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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, [22/08/2005]

Draft

**COMMISSION REGULATION (EC) No .../..**

**of [...]**

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

Draft

**COMMISSION REGULATION (EC) No .../..**

**of [...]**

**laying down transitional arrangements for the implementation of Regulations (EC) Nos 853/2004, 854/2004 and 882/2004 of the European Parliament and of the Council and amending Regulations (EC) Nos 853/2004 and 854/2004**

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 Articles 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) Nos 852/2004, 853/2004, 854/2004 and 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.

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<sup>1</sup> OJ L 226, 25.6.2004, p. 22.

<sup>2</sup> OJ L 226, 25.6.2004, p. 83.

<sup>3</sup> OJ L 191, 28.5.2004, p. 1

- (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.
- (5) 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.
- (6) 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.
- (7) 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.
- (8) 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.
- (9) 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 seawater 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 seawater 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.

- (10) 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.
- (11) 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.
- (12) 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.
- (13) 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 consequently the requirement to ensuring that slaughterhouse staff is trained for the specific tasks they are allowed to carry out.
- (14) 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.
- (15) 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 [...].

## CHAPTER II

# TRANSITIONAL ARRANGEMENTS FOR THE IMPLEMENTATION OF REGULATION (EC) No 853/2004

### *Article 2* *Stocks of food of animal origin*

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>4</sup>.

Where the shelf-life of such products is less than four years, they shall not be placed on the market for longer than their shelf-life.

### *Article 3* *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.

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<sup>4</sup> OJ L 195, 2.6.2004, p. 12.

*Article 4*  
*Wrapping, packaging and labelling materials bearing pre-printed health or identification marks*

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

The competent authority may extend that one-year period until no later than 31 December 2007, provided that the food business operator demonstrates that the quantity of such materials purchased before 1 January 2006 clearly does not exceed the quantity that may be regarded as reasonable for the annual activity of the establishment concerned .

*Article 5*  
*Marking equipment*

Food business operators 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 6*  
*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.

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.

*Article 7*  
*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 available to the slaughterhouse operator in good time before the animals arrive at the slaughterhouse.

*Article 8*  
*Use of clean seawater*

1. 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 on-land handling fishery products may use clean seawater.
2. 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 cooking crustaceans and molluscs may use clean seawater.

*Article 9*  
*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 10*  
*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 second sentence of Chapter II(II)(1) of Section X of Annex III to Regulation (EC) No 853/2004 is complied with.

CHAPTER III

**TRANSITIONAL ARRANGEMENTS FOR THE  
IMPLEMENTATION OF REGULATION (EC) No 854/2004**

*Article 11*  
*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 12*  
*Certification of the establishments using own inspectors*

By way of derogation from the second subparagraph of Chapter III(A)(a) of Section III of Annex I to Regulation 854/2004, establishments wishing to use their own inspectors 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 EN ISO 9000: 2000 series on quality management systems and ISO 14000 series on environmental management.

*Article 13*  
*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.

CHAPTER IV

**TRANSITIONAL ARRANGEMENTS FOR THE  
IMPLEMENTATION OF REGULATION (EC) No 882/2004**

*Article 14*  
*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 15*  
*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) Nos 853/2004, 854/2004 and 882/2004.

*Article 16*  
*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 17*  
*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 18*  
*Entry into force*

This Regulation shall enter into force on the **twentieth** 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.

Done at Brussels, [...]

*For the Commission*  
[...]  
*Member of the Commission*