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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 15.06.2008

Draft

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

of [...]

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin and repealing certain provisions of Commission Regulation (EC) No 2076/2005 as regards identification marking, raw milk and dairy products, eggs and egg products and certain fishery products

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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 853/2004 of the European Parliament and the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin¹, and in particular Article 9 and Article 10(1) thereof,

Whereas:

- (1) The Pprovisions regarding identification marking laid down in Annex II to Regulation (EC) No 853/2004 have led to implementing difficulties in some Member States and created confusion in the identification of products produced within the Community territory and products produced outside that Community territory. It is therefore appropriate to clarify those provisions in order to ensure their smooth implementation. However, in order not to disrupt trade in the products of animal origin concerned, it should be provided that products for which an identification mark has been applied in accordance with Regulation (EC) No 853/2004 before 1 November 2009 may be imported into the Community until 31 December 2009.
- (2) 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 Part A of Annex I and in Chapter VII of Annex II to Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs² and in Part II of Chapter I and

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version in OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1243/2007 (OJ L 281, 25.10.2007, p. 8).

² OJ L 139, 30.4.2004, p. 1; corrected version OJ L 226, 25.6.2004, p. 3.

Chapters III and IV of Section VIII of Annex III to Regulation (EC) No 853/2004, in particular for handling fishery products on board vessels.

- (3) Article 11 of 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 Council³ 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 provides that lays down a transitional measure extending the scope of the relevant provisions in Regulation (EC) No 853/2004 clean water may also be used into land-based establishments until 31 December 2009 during the transitional period.
- (4) It has long been scientifically recognised that the use of seawater is of technological interest for fishery products as it helps in maintaining intact their organoleptic characteristics by eliminating the risk of osmotic shock.
- (5) ~~Since~~ The use of clean seawater for the handling and washing of fishery products does not represent a risk for public health as long as control procedures based, in particular, on the Hazard Analysis and Critical Control Points (HACCP) principles have been developed and put in place by food business operators to ensure that it complies with the definition of clean seawater set out laid down in Regulation (EC) No 852/2004, it is therefore appropriate to delete Article 11 of Regulation (EC) No 2076/2005 and to make these transitional arrangement measure, provided for in that Regulation as regards the use of clean seawater, permanent. . Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.
- (6) ~~Section VIII of Annex III to Regulation (EC) No 853/2004 as amended by Commission Regulation (EC) No 1662/2006⁴ sets out the requirements governing the production and placing on the market of fishery products intended for human consumption, including fish oil.~~
- (7) ~~There have been difficulties in implementing these specific requirements in some Member States and third countries. Problems have also been encountered as regards fish oil imported from third countries. These difficulties mainly relate to the requirements applying to raw materials in order to ensure their suitability for the production of fish oil destined for human consumption and to food manufacturing practices usually in place in the fish oil industry. It is therefore appropriate to clarify those provisions in order to harmonise their implementation. Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.~~
- (8) The opinion of the European Food Safety Authority adopted on 30 August 2004 on contaminants in the food chain related to the toxicity of fishery products belonging to the family of *Gempylidae* 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. Chapter V of Section VIII of Annex III to Regulation (EC) No

³ OJ L 338, 22.12.2005, p. 83. Regulation as last amended by Regulation (EC) No 439/2008 (OJ L 132, 22.5.2008, p. 16).

⁴ OJ L 320, 18.11.2006, p. 1.

853/2004 as amended by Regulation (EC) No 2074/2005⁵ lays down specific marketing conditions for these fishery products.

- (9) 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 the fish-family of *Gempylidae*. It is therefore appropriate to require similar protective and informative conditions for those frozen fishery products. this latter presentation of the products. Section VIII of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.
- (10) Point 1(a) of 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.
- (11) Compliance with this limit is particularly important for food safety where the milk has to be heat-treated by a pasteurisation process or a process which is less strict lower than a pasteurisation, and has not been heat-treated ~~so~~ within a pre-defined time. In such circumstances, the application of such heat-treatments does not have a sufficient bactericidal effect, which may lead to an early spoilage of the resulting dairy product.
- (12) Article 12 of Regulation (EC) No 2076/2005 provides for a transitional measure arrangement aiming at limiting the verification of compliance with this criterion to such circumstances. It is therefore appropriate to delete Article 12 of Regulation (EC) No 2076/2005 and to make that transitional arrangement retain these requirements on a permanent basis. Section IX of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.

⁵ OJ L 338, 22.12.2005, p. 27.

~~(12)~~(13) Section X of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for eggs and egg products. ~~According to~~ Pursuant to point 2 of Chapter I ~~(2) of that Section~~, eggs must be stored and transported at a preferably constant temperature that is best suited to ensuring optimal conservation of their hygiene properties.

~~(13)~~(14) ~~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 until sale to the consumer. Article 13(1) of Regulation (EC) No 2076/2005 provides that Member States which, before 1 January 2006, applied national temperature requirements for eggs storage facilities and for vehicles transporting eggs between such storage facilities may continue to apply those requirements until 31 December 2009 for an extension of such national arrangements, if still authorised by the competent authority, on a transitional basis. Since this possibility for competent authorities in the Member States does not interfere with the food safety objectives laid down in Regulation (EC) No 853/2004, it is therefore appropriate to make that~~ transitional measure arrangement permanent.

(15) ~~In addition, Under~~ pursuant to point 1 of ~~-Part II (4)-~~ 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. Article 13(2) of Regulation (EC) No 2076/2005 provides that food business operators may, until 31 December 2009, 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. Since the use of such cracked eggs in the production of liquid egg does not represent a risk for public health under such certain as long as it complies with the strict conditions under which such derogation can be granted to establishments manufacturing egg products, it is appropriate to make that transitional arrangement permanent extend this possibility to the establishments producing liquid egg

(16) Article 13 of Regulation (EC) No 2076/2005 should therefore be deleted and Section IX of Annex III to Regulation (EC) No 853/2004 should be amended accordingly.

~~(15)~~(17) Regulations (EC) No 853/2004 and Regulation (EC) No 2076/2005 should therefore be amended accordingly.

~~(16)~~(18) 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

Annex II to Regulation (EC) No 853/2004 is amended in accordance with ~~the~~ Annex I to this Regulation.

Article 2

Annex III to Regulation (EC) No 853/2004 is amended in accordance with the Annex II to this Regulation.

Article 3

~~Products of animal origin for which an identification 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 43

~~In Regulation (EC) No 2076/2005, Articles 11, 12 and 13 of Regulation (EC) No 2076/2005 are hereby deleted.~~

Article 54

Products of animal origin for which an identification mark has been applied in accordance with point 8 of Part B of Section I of Annex II to Regulation (EC) No 853/2004 before 1 November 2009 may be imported into the Community until 31 December 2009.

Article 5

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

However, Ppoint 1(b) of Annex I 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 I

Annex II to Regulation (EC) No 853/2004 is amended as follows:

(1) ~~In Section I, Parts A and B are~~ is amended as follows:

(a) ~~Points 1 and 3 of Part A~~ is amended as follows ~~are replaced by the following:~~

(i) Point 1 is replaced by the following:

"1. The identification mark must be applied before the product leaves the establishment of its production."

(ii) Point 3 is replaced by the following:

"3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Part A of Annex XIV to Council Regulation (EC) No ~~10281234/2006~~2007⁶.

* OJ L 299, 16.11.2007, p. 1."

(b) ~~Point 8 of~~ In Part B, point 8 is replaced by the following:

"8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EB, EC, EF, EG, EK, EO, EY, ES, EÜ, EK or WE.

However, ~~that~~ Those abbreviations must ~~not~~ only be included in marks applied on products imported into the Community from establishments located outside the Community ~~in establishments located within the Community."~~

(2) ~~In Section III~~ is amended as follows:

(a) Point 1 is replaced by the following:

"1. Slaughterhouse operators must not accept animals onto the slaughterhouse premises unless they have requested, and been provided with, relevant food chain information contained in the records kept at the holding of provenance in accordance with Regulation (EC) No 852/2004."

(b) ~~In P~~ point 3, the introductory ~~in~~ phrase is replaced by the following:

"3. The relevant food chain information referred to in point 1 is to cover, in particular:"

⁶ ~~OJ L 299, 16.11.2007, p. 1.~~ OJ L 186, 7.7.2006, p. 1.

ANNEX II

Annex III to Regulation (EC) No 853/2004 is amended as follows:

(1) ~~In Section VIII is, the introductory Part and Chapters I, III, IV and V are amended as follows:~~

(a) ~~In ~~the introductory Part of Section VIII, point 2 is replaced by the following is amended as follows:~~~~

~~(i) point 2 is replaced by the following:~~

~~"2. Chapter III, Parts A, C and D, Chapter IV, Part A and Chapter V apply to retail."~~

~~(ii) In the first subparagraph of point 3, the following point (c) is added:~~

~~"(c) In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation; clean seawater may be used with fishery products for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking."~~

~~(b) In the introductory Part of Section VIII, a new point (e) is added to point 3 as follows:~~

~~"(e) In the case of water supply, they supplement the requirements of Annex II, Chapter VII to that Regulation. Clean seawater may be used with fishery products for the handling and washing of fishery products, the production of ice used to chill fishery products and the rapid cooling of crustaceans and molluscs after their cooking."~~

~~(eb) In Chapter I, point 2 of Part II Part II is replaced amended as follows by the following:~~

~~(i) In point 2, the second sentence is deleted.~~

~~"2. As soon as possible after they are taken on board, fishery products must be protected from contamination and from the effects of the sun or any other source of heat."~~

~~(ii) Point 5 is deleted~~

~~(d) In Chapter I, point 5 of Part II is hereby deleted.~~

~~(iie) In Chapter I, Point 6 of Part II is replaced by the following:~~

~~"6. Where fish are headed and/or gutted on board, such operations must be carried out hygienically as soon as possible after capture, and the products must be washed immediately and thoroughly. In that event, the viscera and parts that may constitute a danger to public health must be removed as soon as possible and kept apart from products intended for~~

human consumption. Livers and roes intended for human consumption must be preserved under ice, at a temperature approaching that of melting ice, or be frozen."

(fc) ~~In Chapter III, Point 2 of Part A is replaced by the following amended as follows:~~

(i) ~~In Part A, point 2 is replaced by the following:~~

"2. Operations such as heading and gutting must be carried out hygienically. Where gutting is possible from a technical and commercial viewpoint, it must be carried out as quickly as possible after the products have been caught or landed. The products must be washed thoroughly immediately after these operations."

(gii) ~~In Chapter III, Part E is deleted.~~

(hd) Chapter IV is replaced by the following:

Chapter IV: REQUIREMENTS FOR CERTAIN PROCESSED FISHERY PRODUCTS

Food business operators must ensure compliance with the following requirements, ~~where relevant~~, in establishments handling certain processed fishery products.

A. REQUIREMENTS FOR COOKING OF CRUSTACEANS AND MOLLUSCS

1. Rapid cooling must follow cooking. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.
2. Shelling or shucking must be carried out hygienically, avoiding contamination of the product. Where such operations are done by hand, workers must pay particular attention to washing their hands.
3. After shelling or shucking, cooked products must be frozen immediately, or be chilled as soon as possible to the temperature ~~laid down~~set out in Chapter VII.

B. REQUIREMENTS FOR FISH OIL INTENDED FOR HUMAN CONSUMPTION

1. Raw materials used in the preparation of fish oil for human consumption must:
 - (a) (i) ~~come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;~~
 - (ii) ~~derive from fishery products which are fit for human consumption and which comply with the provisions laid down~~set out in this Section;
 - (iii) ~~be transported and stored in hygienic conditions;~~
 - (iv) ~~be chilled as soon as possible and remain at the temperatures specified~~set out in Chapter VII.
- (b) ~~By way of derogation from the provisions of Point 1 (a)(iv), the food business operator may refrain from chilling the fishery products; when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits~~ set out

in point 1 of Chapter I of Section II of Annex II to Commission Regulation (EC) No 2074/2005⁷.

2. The production process for fish oil must ensure that all raw material intended ~~for the production to produce~~ of crude fish oil is subject to a treatment including, where relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the market for the final consumer.
3. Provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption a food business operator may produce and store both fish oil for human consumption and fish oil and fish meal not intended for human consumption in the same establishment
4. Pending the establishment of specific Community legislation food business operators must ensure compliance with national standards rules for fish oil ~~to being~~ placed on the market for the final consumer.

* OJ L 338, 22.12.2005, p. 27."

(ie) In Chapter V is amended as follows:

(i) , the ~~The following sentence is added to the introductory sentence paragraph is amended as follows:~~

~~"In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure, depending on the nature of the product or the species, that fishery products placed on the market for human consumption meet the standards laid down in this Chapter. The requirements of point~~Parts B and D ~~shall not apply~~ are not applicable to whole fishery products that are used directly for the preparation of fish oil intended for human consumption."

(jii) In Chapter V, Part E, Ppoint 1 of Part E is replaced by the following:

~~"1. Fishery products derived from poisonous fish of the following families must not be placed on the market: Tetraodontidae, Molidae, Diodontidae and Canthigasteridae.~~

~~-Fresh, prepared, frozen and processed fishery products belonging to the family Gempylidae, in particular Ruvettus pretiosus and Lepidocybium flavobrunneum, may only be placed on the market in wrapped/packaged form and must be 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.~~

⁷ OJ L 338, 22.12.2005, p. 27.

The scientific name of the fishery products must accompany the common name on the label.""

(2) In Section IX, Chapter II Point 1 of Part III, point 1 to Chapter II is replaced by the following:

"1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before being heat treated and if its period of acceptance defined-specified in the HACCP-based procedures is exceeded:

(a) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml; and

and

(b) heat treated cows' milk used to prepare dairy products has a plate count at 30°C of less than 100 000 per ml.""

(3) In Section X is, Chapters I and II are is amended as follows:

(a) In Chapter I, Ppoint 2 is replaced by the following:

"2. Eggs must be stored and transported until sale to the final consumer at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties, unless the competent authorities imposes national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities.""

(b) In Chapter II, Part II, Ppoint 1 of Part II is replaced by the following:

"1. The shells of eggs used in the manufacture of egg products must be fully developed and contain no breaks. However, cracked eggs may be used for the manufacture of liquid egg or egg products if the establishment of production or a packing centre delivers them directly to an establishment approved for the manufacture of liquid egg or a processing establishment, where they must be broken as soon as possible.""

