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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 18.06.2008

Draft

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

**of [...]**

**amending Annexes I, II and III to Regulation (EC) No 854/2004 of the European Parliament and the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption and repealing certain provisions of Commission Regulation (EC) No 2076/2005**

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption<sup>1</sup>, and in particular Article 17 thereof,

Whereas:

- (1) Provisions regarding health marking laid down in Section I of Annex I to Regulation (EC) No 854/2004 have led to implementing difficulties in some Member States and created confusion in the identification of products produced on the Community territory and products produced outside that territory. It is therefore appropriate to clarify those provisions in order to ensure their smooth implementation.
- (2) Article 5(6) of Regulation (EC) No 854/2004 allows Member States to authorise slaughterhouse staff to carry out certain control tasks of official auxiliaries in relation to the production of meat from poultry and lagomorphs. This authorisation may only be granted if the staff of the establishment have been trained, to the satisfaction of the competent authority, in the same way as official auxiliaries for the tasks of official auxiliaries. During the transitional period provided for by Regulation (EC) No 2076/2005<sup>2</sup>, the training requirement may be limited to ensuring that slaughterhouse staff is trained for the specific tasks they are allowed to carry out.
- (3) Since limiting the training to the specific tasks for which slaughterhouse staff has been authorised to perform does not undermine the objective set out in Article 5, it is appropriate to permit the Member States to implement a complete or limited training system and to decide upon its practical arrangements.

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<sup>1</sup> OJ L 139, 30.4.2004, p. 206; corrected version OJ L226, 25.6.2004, p. 83. Regulation as last amended by Council Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

<sup>2</sup> OJ L 338, 22.12.2005, p. 83

- (4) According to the general principle laid down in Annex II, Chapter II, Part A, point 4 of Regulation (EC) No 854/2004, live bivalve molluscs from classified B areas must not exceed the limits of 4600 *E.coli* per 100 g of flesh and intravalvular liquid. Regulation (EC) No 2076/2005 introduces a tolerance in 10% of samples for live bivalve molluscs originating from those areas on a transitional basis.
- (5) Since allowing this tolerance does not represent a risk for public health provided that in the 10% of samples, live bivalve molluscs do not exceed an upper limit of 46000 *E. coli* per 100g of flesh and intravalvular liquid, it is therefore appropriate to retain this tolerance with an upper limit on a permanent basis.
- (6) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if not consumed under certain conditions. Regulation (EC) No 854/2004 as amended by Commission Regulation (EC) No 2074/2005<sup>3</sup> requires competent authorities in the Member States to carry out checks regarding the marketing conditions that food business operators must comply with in relation to these fishery products.
- (7) These conditions apply to fresh, prepared and processed fishery products derived from these species. However, similar risks for the consumer may be encountered with frozen fishery products derived from this fish family. It is therefore appropriate to require competent authorities to carry out also checks for this latter presentation of the products.
- (8) Regulation (EC) No 854/2004 should therefore be amended accordingly.
- (9) 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*

Regulation (EC) No 854/2004 is amended in accordance with the Annex to this Regulation.

*Article 2*

Products of animal origin for which a health mark has been applied in accordance with Community rules in force before 1 November 2009 may be imported into the Community until 31 December 2009.

*Article 3*

Articles 14 and 17a of Regulation (EC) No 2076/2005 are hereby deleted.

<sup>3</sup> OJ L 338, 22.12.2005, p. 27

*Article 3*

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

Point 1(a) of the Annex to this Regulation shall apply as from 1 November 2009.

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*

## ANNEX

Regulation (EC) No 854/2004 is amended as follows:

1. Annex I is amended as follows:

(a) In Chapter III of Section I, Point (c) of Paragraph 3 is replaced by the following:

'(c) When applied in a slaughterhouse located within the Community, the mark must include the abbreviation CE, EB, EC, EF, EG, EK, EO, EY, ES, EÜ, EK or WE.

However, that abbreviation can only be included in marks applied in slaughterhouses located within the Community.'

(b) In Chapter III of Section III, Point (a) of Part A is replaced by the following:

'(a) Where the establishment has used good hygiene practice in accordance with Article 4, paragraph 4 of this Regulation and the HACCP procedure for at least twelve months, the competent authority may authorise staff of the establishment to carry out tasks of official auxiliaries. This authorisation may only be granted if the staff of the establishment have been trained, to the satisfaction of the competent authority, in the same way as the official auxiliaries for the tasks of official auxiliaries or for the specific tasks they are authorised to perform. This staff must be placed under the supervision, direction and responsibility of the official veterinarian. In these circumstances, the official veterinarian shall be present at ante-mortem and post-mortem examinations, shall supervise these activities and carry out regular performance tests to ensure that the performance of the slaughterhouse staff meets the specific criteria laid down by the competent authority, and shall document the results of those performance tests. Detailed rules for the performance tests may be laid down in accordance with the procedure set out in Article 18. Where the level of hygiene of the establishment is affected by the work of this staff, where this staff does not carry out the tasks properly or where in general this staff carries out its work in a manner that the competent authority considers unsatisfactory, this staff shall be replaced by official auxiliaries.'

2. In Part A of Chapter II to Annexe II, Point 4 is replaced by the following:

- '4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed, in 90% of the samples, 4600 *E. coli* per 100 g of flesh and intravalvular liquid. In the remaining 10% of samples, live bivalve molluscs must not exceed 46000 *E. coli* per 100 g of flesh and intravalvular liquid.

The reference method for this analysis is the five-tube, three dilutions Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.'

3. In Chapter II of Annex III, Part G is replaced by the following:

#### 'G. POISONOUS FISHERY PRODUCTS

Checks are to take place to ensure that:

1. fishery products derived from poisonous fish of the following families are not placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae;
2. fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, are only placed on the market in wrapped/packaged form and are appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific and the common names appear on the label;  
and
3. fishery products containing biotoxins such as Ciguatera or other toxins dangerous to human health are not placed on the market. However, fishery products derived from bivalve molluscs, echinoderms, tunicates and marine gastropods may be placed on the market if they have been produced in accordance with Section VII of Annex III to Regulation (EC) No853/2004 and comply with the standards laid down in Chapter V, point 2, of that Section.'

