

The form contains all information necessary for export and exit data where export and security data are provided together. The form includes information at header level and for one item of goods. It is designed to be used in the context of the BCP.

There are three copies of the Export/Security SAD:

Copy 1 is kept by the authorities of the Member State in which export (dispatch) or Community transit formalities are completed;

Copy 2 is used for statistical purposes by the Member State of export;

Copy 3 is returned to the exporter after being stamped by the customs authority.

The Export/Security SAD contains data valid for the whole of the declaration.

The information contained in the Export/Security SAD shall be based on data derived from the export and exit declaration; where necessary, that information will be amended by the declarant/representative and/or verified by the office of export.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, particulars have to be printed as follows:

1. Box MRN (movement reference number):

The MRN is to be printed on the first page and on all lists of items except where these forms are used in the context of the BCP in which cases no MRN is allocated.

The information is alphanumerical and comprises 18 characters following the prescriptions below:

Field	Content	Field type	Examples
1	Last two digits of year of formal acceptance of the export declaration (YY)	Numeric 2	06
2	Identifier of the country of export. (alpha 2 code as provided for box 2 of the Single Administrative Document in Annex 38)	Alphabetic 2	RO
3	Unique identifier for export operation per year and country	Alphanumeric 13	9876AB8890123
4	Check digit	Alphanumeric 1	5

Fields 1 and 2 as explained above.

Field 3 shall be filled in with an identifier for the export control system transaction. The way that field is used is under the responsibility of national administrations but each export transaction handled during one year within the given country must have a unique number. National administrations that want to have the office reference number of the competent authorities included in the MRN, could use up to the first 6 characters to insert the national number of the office.

Field 4 shall be filled with a value that is a check digit for the whole MRN. This field allows for detection of an error when capturing the whole MRN.

The "MRN" shall also be printed in bar code mode using the standard "code 128", character set "B".

2. Box 7 reference numbers:

Indicate LRN or/and UCR.

LRN — a local reference number as defined in Annex 37a.

UCR — a Unique Consignment Reference Number as referred to in Annex 37, title II, box 7.

3. Box Other SCI (S32):

Enter other specific circumstance indicator.

The Export/Security SAD shall not be modified nor shall any addition or deletion be made thereto unless otherwise specified in this Regulation.'

*ANNEX VIII**'ANNEX 45I**(referred to in Article 787)***EXPORT/SECURITY SAD LIST OF ITEMS (ESSLoI)**

CHAPTER I

Specimen of the Export/Security SAD List of Items

EUROPEAN COMMUNITY

EXP-SAD/SEC - LIST OF ITEMS

A OFFICE OF DISPATCH/EXPORT

Forms (3)

[illegible]

CHAPTER II

Explanatory notes and particulars (data) for the Export/Security SAD List of Items

The Export/Security SAD List of Items contains the data specific to items of goods within the declaration.

The boxes of the list of items are vertically expandable.

In addition to the provisions in the explanatory notes of Annexes 30A and 37, particulars have to be printed as follows:

1. Box MRN — movement reference number as defined in Annex 45k. The MRN shall be printed on the first page and on all lists of items.
 2. The particulars of the different boxes at item level have to be printed as follows:
 - Box Item No (32) — serial number of the current item,
 - Box Documents produced/ Certificates (44/1): this box contains also the transport document number, where appropriate,
 - Box UNDG (44/4) — UN Dangerous Goods code.'
-

COMMISSION REGULATION (EC) No 415/2009**of 20 May 2009****amending Directive 2007/68/EC amending Annex IIIa to Directive 2000/13/EC of the European Parliament and of the Council as regards certain food ingredients****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Directive 2000/13/EC of the European Parliament and of the Council of 20 March 2000 on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs ⁽¹⁾ and in particular Article 21 thereof,

Whereas:

- (1) Commission Directive 2007/68/EC ⁽²⁾ establishes the list of food ingredients or substances excluded from the labelling requirement.
- (2) Since changes in labelling rules affect industry, mainly small and medium-sized enterprises, which need an adaptation period to smooth the transition towards new labelling requirements, Directive 2007/68/EC provides for temporary measures to facilitate the application of the new rules by allowing the marketing of foodstuffs placed on the market or labelled before 31 May 2009 that comply with Commission Directive 2005/26/EC ⁽³⁾ until stocks are exhausted.
- (3) Council Regulation (EC) No 479/2008 of 29 April 2008 on the common organisation of the market in wine, amending Regulations (EC) No 1493/1999, (EC) No 1782/2003, (EC) No 1290/2005, (EC) No 3/2008 and repealing Regulations (EEC) No 2392/86 and (EC) No 1493/1999 ⁽⁴⁾ reorganises the way the EU wine market is managed. According to Article 129(1)(e) of that Regulation, Chapters II, III, IV, V and VI of Title III, Articles 108, 111 and 112 and the corresponding provisions in particular in the relevant Annexes are to apply from 1 August 2009 save as otherwise provided by way of regulation to be adopted in accordance with the procedure referred to in Article 113(1). Implementing rules of that Regulation, providing, *inter alia*, for specific labelling rules applicable to the wine sector are currently being prepared and, because of their applica-

bility as from the 1 August 2009, a transitional period is provided in order to ease the transition from the previous wine sector legislation, notably Council Regulation (EC) No 1493/1999 of 17 May 1999 on the common organisation of the market in wine ⁽⁵⁾ to Regulation (EC) No 479/2008 to allow economic operators to comply with the new labelling requirements.

- (4) Given that wine operators would be subject to two sets of labelling requirements, those provided under Directive 2007/68/EC and those of the implementing rules of Regulation (EC) No 479/2008, and given that the transitional periods do not coincide, as under Directive 2007/68/EC foodstuffs placed on the market or labelled before 31 May 2009 that comply with Directive 2005/26/EC can be marketed until stocks are exhausted, in the interests of sound administration and to avoid unnecessary burdens on the authorities of the Member States as well as economic operators, a single date should be established for the mandatory application to the wine sector of Directive 2007/68/EC and of the implementing rules adopted in the framework of Regulation (EC) No 479/2008.
- (5) As regards products covered by Regulation (EC) No 479/2008, the end of the transitional period foreseen in Directive 2007/68/EC should therefore be fixed at 31 December 2010.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

In Article 3 of Directive 2007/68/EC the following paragraph is added:

'By way of derogation from the second paragraph of this Article, Member States shall allow wines, as defined in Annex IV to Council Regulation (EC) No 479/2008 ^(*) placed on the market or labelled before 31 December 2010, and which comply with the provisions of Directive 2005/26/EC, to be marketed until stocks are exhausted.

⁽¹⁾ OJ L 109, 6.5.2000, p. 29.

⁽²⁾ OJ L 310, 28.11.2007, p. 11.

⁽³⁾ OJ L 75, 22.3.2005, p. 33.

⁽⁴⁾ OJ L 148, 6.6.2008, p. 1.

^(*) OJ L 148, 6.6.2008, p. 1.'

⁽⁵⁾ OJ L 179, 14.7.1999, p. 1.

Article 2

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

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

Done at Brussels, 20 May 2009.

For the Commission
Androulla VASSILIOU
Member of the Commission

COMMISSION REGULATION (EC) No 416/2009**of 20 May 2009****on the division between 'deliveries' and 'direct sales' of national milk quotas fixed for 2008/2009 in Annex IX to Council Regulation (EC) No 1234/2007**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 69(1) in conjunction with Article 4 thereof,

Whereas:

- (1) Article 67(2) of Regulation (EC) No 1234/2007 provides that producers may have one or two individual quotas, one for deliveries and the other for direct sales and quantities may be converted from one quota to the other only by the competent authority of the Member State, at the duly justified request of the producer.
- (2) Commission Regulation (EC) No 415/2008 of 8 May 2008 on the division between 'deliveries' and 'direct sales' of national reference quantities fixed for 2007/2008 in Annex I to Council Regulation (EC) No 1788/2003 ⁽²⁾ sets out the division between 'deliveries' and 'direct sales' for the period from 1 April 2007 to 31 March 2008 for all Member States.
- (3) In accordance with Article 25(2) of Commission Regulation (EC) No 595/2004 of 30 March 2004 laying down detailed rules for applying Council Regulation (EC) No 1788/2003 establishing a levy in the milk and milk products sector ⁽³⁾, Member States have notified the quantities which have been definitively converted at

the request of the producers between individual quotas for deliveries and for direct sales.

- (4) In accordance with Council Regulation (EC) No 248/2008 of 17 March 2008 amending Regulation (EC) No 1234/2007 as regards the national quotas for milk ⁽⁴⁾, the total national quotas for all Member States were increased with effect from 1 April 2008. Member States, except Malta which has no direct sales part of its national quota, have notified the Commission of the division between 'deliveries' and 'direct sales' of the additional quota.
- (5) It is therefore appropriate to establish the division between 'deliveries' and 'direct sales' of the national quotas applicable for the period from 1 April 2008 to 31 March 2009 fixed in Annex IX to Regulation (EC) No 1234/2007.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The division, applicable for the period from 1 April 2008 to 31 March 2009, between 'deliveries' and 'direct sales' of the national quotas fixed in Annex IX to Regulation (EC) No 1234/2007 is set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 20 May 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 125, 9.5.2008, p. 22.

⁽³⁾ OJ L 94, 31.3.2004, p. 22.

⁽⁴⁾ OJ L 76, 19.3.2008, p. 6.

ANNEX

(tonnes)

Member States	Deliveries	Direct sales
Belgium	3 371 559,558	55 729,182
Bulgaria	912 238,158	86 341,842
Czech Republic	2 785 413,892	7 275,728
Denmark	4 612 376,648	242,872
Germany	28 755 245,289	92 175,102
Estonia	650 386,770	8 908,590
Ireland	5 501 532,799	2 146,481
Greece	835 781,260	1 142,000
Spain	6 173 230,927	66 058,073
France	24 738 890,113	352 431,587
Italy	10 474 131,877	266 529,323
Cyprus	146 970,338	1 133,662
Latvia	725 538,102	17 682,858
Lithuania	1 674 056,192	64 879,588
Luxembourg	278 070,680	475,000
Hungary	1 921 492,480	108 368,720
Malta	49 671,960	0,000
Netherlands	11 392 464,000	73 166,280
Austria	2 755 298,641	92 179,828
Poland	9 403 080,692	164 665,168
Portugal ⁽¹⁾	1 979 091,285	8 429,715
Romania	1 429 140,086	1 688 999,914
Slovenia	567 987,116	20 183,644
Slovakia	1 049 485,430	12 118,330
Finland	2 486 700,282	6 015,111
Sweden	3 415 795,900	3 800,000
United Kingdom	14 988 515,859	136 653,081

⁽¹⁾ Except Madeira.

COMMISSION REGULATION (EC) No 417/2009**of 20 May 2009****entering a designation in the register of protected designations of origin and protected geographical indications (Mariánskolázeňské oplatky (PGI))**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 7(4) thereof,

Whereas:

- (1) In accordance with Article 6(2) of Regulation (EC) No 510/2006, and pursuant to Article 17(2) of the same Regulation, the Czech Republic's application to enter the designation 'Mariánskolázeňské oplatky' in the register was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) Germany has stated its objection to this registration in accordance with Article 7(3)(a) and (d) of Regulation (EC) No 510/2006.

(3) By way of a letter dated 5 March 2008 the Commission invited the interested parties to hold appropriate consultations with each other. Although no agreement was reached between the Czech Republic and Germany within a time frame of six months, Germany withdrew its objection on 12 March 2009.

(4) Accordingly this name should be entered into the register,

HAS ADOPTED THIS REGULATION:

Article 1

The designation contained in the Annex to this Regulation shall be entered in the register.

Article 2

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

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

Done at Brussels, 20 May 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 107, 11.5.2007, p. 28.

ANNEX

Foodstuffs listed in Annex I to Regulation (EC) No 510/2006:

Class 2.4. Bread, pastry, cakes, confectionery, biscuits and other baker's wares

CZECH REPUBLIC

Mariánskolázeňské oplatky (PGI)

COMMISSION REGULATION (EC) No 418/2009**of 20 May 2009****entering a name in the register of protected designations of origin and protected geographical indications (Petit Épeautre de Haute Provence (PGI))**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

(2) As no objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, this name should be entered in the register,

Having regard to the Treaty establishing the European Community,

HAS ADOPTED THIS REGULATION:

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 7(4) thereof,*Article 1*

The name contained in the Annex to this Regulation is hereby entered in the register.

Whereas:

(1) Pursuant to Article 6(2) of Regulation (EC) No 510/2006, France's application to register the name 'Petit Épeautre de Haute Provence' has been published in the *Official Journal of the European Union* ⁽²⁾.*Article 2*This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 20 May 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission⁽¹⁾ OJ L 93, 31.3.2006, p. 12.⁽²⁾ OJ C 261, 14.10.2008, p. 11.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty

Class 1.6. Fruit, vegetables and cereals, fresh or processed

FRANCE

Petit Épeautre de Haute Provence (PGI)

COMMISSION REGULATION (EC) No 419/2009**of 20 May 2009****entering a name in the register of protected designations of origin and protected geographical indications (Kiwi de l'Adour (PGI))**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 510/2006 of 20 March 2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 7(4) thereof,

Whereas:

- (1) In accordance with the first subparagraph of Article 6(2) of Regulation (EC) No 510/2006, and pursuant to Article 17(2) of the same Regulation, France's application to enter the name 'Kiwi de l'Adour' in the register was published in the *Official Journal of the European Union* ⁽²⁾.

- (2) As no objection under Article 7 of Regulation (EC) No 510/2006 has been received by the Commission, this name should be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name contained in the Annex to this Regulation is hereby entered in the register.

*Article 2*This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

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

Done at Brussels, 20 May 2009.

For the Commission

Mariann FISCHER BOEL

Member of the Commission

⁽¹⁾ OJ L 93, 31.3.2006, p. 12.

⁽²⁾ OJ C 263, 16.10.2008, p. 5.

ANNEX

Agricultural products intended for human consumption listed in Annex I to the Treaty:

Class 1.6. Fruit, vegetables and cereals, fresh or processed

FRANCE

Kiwi de l'Adour (PGI)

COMMISSION REGULATION (EC) No 420/2009**of 20 May 2009****fixing the maximum export refund for butter in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

- (1) Commission Regulation (EC) No 619/2008 of 27 June 2008 opening a standing invitation to tender for export refunds concerning certain milk products ⁽²⁾ provides for a standing invitation to tender procedure.
- (2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for fixing export refunds for certain agricultural products ⁽³⁾, and following an examination of the tenders submitted in response to

the invitation to tender, it is appropriate to fix a maximum export refund for the tendering period ending on 19 May 2009.

- (3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 19 May 2009, the maximum amount of refund for the products and destinations referred to in Article 1(a) and (b) and in Article 2 respectively of that Regulation shall be as shown in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 168, 28.6.2008, p. 20.

⁽³⁾ OJ L 325, 11.12.2007, p. 69.

ANNEX

(EUR/100 kg)

Product	Export refund Code	Maximum amount of export refund for exports to the destinations referred to in Article 2 of Regulation (EC) No 619/2008
Butter	ex 0405 10 19 9700	60,00
Butteroil	ex 0405 90 10 9000	73,00

COMMISSION REGULATION (EC) No 421/2009**of 20 May 2009****fixing the maximum export refund for skimmed milk powder in the framework of the standing invitation to tender provided for in Regulation (EC) No 619/2008**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 164(2), in conjunction with Article 4, thereof,

Whereas:

(1) Commission Regulation (EC) No 619/2008 of 27 June 2008 opening a standing invitation to tender for export refunds concerning certain milk products ⁽²⁾ provides for a standing invitation to tender procedure.

(2) Pursuant to Article 6 of Commission Regulation (EC) No 1454/2007 of 10 December 2007 laying down common rules for establishing a tender procedure for fixing export

refunds for certain agricultural products ⁽³⁾ and following an examination of the tenders submitted in response to the invitation to tender, it is appropriate to fix a maximum export refund for the tendering period ending on 19 May 2009.

(3) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the standing invitation to tender opened by Regulation (EC) No 619/2008, for the tendering period ending on 19 May 2009, the maximum amount of refund for the product and destinations referred to in Article 1(c) and in Article 2 of that Regulation shall be EUR 22,00/100 kg.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 168, 28.6.2008, p. 20.

⁽³⁾ OJ L 325, 11.12.2007, p. 69.

COMMISSION REGULATION (EC) No 422/2009
of 20 May 2009
fixing the export refunds on eggs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products ⁽¹⁾, and in particular Article 164(2), last subparagraph, and Article 170 thereof,

Whereas:

- (1) Article 162(1) of Regulation (EC) No 1234/2007 provides that the difference between prices on the world market for the products referred to in Part XIX of Annex I to that Regulation and prices in the Community for those products may be covered by an export refund.
- (2) In view of the current situation on the market in eggs, export refunds should be fixed in accordance with the rules and certain criteria provided for in Articles 162 to 164, 167, 169 and 170 of Regulation (EC) No 1234/2007.
- (3) Article 164(1) of Regulation (EC) No 1234/2007 provides that refunds may vary according to destination, especially where the world market situation, the specific requirements of certain markets, or obligations resulting from agreements concluded in accordance with Article 300 of the Treaty make this necessary.
- (4) Refunds should be granted only on products which are authorised to move freely within the Community and

comply with requirements under Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs ⁽²⁾ and of Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ⁽³⁾, as well as marking requirements under point A of Annex XIV to Regulation (EC) No 1234/2007.

- (5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

1. The products on which the export refunds provided for in Article 164 of Regulation (EC) No 1234/2007 may be paid, subject to the conditions laid down in paragraph 2 of this Article, and the amounts of those refunds are specified in the Annex to this Regulation.

2. The products on which a refund may be paid under paragraph 1 shall meet the requirements under Regulations (EC) Nos 852/2004 and 853/2004 and, in particular, shall be prepared in an approved establishment and comply with the marking conditions laid down in Section I of Annex II to Regulation (EC) No 853/2004 and those defined in point A of Annex XIV to Regulation (EC) No 1234/2007.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 139, 30.4.2004, p. 1. Corrected version in OJ L 226, 25.6.2004, p. 3.

⁽³⁾ OJ L 139, 30.4.2004, p. 55. Corrected version in OJ L 226, 25.6.2004, p. 22.

ANNEX

Export refunds on eggs applicable from 21 May 2009

Product code	Destination	Unit of measurement	Amount of refund
0407 00 11 9000	A02	EUR/100 pcs	0,39
0407 00 19 9000	A02	EUR/100 pcs	0,20
0407 00 30 9000	E09	EUR/100 kg	0,00
	E10	EUR/100 kg	16,00
	E19	EUR/100 kg	0,00
0408 11 80 9100	A03	EUR/100 kg	56,48
0408 19 81 9100	A03	EUR/100 kg	28,35
0408 19 89 9100	A03	EUR/100 kg	28,35
0408 91 80 9100	A03	EUR/100 kg	35,78
0408 99 80 9100	A03	EUR/100 kg	9,00

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

The other destinations are defined as follows:

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

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

E19 all destinations except Switzerland and those of E09 and E10.

COMMISSION REGULATION (EC) No 423/2009**of 20 May 2009****on the issue of licences for importing rice under the tariff quotas opened for the May 2009 subperiod by Regulation (EC) No 1529/2007**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾,

Having regard to Commission Regulation (EC) No 1529/2007 of 21 December 2007 opening and providing for the administration in 2008 and 2009 of import quotas for rice originating in the ACP States which are part of the Cariforum region and the overseas countries and territories (OCTs) ⁽²⁾, and in particular Article 4(1) thereof,

Whereas:

- (1) Regulation (EC) No 1529/2007 opens and provides for the administration of an annual import tariff quota for 2009 of 250 000 tonnes of rice, in husked-rice equivalent, originating in States that are part of the Cariforum region (order number 09.4220), an import tariff quota of 25 000 tonnes of rice, in husked-rice equivalent, originating in the Netherlands Antilles and Aruba (order number 09.4189) and an import tariff quota of 10 000 tonnes of rice, in husked-rice equivalent, originating in the least-developed OCTs (order number 09.4190).

- (2) May is the second subperiod for the quota laid down in Article 1(1) and (2) of Regulation (EC) No 1529/2007.

- (3) The notification sent in accordance with Article 6(a) of Regulation (EC) No 1529/2007 shows that, for the quotas with order numbers 09.4220, 09.4189, and 09.4190, the applications lodged in the first seven days of May 2009 under Article 2(1) of the Regulation cover a quantity, in husked-rice equivalent, lower than that available.

- (4) The total quantities available for the following subperiod should therefore be fixed for the quotas with order numbers 09.4220, 09.4189, and 09.4190, in accordance with Article 4(1) of Regulation (EC) No 1529/2007,

HAS ADOPTED THIS REGULATION:

Article 1

The total quantities available for the following subperiod under the quotas with order numbers 09.4220, 09.4189, and 09.4190 as referred to in Regulation (EC) No 1529/2007 are set out in the Annex to this Regulation.

Article 2

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

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 348, 31.12.2007, p. 155.

ANNEX

Quantities to be allocated for the May 2009 subperiod and quantities available for the following subperiod under Regulation (EC) No 1529/2007

Origin/product	Order number	Allocation coefficient for the month of May 2009 subperiod	Total quantities available for the September 2009 subperiod (kg)
States forming part of the Cariforum region (Article 1(1)(b) of Regulation (EC) No 1529/2007) — CN codes 1006, except CN code 1006 10 10	09.4220	— ⁽²⁾	130 197 633
OCTs (Article 1(2)(a) and (b) of Regulation (EC) No 1529/2007) — CN code 1006			
(a) Netherlands Antilles and Aruba:	09.4189	— ⁽²⁾	21 500 000
(b) least-developed OCTs:	09.4190	— ⁽¹⁾	10 000 000

⁽¹⁾ Applications cover quantities less than or equal to the quantities available; all applications are therefore acceptable.

⁽²⁾ No allocation coefficient applied for this subperiod: no licence applications were sent to the Commission.

COMMISSION REGULATION (EC) No 424/2009**of 20 May 2009****fixing representative prices in the poultrymeat and egg sectors and for egg albumin, and amending
Regulation (EC) No 1484/95**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 143 thereof,

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

Whereas:

- (1) Commission Regulation (EC) No 1484/95 ⁽²⁾ lays down detailed rules for implementing the system of additional import duties and fixes representative prices for poultrymeat and egg products and for egg albumin.
- (2) Regular monitoring of the data used to determine representative prices for poultrymeat and egg products and

for egg albumin shows that the representative import prices for certain products should be amended to take account of variations in price according to origin. The representative prices should therefore be published.

- (3) In view of the situation on the market, this amendment should be applied as soon as possible.
- (4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 145, 29.6.1995, p. 47.

ANNEX

**to the Commission Regulation of 20 May 2009 fixing representative prices in the poultrymeat and egg sectors
and for egg albumin, and amending Regulation (EC) No 1484/95**

‘ANNEX I

CN code	Description of goods	Representative price (EUR/100 kg)	Security under Article 3(3) (EUR/100 kg)	Origin ⁽¹⁾
0207 12 10	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as “70 % chickens”, frozen	105,0	0	BR
		96,5	0	AR
0207 12 90	Fowls of the species <i>Gallus domesticus</i> , not cut in pieces, presented as “65 % chickens”, frozen	105,4	4	BR
		103,1	4	AR
0207 14 10	Fowls of the species <i>Gallus domesticus</i> , boneless cuts, frozen	205,3	28	BR
		207,1	28	AR
		263,5	11	CL
0207 14 50	Fowls of the species <i>Gallus domesticus</i> , breasts, frozen	189,6	7	BR
		146,3	20	AR
0207 14 60	Fowl of the species <i>Gallus domesticus</i> , legs, frozen	104,1	12	BR
		99,4	13	AR
0207 25 10	Turkeys, not cut in pieces, presented as “80 % turkeys”, frozen	223,4	0	BR
0207 27 10	Turkeys, boneless cuts, frozen	222,1	22	BR
		237,6	18	CL
0408 11 80	Egg yolks	368,7	0	AR
0408 91 80	Eggs, not in shell, dried	334,9	0	AR
1602 32 11	Preparations of fowls of the species <i>Gallus domesticus</i> , uncooked	262,1	7	BR
3502 11 90	Egg albumin, dried	601,4	0	AR

⁽¹⁾ Nomenclature of countries laid down by Commission Regulation (EC) No 1833/2006 (OJ L 354, 14.12.2006, p. 19). The code “ZZ” represents “other origins”.

COMMISSION REGULATION (EC) No 425/2009**of 20 May 2009****fixing the maximum buying-in price for butter for the 5th individual invitation to tender within the tendering procedure opened by Regulation (EC) No 186/2009**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 43, in conjunction with Article 4 thereof,

Whereas:

(1) Commission Regulation (EC) No 186/2009 ⁽²⁾ has opened buying-in of butter by a tendering procedure for the period expiring on 31 August 2009, in accordance with the conditions provided for in Commission Regulation (EC) No 105/2008 of 5 February 2008 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in butter ⁽³⁾.

(2) In the light of the tenders received in response to individual invitations to tender, a maximum buying-in price is to be fixed or a decision to make no award is to be

taken, in accordance with Article 16(2) of Regulation (EC) No 105/2008.

(3) In the light of the tenders received for the 5th individual invitation to tender, a maximum buying-in price should be fixed.

(4) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

For the 5th individual invitation to tender for the buying-in of butter within the tendering procedure opened by Regulation (EC) No 186/2009, in respect of which the time limit for the submission of tenders expired on 19 May 2009, the maximum buying-in price shall be EUR 220,00/100 kg.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 64, 10.3.2009, p. 3.

⁽³⁾ OJ L 32, 6.2.2008, p. 3.

COMMISSION REGULATION (EC) No 426/2009**of 20 May 2009****fixing the maximum buying-in price for skimmed milk powder for the 3rd individual invitation to tender within the tendering procedure opened by Regulation (EC) No 310/2009**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural markets and on specific provisions for certain agricultural products (Single CMO Regulation) ⁽¹⁾, and in particular Article 43, in conjunction with Article 4 thereof,

Whereas:

- (1) Commission Regulation (EC) No 310/2009 ⁽²⁾ has opened buying-in of skimmed milk powder by a tendering procedure for the period expiring on 31 August 2009, in accordance with the conditions provided for in Commission Regulation (EC) No 214/2001 of 12 January 2001 laying down detailed rules for the application of Council Regulation (EC) No 1255/1999 as regards intervention on the market in skimmed milk powder ⁽³⁾.
- (2) In the light of the tenders received in response to individual invitations to tender, a maximum buying-in price

is to be fixed or a decision to make no award is to be taken, in accordance with Article 17 of Regulation (EC) No 214/2001.

- (3) In the light of the tenders received for the 3rd individual invitation to tender, a maximum buying-in price should be fixed.
- (4) The Management Committee for the Common Organisation of Agricultural Markets has not delivered an opinion within the time limit set by its Chair,

HAS ADOPTED THIS REGULATION:

Article 1

For the 3rd individual invitation to tender for the buying-in of skimmed milk powder within the tendering procedure opened by Regulation (EC) No 310/2009, in respect of which the time limit for the submission of tenders expired on 19 May 2009, the maximum buying-in price shall be EUR 167,90/100 kg.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Jean-Luc DEMARTY

*Director-General for Agriculture and
Rural Development*

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 97, 16.4.2009, p. 13.

⁽³⁾ OJ L 37, 7.2.2001, p. 100.

COMMISSION REGULATION (EC) No 427/2009**of 20 May 2009****fixing the rates of the refunds applicable to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EC) No 1234/2007 of 22 October 2007 establishing a common organisation of agricultural market and on specific provisions for certain agricultural products (single CMO Regulation) ⁽¹⁾, and in particular Article 164(2) thereof,

Whereas:

(1) Article 162(1) b of Regulation (EC) No 1234/2007 provides that the difference between prices in international trade for the products referred to in Article 1(1) (s) and listed in Part XIX of Annex 1 to of that Regulation and prices within the Community may be covered by an export refund where these goods are exported in the form of goods listed Part V of the Annex XX to that Regulation.

(2) Commission Regulation (EC) No 1043/2005 of 30 June 2005 implementing Council Regulation (EC) No 3448/93 as regards the system of granting export refunds on certain agricultural products exported in the form of goods not covered by Annex I to the Treaty, and the criteria for fixing the amount of such refunds ⁽²⁾, specifies the products for which a rate of refund is to be fixed, to be applied where these products are exported in the form of goods listed in Part V of Annex XX to Regulation (EC) No 1234/2007.

(3) In accordance with paragraph 2 (b) of Article 14 of Regulation (EC) No 1043/2005, the rate of the refund per 100 kilograms for each of the basic products in question is to be fixed for a period of the same duration as that for which refunds are fixed for the same products exported unprocessed.

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

(5) The measures provided for in this Regulation are in accordance with the opinion of the Management Committee for the Common Organisation of Agricultural Markets,

HAS ADOPTED THIS REGULATION:

Article 1

The rates of the refunds applicable to the basic products listed in Annex I to Regulation (EC) No 1043/2005 and in Article 1(1)(s) of Regulation (EC) No 1234/2007, and exported in the form of goods listed in Part V of Annex XX to Regulation (EC) No 1234/2007, shall be fixed as set out in the Annex to this Regulation.

Article 2

This Regulation shall enter into force on 21 May 2009.

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

Done at Brussels, 20 May 2009.

For the Commission

Heinz ZOUREK

Director-General Enterprise and Industry

⁽¹⁾ OJ L 299, 16.11.2007, p. 1.

⁽²⁾ OJ L 172, 5.7.2005, p. 24.

ANNEX

Rates of the refunds applicable from 21 May 2009 to eggs and egg yolks exported in the form of goods not covered by Annex I to the Treaty

(EUR/100 kg)			
CN code	Description	Destination ⁽¹⁾	Rate of refund
0407 00	Birds' eggs, in shell, fresh, preserved or cooked:		
	– Of poultry:		
0407 00 30	– – Other:		
	(a) On exportation of ovalbumin of CN codes 3502 11 90 and 3502 19 90	02	0,00
		03	16,00
		04	0,00
	(b) On exportation of other goods	01	0,00
0408	Birds' eggs, not in shell and egg yolks, fresh, dried, cooked by steaming or by boiling in water, moulded, frozen or otherwise preserved, whether or not containing added sugar or other sweetening matter:		
	– Egg yolks:		
0408 11	– – Dried:		
ex 0408 11 80	– – – Suitable for human consumption:		
	not sweetened	01	56,48
0408 19	– – Other:		
	– – – Suitable for human consumption:		
ex 0408 19 81	– – – – Liquid:		
	not sweetened	01	28,35
ex 0408 19 89	– – – – Frozen:		
	not sweetened	01	28,35
	– Other:		
0408 91	– – Dried:		
ex 0408 91 80	– – – Suitable for human consumption:		
	not sweetened	01	35,78
0408 99	– – Other:		
ex 0408 99 80	– – – Suitable for human consumption:		
	not sweetened	01	9,00

⁽¹⁾ The destinations are as follows:

- 01 Third countries. For Switzerland and Liechtenstein these rates are not applicable to the goods listed in Tables I and II to Protocol No 2 to the Agreement between the European Community and the Swiss Confederation of 22 July 1972,
- 02 Kuwait, Bahrain, Oman, Qatar, United Arab Emirates, Yemen, Turkey, Hong Kong SAR and Russia,
- 03 South Korea, Japan, Malaysia, Thailand, Taiwan and the Philippines,
- 04 all destinations except Switzerland and those of 02 and 03.

DIRECTIVES

DIRECTIVE 2009/41/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 6 May 2009

on the contained use of genetically modified micro-organisms

(Recast)

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 175(1) thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Economic and Social Committee ⁽¹⁾,

Having consulted the Committee of the Regions,

Acting in accordance with the procedure laid down in Article 251 of the Treaty ⁽²⁾,

Whereas:

(1) Council Directive 90/269/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms ⁽³⁾ has been substantially amended several times ⁽⁴⁾. Since further amendments are to be made, it should be recast in the interests of clarity.

(2) Under the Treaty, action by the Community relating to the environment must be based on the principle that preventive action is to be taken and must have as its objective, among other things, the preservation, protection and improvement of the environment and the protection of human health.

(3) Measures concerning the evaluation and best use of biotechnology with regard to the environment are a priority area on which Community action should concentrate.

⁽¹⁾ OJ C 162, 25.6.2008, p. 85.

⁽²⁾ Opinion of the European Parliament of 21 October 2008 (not yet published in the Official Journal) and Council Decision of 30 March 2009.

⁽³⁾ OJ L 117, 8.5.1990, p. 1.

⁽⁴⁾ See Annex VI, Part A.

(4) The development of biotechnology is such as to contribute to the economic expansion of the Member States. This involves the use of genetically modified micro-organisms (GMMs) in operations of various types and scales.

(5) The contained use of GMMs should be such as to limit their possible negative consequences for human health and the environment, due attention being given to the prevention of accidents and the control of waste.

(6) GMMs which are disposed of without appropriate provisions for specific containment measures to limit their contact with the general population and the environment do not fall within the scope of this Directive. Other Community legislation such as Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms ⁽⁵⁾ may apply.

(7) Micro-organisms, if released into the environment in one Member State in the course of their contained use, may reproduce and spread, crossing national frontiers and thereby affecting other Member States.

(8) In order to bring about the safe development of biotechnology throughout the Community, it is necessary to establish common measures for the evaluation and reduction of the potential risks arising in the course of all operations involving the contained use of GMMs and to set appropriate conditions of use.

(9) The precise nature and scale of risks associated with the contained use of GMMs are not yet fully known and the risk involved must be assessed on a case-by-case basis. In order to evaluate the risk to human health and the environment, it is necessary to lay down requirements for risk assessment.

⁽⁵⁾ OJ L 106, 17.4.2001, p. 1.

- (10) Contained uses of GMMs should be classified in relation to the risks they present to human health and the environment. Such classification should be in line with international practice and based on an assessment of the risk.
- (11) In order to ensure a high level of protection, the containment and other protective measures applied to a contained use must correspond to the classification of the contained use. Where there is any uncertainty, the appropriate containment and other protective measures for the higher classification should be applied until less stringent measures are justified by appropriate data.
- (12) For all activities involving GMMs the principles of good microbiological practice and good occupational safety and hygiene should apply in accordance with relevant Community legislation.
- (13) Appropriate containment measures should be applied at the various stages of an operation to control emissions and the disposal of material from contained uses of GMMs, and to prevent accidents.
- (14) Any person, before undertaking for the first time the contained use of a GMM in a particular installation, should forward a notification to the competent authority so that the authority may satisfy itself that the proposed installation is appropriate for the purposes of carrying out the activity in a manner that does not present a hazard to human health and the environment.
- (15) It is also necessary to establish appropriate procedures for the case-by-case notification of specific operations involving the contained use of GMMs, taking account of the degree of risk involved.
- (16) In the case of operations involving high risk, the consent of the competent authority should be given.
- (17) The containment and other protective measures applied to contained uses should be reviewed periodically.
- (18) It may be considered appropriate to consult the public on the contained use of GMMs.
- (19) People employed in contained uses should be consulted in accordance with the requirements of relevant Community legislation, in particular Directive 2000/54/EC of the European Parliament and of the Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work (seventh individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) ⁽¹⁾.
- (20) Appropriate measures should be taken to inform any person liable to be affected by an accident on all matters relating to safety.
- (21) Emergency plans should be established to deal effectively with accidents.
- (22) If an accident occurs, the user should immediately inform the competent authority and communicate the information necessary for assessing the impact of that accident and for taking the appropriate action.
- (23) It is appropriate for the Commission, in consultation with the Member States, to establish a procedure for the exchange of information on accidents and for the Commission to set up a register of such accidents.
- (24) The contained use of GMMs throughout the Community should be monitored, and to this end Member States should supply certain information to the Commission.
- (25) In order to be considered safe for human health and the environment, GMMs should meet the list of criteria as defined in Annex II, Part B. To take account of the pace at which biotechnology is advancing, the nature of the criteria to be developed and the limited scope of that list, it is appropriate for the Council to revise those criteria, which should, where necessary, be supplemented by guidance notes to facilitate their application.
- (26) The measures necessary for the implementation of this Directive should be adopted in accordance with Council Decision 1999/468/EC of 28 June 1999 laying down the procedures for the exercise of implementing powers conferred on the Commission ⁽²⁾.
- (27) In particular, the Commission should be empowered to adopt the amendments necessary to adapt Annexes II, III, IV and V to technical progress, and to adapt Annex II, Part C. Since those measures are of general scope and are designed to amend non-essential elements of this Directive, they must be adopted in accordance with the regulatory procedure with scrutiny provided for in Article 5a of Decision 1999/468/EC.
- (28) The new elements introduced into this Directive concern only the committee procedures. They therefore do not need to be transposed by the Member States.
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- ⁽¹⁾ OJ L 262, 17.10.2000, p. 21.
⁽²⁾ OJ L 184, 17.7.1999, p. 23.

- (29) This Directive should be without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B,

HAVE ADOPTED THIS DIRECTIVE:

Article 1

This Directive lays down common measures for the contained use of genetically modified micro-organisms with a view to protecting human health and the environment.

Article 2

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

- (a) 'micro-organism' means any microbiological entity, cellular or non-cellular, capable of replication or of transferring genetic material, including viruses, viroids, and animal and plant cells in culture;
- (b) 'genetically modified micro-organism' (GMM) means a micro-organism in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination; within the terms of this definition:
 - (i) genetic modification occurs at least through the use of the techniques listed in Annex I, Part A;
 - (ii) the techniques listed in Annex I, Part B, are not considered to result in genetic modification;
- (c) 'contained use' means any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with, and to provide a high level of safety for, the general population and the environment;
- (d) 'accident' means any incident involving a significant and unintended release of GMMs in the course of their contained use which could present an immediate or delayed hazard to human health or the environment;
- (e) 'user' means any natural or legal person responsible for the contained use of GMMs;
- (f) 'notification' means the presentation of the requisite information to the competent authorities of a Member State.

Article 3

1. Without prejudice to Article 4(1), this Directive shall not apply:

- (a) where genetic modification is obtained through the use of the techniques/methods listed in Annex II, Part A; or
- (b) for contained uses involving only types of GMMs meeting the criteria listed in Annex II, Part B which establish their safety for human health and the environment. These types of GMMs shall be listed in Annex II, Part C.

2. Article 4(3) and (6) and Articles 5 to 11 shall not apply to the transport of GMMs by road, rail, inland waterway, sea or air.

3. This Directive shall not apply to the storage, culture, transport, destruction, disposal or use of GMMs which have been placed on the market in accordance with Directive 2001/18/EC or pursuant to other Community legislation which provides for a specific environmental risk assessment similar to that laid down in that Directive, provided that the contained use is in accordance with the conditions, if any, of the consent for placing on the market.

Article 4

1. Member States shall ensure that all appropriate measures are taken to avoid adverse effects on human health and the environment which might arise from the contained use of GMMs.

2. To that end, the user shall carry out an assessment of the contained uses as regards the risks to human health and the environment that those contained uses may pose, using as a minimum the elements of assessment and the procedure set out in Annex III, Sections A and B.

3. The assessment referred to in paragraph 2 shall result in the final classification of the contained uses in four classes applying the procedure set out in Annex III, which will result in the assignment of containment levels in accordance with Article 5:

Class 1: activities of no or negligible risk, that is to say activities for which level 1 containment is appropriate to protect human health and the environment.

Class 2: activities of low risk, that is to say activities for which level 2 containment is appropriate to protect human health and the environment.

Class 3: activities of moderate risk, that is to say activities for which level 3 containment is appropriate to protect human health and the environment.

Class 4: activities of high risk, that is to say activities for which level 4 containment is appropriate to protect human health and the environment.

4. Where there is doubt as to which class is appropriate for the proposed contained use, the more stringent protective measures shall be applied unless, by agreement with the competent authority, there is sufficient evidence to justify the application of less stringent measures.

5. The assessment referred to in paragraph 2 shall especially take into account the question of disposal of waste and effluents. Where appropriate, the safety measures needed in order to protect human health and the environment shall be implemented.

6. A record of the assessment referred to in paragraph 2 shall be kept by the user and made available in an appropriate form to the competent authority as part of the notification pursuant to Articles 6, 8 and 9 or on request.

Article 5

1. Save to the extent that point 2 of Annex IV allows other measures to be applied, the user shall apply the general principles and the appropriate containment and other protective measures set out in Annex IV corresponding to the class of the contained use, so as to keep workplace and environmental exposure to any GMMs to the lowest reasonably practicable level, and so that a high level of safety is ensured.

2. The assessment referred to in Article 4(2) and the containment and other protective measures applied shall be reviewed periodically, and forthwith if:

- (a) the containment measures applied are no longer adequate or the class assigned to the contained uses is no longer correct; or
- (b) there is reason to suspect that the assessment is no longer appropriate judged in the light of new scientific or technical knowledge.

Article 6

When premises are to be used for the first time for contained uses, the user shall be required, before commencing such use, to submit to the competent authorities a notification containing at least the information listed in Annex V, Part A.

Article 7

Following the notification referred to in Article 6, subsequent class 1 contained use may proceed without further notification. Users of GMMs in class 1 contained uses shall be required to keep the record of each assessment referred to in Article 4(6), which shall be made available to the competent authority on request.

Article 8

1. For first and subsequent class 2 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part B shall be submitted.

2. If the premises have been the subject of a previous notification to carry out class 2 or a higher class of contained uses and any associated consent requirements have been satisfied, the class 2 contained use may proceed immediately following the new notification.

However, the applicant may himself request from the competent authority a decision on the grant of a formal authorisation. The decision must be made within a maximum of 45 days from the notification.

3. If the premises have not been the subject of a previous notification to carry out class 2 or a higher class of contained uses, the class 2 contained use may, in the absence of any indication to the contrary from the competent authority, proceed 45 days after submission of the notification referred to in paragraph 1, or earlier with the agreement of the competent authority.

Article 9

1. For first and subsequent class 3 or class 4 contained uses to be carried out in premises notified in accordance with Article 6, a notification containing the information listed in Annex V, Part C shall be submitted.

2. A class 3 or higher class of contained use may not proceed without the prior consent of the competent authority, which shall communicate its decision in writing:

- (a) at the latest 45 days after submission of the new notification, in the case of premises which have been the subject of a previous notification to carry out class 3 or a higher class of contained uses and where any associated consent requirements have been satisfied for the same or a higher class than the contained use with which it is intended to proceed;

- (b) at the latest 90 days after submission of the notification, in other cases.

Article 10

1. Member States shall designate the authority or authorities competent to implement the measures which they adopt in application of this Directive and to receive and acknowledge the notifications referred to in Articles 6, 8 and 9.

2. The competent authorities shall examine the conformity of the notifications with the requirements of this Directive, the accuracy and completeness of the information given, the correctness of the assessment referred to in Article 4(2) and the class of contained uses and, where appropriate, the suitability of the containment and other protective measures, the waste management, and emergency response measures.

3. If necessary, the competent authority may:

- (a) ask the user to provide further information or to modify the conditions of the proposed contained use or to amend the class assigned to the contained use(s). In this case the competent authority may require that the contained use, if proposed, should not begin, or, if in progress, should be suspended or terminated, until the competent authority has given its approval on the basis of the further information obtained or of the modified conditions of the contained use;

- (b) limit the time for which the contained use should be permitted or subject it to certain specific conditions.

4. For the purpose of calculating the periods referred to in Articles 8 and 9, any period of time during which the competent authority:

- (a) is awaiting any further information which it may have requested from the notifier in accordance with point (a) of paragraph 3; or

- (b) is carrying out a public inquiry or consultation in accordance with Article 12;

shall not be taken into account.

Article 11

1. If the user becomes aware of relevant new information or modifies the contained use in a way which could have significant consequences in terms of the risks posed by it, the competent authority shall be informed as soon as possible and the notification pursuant to Articles 6, 8 and 9 shall be modified.

2. If information subsequently becomes available to the competent authority which could have significant consequences in terms of the risks posed by the contained use, the competent authority may require the user to modify the conditions of, or suspend or terminate, the contained use.

Article 12

Where a Member State considers it appropriate, it may provide that the public is to be consulted on aspects of the proposed contained use, without prejudice to Article 18.

Article 13

1. The competent authorities shall ensure that before a contained use commences:

- (a) an emergency plan is drawn up for contained uses where failure of the containment measures could lead to serious danger, whether immediate or delayed, to humans outside the premises and/or to the environment, except where such an emergency plan has been drawn up under other Community legislation;

- (b) information on such emergency plans, including the relevant safety measures to be applied, is supplied in an appropriate manner, and without their having to request it, to bodies and authorities liable to be affected by the accident. The information shall be updated at appropriate intervals. It shall also be made publicly available.

2. The Member States concerned shall at the same time make available to other Member States concerned, as a basis for all necessary consultation within the framework of their bilateral relations, the same information as that which is disseminated to their nationals.

Article 14

1. Member States shall take the necessary measures to ensure that, in the event of an accident, the user is required immediately to inform the competent authority specified in Article 10 and to provide the following information:

- (a) the circumstances of the accident;

- (b) the identity and quantities of the GMMs concerned;

- (c) any information necessary to assess the effects of the accident on the health of the general population and the environment;

- (d) the measures taken.

2. Where information is given pursuant to paragraph 1, the Member States shall be required to:

- (a) ensure that any measures necessary are taken, and immediately alert any Member States which could be affected by the accident;
- (b) collect, where possible, the information necessary for a full analysis of the accident and, where appropriate, make recommendations to avoid similar accidents in the future and to limit the effects thereof.

Article 15

1. Member States shall be required to:

- (a) consult with other Member States likely to be affected in the event of an accident on the proposed implementation of emergency plans;
- (b) inform the Commission as soon as possible of any accident within the scope of this Directive, giving details of the circumstances of the accident, the identity and quantities of the GMMs concerned, the response measures taken and their effectiveness and an analysis of the accident, including recommendations designed to limit its effects and to avoid similar accidents in the future.

2. The Commission, in consultation with the Member States, shall establish a procedure for the exchange of information pursuant to paragraph 1. It shall also set up and keep at the disposal of the Member States a register of accidents within the scope of this Directive, including an analysis of the causes of the accidents, experience gained and measures taken to avoid similar accidents in the future.

Article 16

Member States shall ensure that the competent authority organises inspections and other control measures to ensure that users comply with this Directive.

Article 17

1. Member States shall send to the Commission, at the end of each year, a summary report on class 3 and class 4 contained uses notified during that year pursuant to Article 9, including the description, purpose and risks of the contained use(s).

2. Every three years, and for the first time on 5 June 2003, Member States shall send the Commission a summary report on their experience with this Directive.

3. Every three years, and for the first time on 5 June 2004, the Commission shall publish a summary based on the reports referred to in paragraph 2.

4. The Commission may publish general statistical information on the implementation of this Directive and related matters, as long as it contains no information likely to cause harm to the competitive position of a user.

Article 18

1. Where its disclosure affects one or more of the items mentioned in Article 4(2) of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information⁽¹⁾, the notifier may indicate the information in the notifications submitted pursuant to this Directive that should be treated as confidential. Verifiable justification must be given in such cases.

The competent authority shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decision.

2. In no case may the following information, when submitted pursuant to Articles 6, 8 or 9, be kept confidential:

- (a) the general characteristics of the GMMs, the name and address of the notifier, and the location of use;
- (b) the class of contained use and the containment measures;
- (c) the evaluation of foreseeable effects, in particular any harmful effects on human health and the environment.

3. The Commission and the competent authorities shall not divulge to third parties any information deemed to be confidential according to the second subparagraph of paragraph 1 and notified or otherwise provided pursuant to this Directive, and shall protect intellectual property rights relating to the data received.

4. If, for whatever reasons, the notifier withdraws the notification, the competent authority must respect the confidentiality of the information supplied.

Article 19

The measures designed to amend non-essential elements of this Directive relating to adapting Annexes II, III, IV and V to technical progress, and to adapting Annex II, Part C, shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 20(2).

⁽¹⁾ OJ L 41, 14.2.2003, p. 26.

Article 20

1. The Commission shall be assisted by a committee.
2. Where reference is made to this paragraph, Article 5a(1) to (4) and Article 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.
3. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

Article 21

Directive 90/219/EEC, as amended by the acts listed in Annex VI, Part A, is repealed, without prejudice to the obligations of the Member States relating to the time limits for transposition into national law of the Directives set out in Annex VI, Part B.

References to the repealed Directive shall be construed as references to this Directive and shall be read in accordance with the correlation table in Annex VII.

Article 22

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

Article 23

This Directive is addressed to the Member States.

Done at Strasbourg, 6 May 2009.

For the European Parliament
The President
H.-G. PÖTTERING

For the Council
The President
J. KOHOUT

ANNEX I

PART A

Techniques of genetic modification referred to in point (b)(i) of Article 2 are, inter alia:

1. Recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.
2. Techniques involving the direct introduction into a micro-organism of heritable material prepared outside the micro-organism, including micro-injection, macro-injection and micro-encapsulation.
3. Cell fusion or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally.

PART B

Techniques referred to in point (b)(ii) of Article 2 which are not considered to result in genetic modification, on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs made by techniques/methods other than the techniques/methods excluded by Part A of Annex II:

1. *in vitro* fertilisation;
 2. natural processes such as: conjugation, transduction, transformation;
 3. polyploidy induction.
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ANNEX II

PART A

Techniques or methods of genetic modification yielding micro-organisms to be excluded from this Directive on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below:

1. Mutagenesis.
2. Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material by known physiological processes.
3. Cell fusion (including protoplast fusion) of cells of any eukaryotic species, including production of hybridomas and plant cell fusions.
4. Self-cloning consisting in the removal of nucleic acid sequences from a cell of an organism which may or may not be followed by reinsertion of all or part of that nucleic acid (or a synthetic equivalent), with or without prior enzymic or mechanical steps, into cells of the same species or into cells of phylogenetically closely related species which can exchange genetic material by natural physiological processes where the resulting micro-organism is unlikely to cause disease to humans, animals or plants.

Self-cloning may include the use of recombinant vectors with an extended history of safe use in the particular micro-organisms.

PART B

Criteria establishing the safety of GMMs for human health and the environment

This Annex describes in general terms the criteria to be met when establishing the safety of types of GMMs for human health and the environment and their suitability for inclusion in Part C. Technical guidance notes may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex.

1. Introduction

Types of GMMs listed in Part C in accordance with the regulatory procedure with scrutiny referred to in Article 20(2) are excluded from the scope of this Directive. GMMs will be added to the list on a case-by-case basis and exclusion will relate only to each clearly identified GMM. This exclusion applies only when the GMM is used under conditions of contained use as defined in point (c) of Article 2. It does not apply to the deliberate release of GMMs. For a GMM to be listed in Part C, it must be proved that it meets the criteria given below.

2. General criteria**2.1. Strain verification/authentication**

Identity of the strain must be precisely established. Modification must be known and verified.

2.2. Documented and established evidence of safety

Documented evidence of the safety of the organism must be provided.

2.3. Genetic stability

Where any instability could adversely affect safety, evidence of stability is required.

3. Specific criteria**3.1. Non-pathogenic**

The GMM should not be capable of causing disease or harm to a healthy human, plant or animal. Since pathogenicity includes both toxigenicity and allergenicity, the GMM should therefore be:

3.1.1. Non-toxicogenic

The GMM should not produce increased toxigenicity as a result of the genetic modification nor be noted for its toxigenic properties.

3.1.2. Non-allergenic

The GMM should not produce increased allergenicity as a result of the genetic modification nor be a noted allergen, having, for example, allergenicity comparable in particular with that of the micro-organisms identified in Directive 2000/54/EC.

3.2. No harmful adventitious agents

The GMM should not harbour known harmful adventitious agents such as other micro-organisms, active or latent, existing alongside or inside the GMM, that could cause harm to human health and the environment.

3.3. Transfer of genetic material

The modified genetic material must not give rise to harm if transferred; nor should it be self-transmissible or transferable at a frequency greater than other genes of the recipient or parental micro-organism.

3.4. Safety for the environment in the event of a significant and unintended release

GMMs must not produce adverse effects on the environment, immediate or delayed, should any incident involving a significant and unintended release occur.

GMMs that do not meet the above criteria may not be included in Part C.

PART C

Types of GMMs which meet the criteria listed in Part B:

... (to be completed in accordance with the regulatory procedure with scrutiny referred to in Article 20(2))

ANNEX III

Principles to be followed for the assessment referred to in Article 4(2)

This Annex describes in general terms the elements to be considered and the procedure to be followed to perform the assessment referred to in Article 4(2). Technical guidance notes ⁽¹⁾ may be developed in accordance with the regulatory procedure referred to in Article 20(3) in order to facilitate the implementation and explanation of this Annex, in particular as regards Section B.

A. Elements of assessment

1. The following should be considered as potentially harmful effects:
 - disease to humans, including allergenic or toxic effects,
 - disease to animals or plants,
 - deleterious effects due to the impossibility of treating a disease or providing an effective prophylaxis,
 - deleterious effects due to establishment or dissemination in the environment,
 - deleterious effects due to the natural transfer of inserted genetic material to other organisms.
2. The assessment referred to in Article 4(2) should be based on the following:
 - (a) the identification of any potentially harmful effects, in particular those associated with:
 - (i) the recipient micro-organism;
 - (ii) the genetic material inserted (originating from the donor organism);
 - (iii) the vector;
 - (iv) the donor micro-organism (as long as the donor micro-organism is used during the operation);
 - (v) the resulting GMM;
 - (b) the characteristics of the activity;
 - (c) the severity of the potentially harmful effects;
 - (d) the likelihood of the potentially harmful effects being realised.

B. Procedure

3. The first stage in the assessment process should be to identify the harmful properties of the recipient and, where appropriate, the donor micro-organism, and any harmful properties associated with the vector or inserted material, including any alteration in the recipient's existing properties.
4. In general, only GMMs which show the following characteristics would be considered appropriate for inclusion in class 1 as defined in Article 4(3):
 - (i) the recipient or parental micro-organism is unlikely to cause disease to humans, animals or plants ⁽²⁾;
 - (ii) the nature of the vector and the insert is such that they do not endow the GMM with a phenotype likely to cause disease to humans, animals or plants ⁽²⁾, or likely to have deleterious effects on the environment;
 - (iii) the GMM is unlikely to cause disease to humans, animals or plants ⁽²⁾ and is unlikely to have deleterious effects on the environment.

⁽¹⁾ See Commission Decision 2000/608/EC of 27 September 2000 concerning the guidance notes for risk assessment outlined in Annex III to Directive 90/219/EEC on the contained use of genetically modified micro-organisms (OJ L 258, 12.10.2000, p. 43).

⁽²⁾ This would only apply to animals and plants in the environment likely to be exposed.

5. In order to obtain the necessary information to implement this process the user may firstly take into account relevant Community legislation (in particular Directive 2000/54/EC). International or national classification schemes (e.g. World Health Organisation, National Institutes of Health) and their revisions due to new scientific knowledge and technical progress may also be considered.

These schemes concern natural micro-organisms and as such are usually based on the ability of micro-organisms to cause disease to humans, animals or plants and on the severity and transmissibility of the disease likely to be caused. Directive 2000/54/EC classifies micro-organisms, as biological agents, into four classes of risk on the basis of potential effects on a healthy human adult. These classes of risk can be used as guidance for the purposes of categorisation of the contained use activities in the four classes of risk referred to in Article 4(3). The user may also take into consideration classification schemes referring to plant and animal pathogens (which are usually established on a national basis). The abovementioned classification schemes give only a provisional indication of the risk class of the activity and the corresponding set of containment and control measures.

6. The hazard identification process carried out in accordance with points 3 to 5 should lead to the identification of the level of risk associated with the GMM.
7. Selection of the containment and other protective measures should then be made on the basis of the level of risk associated with the GMMs together with consideration of:
- (i) the characteristics of the environment likely to be exposed (e.g. whether in the environment likely to be exposed to the GMMs there are known biota which can be adversely affected by the micro-organisms used in the contained use activity);
 - (ii) the characteristics of the activity (e.g. its scale and/or nature);
 - (iii) any non-standard operations (e.g. the inoculation of animals with GMMs; use of equipment likely to generate aerosols).

Consideration of items (i) to (iii) for the particular activity may increase, reduce or leave unaltered the level of risk associated with the GMM as identified under point 6.

8. The analysis carried out as described above will finally lead to the assignment of the activity to one of the classes described in Article 4(3).
9. The final classification of the contained use should be confirmed by reviewing the completed assessment referred to in Article 4(2).
-

ANNEX IV

CONTAINMENT AND OTHER PROTECTIVE MEASURES**General principles**

1. These tables present the normal minimum requirements and measures necessary for each level of containment.

Containment is also achieved through the use of good work practices, training, containment equipment and special installation design. For all activities involving GMMs the principles of good microbiological practice and the following principles of good occupational safety and hygiene shall apply:

- (i) to keep workplace and environmental exposure to any GMM to the lowest practicable level;
- (ii) to exercise engineering control measures at source and to supplement these with appropriate personal protective clothing and equipment when necessary;
- (iii) to test adequately and maintain control measures and equipment;
- (iv) to test, when necessary, for the presence of viable process organisms outside the primary physical containment;
- (v) to provide appropriate training of personnel;
- (vi) to establish biological safety committees or subcommittees, if required;
- (vii) to formulate and implement local codes of practice for the safety of personnel, as required;
- (viii) where appropriate, to display biohazard signs;
- (ix) to provide washing and decontamination facilities for personnel;
- (x) to keep adequate records;
- (xi) to prohibit eating, drinking, smoking, applying cosmetics or the storing of food for human consumption in the work area;
- (xii) to prohibit mouth pipetting;
- (xiii) to provide written standard operating procedures where appropriate to ensure safety;
- (xiv) to have effective disinfectants and specified disinfection procedures available in case of spillage of GMMs;
- (xv) to provide safe storage for contaminated laboratory equipment and materials, when appropriate.

2. The titles of the tables are indicative:

Table I A presents minimum requirements for laboratory activities.

Table I B presents additions to and modifications of Table I A for glasshouse/growth-room activities involving GMMs.

Table I C presents additions to and modifications of Table I A for activities with animals involving GMMs.

Table II presents minimum requirements for activities other than laboratory activities.

In some particular cases, it might be necessary to apply a combination of measures, from Table I A and Table II, of the same level.

In some cases users may, with the agreement of the competent authority, not apply a specification under a particular containment level or combine specifications from two different levels.

In these tables 'optional' means that the user may apply these measures on a case-by-case basis, subject to the assessment referred to in Article 4(2).

3. In implementing this Annex, Member States may in addition incorporate in the following tables the general principles set out in points 1 and 2, with a view to clarifying the requirements.

Table I A

Containment and other protective measures for laboratory activities

Specifications		Containment levels			
		1	2	3	4
1	Laboratory suite: isolation ⁽¹⁾	Not required	Not required	Required	Required
2	Laboratory: sealable for fumigation	Not required	Not required	Required	Required

Equipment

3	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench)	Required (bench)	Required (bench, floor)	Required (bench, floor, ceiling, walls)
4	Entry to lab via airlock ⁽²⁾	Not required	Not required	Optional	Required
5	Negative pressure relative to the pressure of the immediate environment	Not required	Not required	Required except for ⁽³⁾	Required
6	Extract and input air from the laboratory should be HEPA ⁽⁴⁾ -filtered	Not required	Not required	Required (HEPA — extract air except for ⁽³⁾)	Required (HEPA — input and extract air ⁽³⁾)
7	Microbiological safety post	Not required	Optional	Required	Required
8	Autoclave	On site	In the building	En suite ⁽⁶⁾	In lab = double-ended

System of work

9	Restricted access	Not required	Required	Required	Required
10	Biohazard sign on the door	Not required	Required	Required	Required
11	Specific measures to control aerosol dissemination	Not required	Required minimise	Required prevent	Required prevent
13	Shower	Not required	Not required	Optional	Required
14	Protective clothing	Suitable protective clothing	Suitable protective clothing	Suitable protective clothing and (optional) footwear	Complete change of clothing and footwear before entry and exit

Specifications		Containment levels			
		1	2	3	4
15	Gloves	Not required	Optional	Required	Required
18	Efficient vector control (e.g. for rodents and insects)	Optional	Required	Required	Required

Waste

19	Inactivation of GMMs in effluent from hand-washing sinks or drains and showers and similar effluents	Not required	Not required	Optional	Required
20	Inactivation of GMMs in contaminated material and waste	Optional	Required	Required	Required

Other measures

21	Laboratory to contain its own equipment	Not required	Not required	Optional	Required
23	An observation window or alternative is to be present so that occupants can be seen	Optional	Optional	Optional	Required

(1) Isolation = the laboratory is separated from other areas in the same building or is in a separate building.

(2) Airlock = entry must be through an airlock which is a chamber isolated from the laboratory. The clean side of the airlock must be separated from the restricted side by changing or showering facilities and preferably by interlocking doors.

(3) Activities where transmission does not occur via airborne route.

(4) HEPA = High efficiency particulate air.

(5) Where viruses which are not retained by HEPA filters are used, extra requirements will be necessary for extract air.

(6) With validated procedures, allowing the safe transfer of material into an autoclave outside the lab, and providing an equivalent level of protection.

Table I B

Containment and other protective measures for glasshouses and growth-rooms

The terms 'glasshouse' and 'growth-room' refer to a structure with walls, a roof and a floor designed and used principally for growing plants in a controlled and protected environment.

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Building					
1	Glasshouse: permanent structure ⁽¹⁾	Not required	Required	Required	Required
Equipment					
3	Entry via a separate room with two interlocking doors	Not required	Optional	Optional	Required
4	Control of contaminated run-off water	Optional	Minimise ⁽²⁾ run-off	Prevent run-off	Prevent run-off

Specifications		Containment levels			
		1	2	3	4
System of work					
6	Measures to control undesired species such as insects, rodents, arthropods	Required	Required	Required	Required
7	Procedures for transfer of living material between the glasshouse/growth-room, protective structure and laboratory shall control dissemination of GMMs	Minimise dissemination	Minimise dissemination	Prevent dissemination	Prevent dissemination

(¹) The glasshouse shall consist of a permanent structure with a continuous waterproof covering, located on a site graded to prevent entry of surface-water run-off, and with self-closing lockable doors.

(²) Where transmission can occur through the ground.

Table I C

Containment and other protective measures for activities in animal units

All provisions of Table I A shall apply with the following additions/modifications:

Specifications		Containment levels			
		1	2	3	4
Facilities					
1	Isolation of animal unit ⁽¹⁾	Optional	Required	Required	Required
2	Animal facilities ⁽²⁾ separated by lockable doors	Optional	Required	Required	Required
3	Animal facilities designed to facilitate decontamination (waterproof and easily washable material (cages, etc.))	Optional	Optional	Required	Required
4	Floor and/or walls easily washable	Optional	Required (floor)	Required (floor and walls)	Required (floor and walls)
5	Animals kept in appropriate containment facilities such as cages, pens or tanks	Optional	Optional	Optional	Optional
6	Filters on isolators or isolated room ⁽³⁾	Not required	Optional	Required	Required

(¹) Animal unit: a building or separate area within a building containing facilities and other areas such as changing rooms, showers, autoclaves, food storage areas, etc.

(²) Animal facility: a facility normally used to house stock, breeding or experimental animals or one which is used for the performance of minor surgical procedures.

(³) Isolators: transparent boxes where small animals are contained within or outside a cage; for large animals, isolated rooms may be more appropriate.

Table II

Containment and other protective measures for other activities

Specifications		Containment levels			
		1	2	3	4
General					
1	Viable micro-organisms should be contained in a system which separates the process from the environment (closed system)	Optional	Required	Required	Required
2	Control of exhaust gases from the closed system	Not required	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
3	Control of aerosols during sample collection, addition of material to a closed system or transfer of material to another closed system	Optional	Required, minimise dissemination	Required, prevent dissemination	Required, prevent dissemination
4	Inactivation of bulk culture fluids before removal from the closed system	Optional	Required, by validated means	Required, by validated means	Required, by validated means
5	Seals should be designed so as to minimise or prevent release	No specific requirement	Minimise dissemination	Prevent dissemination	Prevent dissemination
6	The controlled area should be designed to contain spillage of the entire contents of the closed system	Optional	Optional	Required	Required
7	The controlled area should be sealable to permit fumigation	Not required	Optional	Optional	Required
Equipment					
8	Entry via airlock	Not required	Not required	Optional	Required
9	Surfaces resistant to water, acids, alkalis, solvents, disinfectants and decontamination agents, and easy to clean	Required (bench if any)	Required (bench if any)	Required (bench if any, floor)	Required (bench, floor, ceiling, walls)
10	Specific measures to adequately ventilate the controlled area in order to minimise air contamination	Optional	Optional	Optional	Required
11	The controlled area should be maintained at an air pressure negative to the immediate surroundings	Not required	Not required	Optional	Required

Specifications		Containment levels			
		1	2	3	4
12	Extract and input air from the controlled area should be HEPA filtered	Not required	Not required	Required (extract air, optional for input air)	Required (input and extract air)

System of work

13	Closed systems should be located within a controlled area	Not required	Optional	Required	Required
14	Access should be restricted to nominated personnel only	Not required	Required	Required	Required
15	Biohazard signs should be posted	Not required	Required	Required	Required
17	Personnel should shower before leaving the controlled area	Not required	Not required	Optional	Required
18	Personnel should wear protective clothing	Required (work clothing)	Required (work clothing)	Required	Complete change before exit and entry

Waste

22	Inactivation of GMMs in effluent from hand-washing sinks and showers or similar effluents	Not required	Not required	Optional	Required
23	Inactivation of GMMs in contaminated material and waste, including those in process effluent before final discharge	Optional	Required, by validated means	Required, by validated means	Required, by validated means

ANNEX V

Information required for the notification referred to in Articles 6, 8 and 9

PART A

Information required for the notification referred to in Article 6:

- name of user(s), including those responsible for supervision and safety,
- information on the training and qualifications of the persons responsible for supervision and safety,
- details of any biological committees or subcommittees,
- address and general description of the premises,
- a description of the nature of the work which will be undertaken,
- the class of the contained uses,
- only for class 1 contained uses, a summary of the assessment referred to in Article 4(2) and information on waste management.

PART B

Information required for the notification referred to in Article 8:

- the date of submission of the notification referred to in Article 6,
- the names of the persons responsible for supervision and safety and information on their training and qualification,
- the recipient, donor and/or parental micro-organism(s) used and, where applicable, the host-vector system(s) used,
- the source(s) and the intended function(s) of the genetic material(s) involved in the modification(s),
- the identity and characteristics of the GMM,
- the purpose of the contained use, including the expected results,
- the approximate culture volumes to be used,
- a description of the containment and other protective measures to be applied, including information about waste management, including the wastes to be generated, their treatment, final form and destination,
- a summary of the assessment referred to in Article 4(2),
- the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1).

PART C

Information required for the notification referred to in Article 9:

- (a) — the date of submission of the notification referred to in Article 6,
 - the names of the persons responsible for supervision and safety and information on their training and qualification;
- (b) — the recipient or parental micro-organism(s) to be used,
 - the host-vector system(s) to be used (where applicable),
 - the source(s) and intended function(s) of the genetic material(s) involved in the modification(s),

- the identity and characteristics of the GMM,
 - the culture volumes to be used;
 - (c) — a description of the containment and other protective measures to be applied, including information about waste management, including the type and form of wastes to be generated, their treatment, final form and destination,
 - the purpose of the contained use, including the expected results,
 - a description of the parts of the installation;
 - (d) information about accident prevention and emergency response plans, if any:
 - any specific hazards arising from the location of the installation,
 - the preventive measures applied, such as safety equipment, alarm systems and containment methods,
 - the procedures and plans for verifying the continuing effectiveness of the containment measures,
 - a description of information provided to workers,
 - the information necessary for the competent authority to evaluate any emergency response plans, if required under Article 13(1);
 - (e) a copy of the assessment referred to in Article 4(2).
-

ANNEX VI

PART A

Repealed Directive with list of its successive amendments

(referred to in Article 21)

Council Directive 90/219/EEC
(OJ L 117, 8.5.1990, p. 1)

Commission Directive 94/51/EC
(OJ L 297, 18.11.1994, p. 29)

Council Directive 98/81/EC
(OJ L 330, 5.12.1998, p. 13)

Council Decision 2001/204/EC
(OJ L 73, 15.3.2001, p. 32)

Regulation (EC) No 1882/2003 of the
European Parliament and of the Council
(OJ L 284, 31.10.2003, p. 1)

Annex III, point 19, only

PART B

Time limits for transposition into national law

(referred to in Article 21)

Directive	Time limit for transposition
90/219/EEC	23 October 1991
94/51/EC	30 April 1995
98/81/EC	5 June 2000

ANNEX VII

CORRELATION TABLE

Directive 90/219/EEC	This Directive
Article 1	Article 1
Article 2	Article 2
Article 3, introductory wording	Article 3(1), introductory wording
Article 3, first indent	Article 3(1), point (a)
Article 3, second indent	Article 3(1), point (b)
Article 4, first paragraph	Article 3(2)
Article 4, second paragraph	Article 3(3)
Article 5	Article 4
Article 6	Article 5
Article 7	Article 6
Article 8	Article 7
Article 9	Article 8
Article 10	Article 9
Article 11(1), (2) and (3)	Article 10(1), (2) and (3)
Article 11(4), introductory wording	Article 10(4), introductory wording
Article 11(4), first indent	Article 10(4), point (a)
Article 11(4), second indent	Article 10(4), point (b)
Article 12, first paragraph	Article 11(1)
Article 12, second paragraph	Article 11(2)
Article 13	Article 12
Article 14, first paragraph	Article 13(1)
Article 14, second paragraph	Article 13(2)
Article 15(1), introductory wording	Article 14(1), introductory wording
Article 15(1), first indent	Article 14(1), point (a)
Article 15(1), second indent	Article 14(1), point (b)
Article 15(1), third indent	Article 14(1), point (c)
Article 15(1), fourth indent	Article 14(1), point (d)
Article 15(2), introductory wording	Article 14(2), introductory wording
Article 15(2), first indent	Article 14(2), point (a)
Article 15(2), second indent	Article 14(2), point (b)
Article 16	Article 15
Article 17	Article 16
Article 18	Article 17
Article 19(1)	Article 18(1), first subparagraph
Article 19(2)	Article 18(1), second subparagraph
Article 19(3), introductory wording	Article 18(2), introductory wording
Article 19(3), first indent	Article 18(2), point (a)
Article 19(3), second indent	Article 18(2), point (b)
Article 19(3), third indent	Article 18(2), point (c)
Article 19(4)	Article 18(3)
Article 19(5)	Article 18(4)
Article 20	Article 19

Directive 90/219/EEC	This Directive
Article 20a	—
Article 21(1)	Article 20(1)
Article 21(2), first subparagraph	Article 20(2) and (3), first subparagraph
Article 21(2), second subparagraph	Article 20(3), second subparagraph
Article 21(3)	—
Article 22	—
—	Article 21
—	Article 22
Article 23	Article 23
Annexes I-V	Annexes I-V
—	Annex VI
—	Annex VII

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