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**COMMISSION REGULATION (EC) No 2076/2005**

**of 5 December 2005**

**laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004**

(Text with EEA relevance)

(OJ L 338, 22.12.2005, p. 83)

Amended by:

		Official Journal		
		No	page	date
► <b><u>M1</u></b>	Commission Regulation (EC) No 1666/2006 of 6 November 2006	L 320	47	18.11.2006
► <b><u>M2</u></b>	Commission Regulation (EC) No 479/2007 of 27 April 2007	L 111	46	28.4.2007
► <b><u>M3</u></b>	Commission Regulation (EC) No 1246/2007 of 24 October 2007	L 281	21	25.10.2007

**COMMISSION REGULATION (EC) No 2076/2005****of 5 December 2005****laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004****(Text with EEA relevance)**

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to 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 <sup>(1)</sup>, and in particular Article 9 thereof,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption <sup>(2)</sup>, and in particular Article 16 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules <sup>(3)</sup>, and in particular Article 63(1) thereof,

Whereas:

- (1) The entry into application on 1 January 2006 of Regulations (EC) No 852/2004 of the European Parliament and of the Council <sup>(4)</sup>, (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 will entail considerable changes to the rules and procedures to be followed by food operators and the competent authorities of the Member States. The application of some of these measures with immediate effect from 1 January 2006 would present practical difficulties in some cases. A period should therefore be envisaged in order to permit a smooth transition to the full implementation of the new rules and procedures.
- (2) It is appropriate that the duration of the transitional period be fixed taking into account a first review of the new regulatory framework on hygiene scheduled within the first four years.
- (3) Provision should therefore be made for a transitional period during which certain requirements laid down in those Regulations can be progressively implemented. With a view to a harmonised approach, that transitional period should in principle last four years but could, where justified, be shorter. Provision should also be made for the possibility of reviewing any of those arrangements in the light of experience gained.
- (4) As a standard transitional arrangement, it should continue to be possible to place on the market products produced before the application of the new rules. The arrangement should apply for the whole of the transitional period, unless the shelf-life of the product is shorter.

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(3)</sup> OJ L 165, 30.4.2004, p. 1, corrected by OJ L 191, 28.5.2004, p. 1

<sup>(4)</sup> OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

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- (5) Regulation (EC) No 853/2004 excludes from its scope the direct supply by the producer of small quantities of meat from poultry and lagomorphs to the final consumer or to local retail establishments supplying directly the final consumer as fresh meat. Council Directive 71/118/EEC of 15 February 1971 <sup>(1)</sup> on health problems affecting the production and placing on the market of fresh poultrymeat and Council Directive 91/495/EEC of 27 November 1991 <sup>(2)</sup> concerning public health and animal health problems affecting the production and placing on the market of rabbit meat and farmed game meat also allowed the Member States to derogate from the general requirements for such a purpose without limiting it to fresh meat. That possibility should be maintained during the transitional period.
- (6) The work of approving establishments, in particular those that did not have to be approved under the previously applicable rules but were allowed to market their production on their national market only, places a heavy burden on the competent authorities. Provision should therefore be made for a transitional arrangement to allow such establishments to continue marketing on their national markets until they are actually approved.
- (7) The transitional arrangement covering the use of wrapping and packaging materials and marking equipment in point 6 of Section I of Annex II to Regulation (EC) No 853/2004 needs to be reviewed in order to tighten up the previous rules on the use of marking equipment while giving due consideration to the expectations of food business operators concerning the tolerance regarding the use of marking material purchased prior to the implementation of the new framework. The relevant provisions of that Regulation should therefore be deleted and a new arrangement adopted under this Regulation. Given the risk of abuse of such a transitional arrangement, its duration should be limited and care taken to ensure that old marking equipment not complying with the new rules is withdrawn as soon as possible and not later than the end of the transitional period. Annex II to Regulation (EC) No 853/2004 and Annex I to Regulation (EC) No 854/2004 should be amended accordingly.
- (8) The health import requirements for food of animal origin will not be completely harmonised for certain types of products and the import conditions applicable to such products during the transitional period should be made clear.
- (9) The provision of food chain information is a new requirement on food business operators. A transitional period should be introduced for the full implementation of food chain information requirements. In particular, a smooth flow of information from the farm to the slaughterhouse should be facilitated by a transitional arrangement relaxing the requirement to supply the information 24 hours in advance of the animals' arrival at the slaughterhouse.
- (10) Section III of Annex III to Regulation (EC) No 853/2004 requires the official veterinarian or approved veterinarian to sign the certificate accompanying the farmed non domestic ungulates from the farm to the slaughterhouse. Directive 91/495/EEC requires the signature of the veterinary service. That provision should be maintained during the transitional period.
- (11) The certificate required by Regulation (EC) No 854/2004 in Chapter X Part B of Annex I is more detailed than the certificate previously prescribed. The model certificate set out in Annex III to Directive 91/495/EEC should be accepted during the transitional period.

<sup>(1)</sup> OJ L 55, 8.3.1971, p. 23.

<sup>(2)</sup> OJ L 268, 24.9.1991, p. 41.

**▼B**

- (12) Section V of Annex III to Regulation (EC) No 853/2004 requires the raw material for minced meat to meet certain criteria and lays down labelling requirements. Composition criteria of minced meat regarding in particular the content of fat and the connective tissue: meat protein ratio should be assessed. Pending the outcome of this assessment, it is appropriate to maintain current criteria established by Council Directive 94/65/EC of 14 December 1994 <sup>(1)</sup> laying down the requirements for the production and placing on the market of minced meat and meat preparations.
- (13) Notwithstanding the general principle laid down in Article 3(2) of Regulation (EC) No 853/2004 whereby food business operators are not to use, where hygiene so requires, any substance other than potable water, provisions allowing the use of clean water for the handling of fish are set out in Chapter VII of Annex II to Regulation (EC) No 852/2004 and Part II of Chapter I and Chapters III and IV of Section VIII of Annex III to Regulation (EC) No 853/2004, in particular for handling fish on board vessels. Since the use of clean water does not represent a risk for public health as long as it meets the definition laid down in Regulation (EC) No 852/2004, and with a view to allowing land-based establishments handling fishery products to adapt progressively, the scope of the relevant provisions in Regulation (EC) No 853/2004 should be extended to such establishments during the transitional period.
- (14) Part III(1)(a) of Chapter II of Section IX of Annex III to Regulation (EC) No 853/2004 provides that food business operators manufacturing dairy products must ensure that raw cows' milk meets a limit criterion before processing. Compliance with that limit is particularly important for food safety where the milk has to be heat-treated and has not been processed within a pre-defined time. By way of a transitional measure, verification of compliance with this criterion immediately before processing should be limited to such circumstances.
- (15) Section X of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for eggs and egg products. According to Chapter I(2), eggs should be stored and transported at a constant temperature that is best suited to ensuring optimal conservation of their hygiene properties. As before 1 January 2006 Member States were authorised to apply controlled temperature standards within their territory to egg storage facilities and to transport from one facility to another, it should be made clear that those standards may continue to apply on a transitional basis if still authorised by the competent authority. This will give operators time to adapt their activities and procedures to new temperature standards that may be required by the competent authority.
- (16) Under Part II(1) of Chapter II of Section X of Annex III to Regulation (EC) No 853/2004, cracked eggs may be used for the manufacture of egg products under certain conditions. As a transitional arrangement, provision should be made to extend this possibility to other establishments producing liquid egg, where they comply with the same conditions.
- (17) Regulation (EC) No 854/2004 requires the slaughterhouse staff authorised by the competent authority to carry out tasks of official auxiliaries to be trained and qualified in the same way as the official auxiliaries. During the transitional period, it is appropriate to allow the competent authority time for planning and organising additional training and qualification of slaughterhouse staff assisting with official controls, and to limit conse-

<sup>(1)</sup> OJ L 368, 31.12.1994, p. 10.

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quently the requirement to ensuring that slaughterhouse staff is trained for the specific tasks they are allowed to carry out.

- (18) Article 12 of Regulation (EC) No 882/2004 requires laboratories carrying out analysis of samples taken during official controls to be accredited. Laboratories, which were not required under previous Community legislation to be accredited, might require some additional time to obtain full accreditation, since accreditation is an intricate and laborious process. It is appropriate to give to such laboratories additional time to enable them to arrange for accreditation.
- (19) 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:

CHAPTER I  
**GENERAL PROVISION**

*Article 1*

**Transitional period**

For the purposes of this Regulation, a transitional period of four years ending on 31 December 2009 (hereinafter referred to as the transitional period) is established.

The transitional arrangements provided for in this Regulation shall apply for the transitional period, except where otherwise provided for in Articles 5 and 8.

CHAPTER II  
**TRANSITIONAL ARRANGEMENTS FOR THE  
IMPLEMENTATION OF REGULATION (EC) No 853/2004**

*Article 2*

**Stocks of food of animal origin**

1. Without prejudice to relevant Community legislation, and in particular Directive 2000/13/EC of the European Parliament and of the Council<sup>(1)</sup> on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of food-stuffs, stocks of food of animal origin produced before 1 January 2006 may be placed on the market provided that they bear, as appropriate, the marks provided for in the Acts listed in Article 2 of Directive 2004/41/EC of the European Parliament and of the Council<sup>(2)</sup>.

2. Products referred to in paragraph 1, for which the food business operator has defined a shelf-life longer than the transitional period, may remain on the market until the end of their shelf-life.

<sup>(1)</sup> OJ L 109, 6.5.2000, p. 29.

<sup>(2)</sup> OJ L 157, 30.4.2004, p. 33, corrected by OJ L 195, 2.6.2004, p. 12.

*Article 3***Direct supply of small quantities of meat from poultry and lagomorphs**

By way of derogation from Article 1(3)(d) and without prejudice to Article 1(4) of Regulation (EC) No 853/2004, the provisions laid down in that Regulation shall not apply to the direct supply, by the producer, of small quantities of meat from poultry and lagomorphs slaughtered on the farm to the final consumer or to local retail establishments directly supplying such meat to the final consumer.

*Article 4***Placing of food of animal origin on the national market pending the approval of establishments**

By way of derogation from Article 4(1) of Regulation (EC) No 853/2004, food business operators who before 1 January 2006 were allowed to place food of animal origin on their national market may continue to place such products on this market under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004 until such time as the competent authority, in accordance with Article 4(2) of Regulation (EC) No 853/2004, has approved the establishments handling such products.

Food of animal origin bearing such national marks may be marketed only in the national territory of the Member State where they are produced.

*Article 5***Wrapping, packaging and labelling materials bearing pre-printed health or identification marks**

Food business operators may continue until 31 December 2007 to use stocks of wrapping, packaging and labelling materials bearing pre-printed health or identification marks purchased by them before 1 January 2006.

*Article 6***Marking equipment**

Food business operators and competent authorities may continue to use marking equipment with which they are equipped on 31 December 2005 until its replacement or until the end of the transitional period at the latest, provided that the approval number of the establishment concerned remains unchanged.

When that equipment is replaced, the competent authority shall ensure that it is withdrawn so that it cannot be used any more.

*Article 7***Health import conditions**

1. Article 6(1) of Regulation (EC) No 853/2004 shall not apply to imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

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Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

2. By way of derogation from Article 6(4) of Regulation (EC) No 853/2004, food business operators importing food containing both products of plant origin and processed products of animal origin shall be exempt from the obligation provided for in that Article.

Pending the development of a risk-based approach for the implementation of harmonised health import conditions and checks of such food products, imports shall comply with the harmonised Community rules in force before 1 January 2006 where applicable, and with the national rules implemented by the Member States before that date in other cases.

**▼ M1**

3. By way of derogation from Annex III, Section VIII, Chapter III, Part E to Regulation 853/2004, food business operators may continue until ► **M3** 31 October 2008 ◀ to import fish oil from establishments in third countries that were approved for that purpose before the entry into force of Commission Regulation (EC) No 1664/2006 <sup>(1)</sup>.

**▼ M2**

4. By way of derogation from Annex VI to Regulation (EC) No 2074/2005:

- (a) products referred to in that Annex for which a certificate has been issued in accordance with the harmonised Community rules in force before 1 January 2006, where applicable, and with the national rules implemented by the Member States before that date in other cases, duly completed and signed prior to 1 May 2007, may be imported into the Community until 30 June 2007;
- (b) fish oil for which a certificate has been issued in accordance with national rules applicable before the entry into force of Commission Regulation (EC) No 2074/2005, duly completed and signed prior to ► **M3** 31 October 2008 ◀, may be imported into the Community until ► **M3** 31 December 2008 ◀.

**▼ B***Article 8***Food chain information**

1. By way of derogation from the requirements laid down in Section III of Annex II to Regulation (EC) No 853/2004, the Member States shall progressively implement these requirements in various sectors in addition to the poultry sector where they shall apply immediately, so that the porcine sector in that Member State is covered by the implementation of food chain information requirements by the end of the second year of transition, and the equine and veal calf sectors by the end of the third year.

Member States applying that transitional arrangement shall report to the Commission on its implementation at the end of each year.

2. By way of derogation from the requirements laid down in point 2 of Section III of Annex II to Regulation (EC) No 853/2004 concerning the provision of food chain information to slaughterhouse operators no less than 24 hours in advance, the competent authority may permit such information to be sent to the slaughterhouse operator with animals of all species to which it relates and in all circumstances where this does not jeopardise the objectives of Regulation (EC) No 853/2004.

However, any item of food chain information, knowledge of which may result in serious disruption of the slaughterhouse activity, shall be made

<sup>(1)</sup> OJ L 320, 18.11.2006, p. 13.

**▼B**

available to the slaughterhouse operator in good time before the animals arrive at the slaughterhouse.

*Article 9***Meat of farmed non-domestic ungulates**

By way of derogation from the requirements laid down in point (3)(j) of Section III of Annex III to Regulation (EC) No 853/2004, the certificate referred to in Article 16, attesting to a favourable result of the ante-mortem inspection, is issued and signed by the veterinary service.

*Article 10***Composition criteria and labelling requirements for minced meat**

1. By way of derogation from the requirements laid down in Chapter II(1) of Section V of Annex III of Regulation (EC) No 853/2004, the food business operator must check the raw materials entering the establishment to ensure compliance with the name of the product in the table below in respect of the final product.

*Table:* Composition criteria checked on the basis of a daily average

	Fat content	Connective tissue: meat protein ratio
— lean minced meat	≤ 7 %	≤ 12
— minced pure beef	≤ 20 %	≤ 15
— minced meat containing pigmeat	≤ 30 %	≤ 18
— minced meat of other species	≤ 25 %	≤ 15

2. By way of derogation from the requirements laid down in Chapter IV of Section V of Annex III of Regulation (EC) No 853/2004, the labelling must also display the following words:

- ‘percentage of fat under...’,
- ‘connective tissue: meat protein ratio under...’.

3. The Member States may allow the placing on their national market of minced meat which does not comply with these criteria under a national mark that cannot be confused with the marks provided for in Article 5(1) of Regulation (EC) No 853/2004.

*Article 11***Use of clean water**

1. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter III(A)(1) of Section VIII of Annex III to that Regulation, ice used to chill fresh fishery products may be made from clean water in establishments on land.

2. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter III(A)(2) and (3) of Section VIII of Annex III to that Regulation, food business operators in establishments, including vessels, handling fishery products may use clean water.

3. By way of derogation from Article 3(2) of Regulation (EC) No 853/2004 and Chapter IV(1) of Section VIII of Annex III to that Regulation, food business operators in establishments on land may use clean water for cooling after cooking crustaceans and molluscs.



*Article 12***Raw milk and dairy products**

By way of derogation from the requirement set out in Chapter II(III)(1) (a) of Section IX of Annex III to Regulation (EC) No 853/2004, the maximum plate count for raw cows' milk shall apply only where such milk is to be heat-treated and has not been so treated within the period of acceptance specified in the HACCP-based procedures put in place by food business operators.

*Article 13***Eggs and egg products**

1. Member States which, before 1 January 2006, applied national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities may continue to apply those requirements.
2. Food business operators may use cracked eggs for the production of liquid egg in an establishment approved for that purpose, provided that the establishment of production or a packing centre has delivered them directly and they are broken as soon as possible.

## CHAPTER III

**TRANSITIONAL ARRANGEMENTS FOR THE  
IMPLEMENTATION OF REGULATION (EC) No 854/2004***Article 14***Training of slaughterhouse staff assisting with official controls**

By way of derogation from Article 5(6)(a)(i) to Regulation (EC) No 854/2004 and Chapter III(A)(a) of Section III of Annex I to that Regulation, slaughterhouse staff authorised by the competent authority to carry out specific tasks of official auxiliaries shall be trained in the same way as official auxiliaries only with regard to the specific tasks they are authorised to perform and shall not be required to have passed the same examination as official auxiliaries.

The competent authority shall ensure that such training is satisfactory before authorising slaughterhouse staff to take over tasks of official auxiliaries.

It shall check that the additional training and organisation necessary for slaughterhouse staff to qualify through the examination procedure that apply to official auxiliaries are in place as soon as possible and at the latest by the end of the transitional period.

*Article 15***Certification of establishments using staff assisting with official  
controls in slaughterhouses**

By way of derogation from the second subparagraph of Chapter III(A) (a) of Section III of Annex I to Regulation (EC) No 854/2004, establishments wishing to use their staff assisting with official controls shall, during the transitional period, be exempted from the requirement to possess an internationally recognised certification, provided that the establishment demonstrates that it has initiated and is pursuing certification in accordance with international standards, such as relevant EN ISO standards on quality management or food safety.

**▼B***Article 16***Model certificate for meat from farmed non domestic ungulates**

By way of derogation from Chapter VII (A)(4) of Section IV of Annex I to Regulation (EC) No 854/2004, the model certificate set out in Annex III to Directive 91/495/EEC may be used for the transportation from the farm to the slaughterhouse of farmed non domestic ungulates.

*Article 17***Health import conditions**

Chapter III of Regulation (EC) No 854/2004 shall not apply to imports of food of animal origin for which no harmonised health import conditions have been established, including lists of third countries and parts of third countries and of establishments from which imports are permitted.

Pending future harmonisation of Community legislation concerning imports of such products, such imports shall comply with the health import conditions of the Member State concerned.

**▼M1**

By way of derogation from Article 11(1) of Regulation (EC) No 854/2004, the Member States may authorise the import of bivalve molluscs and fishery products from the countries listed respectively in Annex I and Annex II to this Regulation, provided that:

(a) the competent authority of the third country or territory has provided to the Member State concerned the guarantees that the products in question have been obtained in conditions at least equivalent to those governing the production and placing on the market of Community products and

**▼M2**

(b) The competent authority of the importing Member State shall ensure that these imported products are marketed only on its domestic market or on the domestic markets allowing the same imports and

(c) The competent authority of the third country or territory takes appropriate measures in order to ensure that these imported products are accompanied as from 31 October 2007 by the model health certificates laid down in Annex VI to Regulation (EC) No 2074/2005.

However, these products for which a certificate has been issued, duly completed and signed in accordance with national rules applicable before 31 October 2007 may be imported into the Community until 31 December 2007.

**▼M1***Article 17a***Classification of production and relaying areas for live bivalve molluscs**

By way of derogation from Chapter II (A) (4) of Annex II to Regulation (EC) No 854/2004, the competent authority may continue to classify as being of Class B areas for which the relevant limits of 4 600 *E. coli* par 100 g are not exceeded in 90 % of samples.



## CHAPTER IV

**TRANSITIONAL ARRANGEMENTS FOR THE  
IMPLEMENTATION OF REGULATION (EC) No 882/2004***Article 18***Accreditation of laboratories**

By way of derogation from Article 12(2) of Regulation (EC) No 882/2004, the competent authority may designate a laboratory not accredited, provided that the laboratory:

- (a) demonstrates that it has initiated and is pursuing the necessary accreditation procedures in accordance with Regulation (EC) No 882/2004;
- (b) provides the competent authority with satisfactory guarantees that quality control schemes for the analyses it conducts for the purpose of official controls are in place by 1 January 2006.

## CHAPTER V

**FINAL PROVISIONS***Article 19***Review**

The transitional arrangements, including the conditions thereof, laid down in this Regulation may be reviewed at any time in the light of experience gained in the implementation of those arrangements and of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004.

*Article 20***Amendment to Regulation (EC) No 853/2004**

In Section I(B)(6) of Annex II to Regulation (EC) No 853/2004, the third subparagraph is deleted.

*Article 21***Amendment to Regulation (EC) No 854/2004**

In point (6) in Section I, Chapter III of Annex I to Regulation (EC) No 854/2004, the second sentence is deleted.

*Article 22***Entry into force**

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

It shall apply from 1 January 2006.

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

▼ M1

*ANNEX I*

**List of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates and marine gasteropods in whatever form for human consumption may be permitted**

CA — CANADA

GL — GREENLAND

US — UNITED STATES OF AMERICA

**▼M1***ANNEX II***List of third countries and territories from which imports of fishery products in whatever form for human consumption may be permitted**

AO	—	ANGOLA
AZ	—	AZERBAIJAN <sup>(1)</sup>
BJ	—	BENIN
CG	—	REPUBLIC OF CONGO <sup>(2)</sup>
CM	—	CAMEROON
ER	—	ERITREA
FJ	—	FIJI
IL	—	ISRAEL
MM	—	MYANMAR
SB	—	SOLOMON ISLANDS
SH	—	ST HELENA
TG	—	TOGO

<sup>(1)</sup> Authorised only for imports of caviar.

<sup>(2)</sup> Authorised only for imports of fishery products caught, frozen and packed in their final packaging at sea.