

19/05/2008

Revision 2 of Draft Proposal as regards Fish Oil for Human Consumption, rev 2

Revision 2 of Draft Proposal as regards Fish Oil for Human Consumption

Following the discussions in the Working Group on Implementing Measures of the Hygiene Regulations 14 April 2008 the version dated 7 April has been revised (file: FishOil 05052008-rev2). The intention is to finalise the discussions of the draft in the Working Group on the 19 May 2007 for the changes to be adopted before the end of the transitional period.

The following changes have been made to the document:

A small adjustment is proposed in Point 2 of Section VIII of Annex III to Regulation (Ec) No 853/2004 as the requirements for production of fish oil do not apply to retail.

The term "fish" has been substituted by "whole fishery products", inter alia in Annex I of the draft (Chapter IV, point 2 (B) (1)(b)), to clarify when the proposed derogation can be used.

The proposed TVB-N parameter in Annex II ((Point 1 (d)) has been reduced to 60 mg of Nitrogen/100g when food business operators use the possibility for the derogation when production establishments for fish oil are being supplied with raw material by vessels with no chilling onboard. This will then be the freshness criteria referred to in "Organoleptic properties for fishery product" in Point A of Chapter V, Section VIII of Annex III to Regulation 853/2004.

Competent authorities may lay down higher levels for certain species. However, the requirement still applies that the raw material must derive from fish which is fit for human consumption.

Regarding the issue on who is responsible for checking the TVB-N value if the derogation is used, no change of text has been made. According to the new chapeau to chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004, where the derogation is introduced, it is stated that "Food business operators must ensure compliance with the following requirements, where relevant, in establishments handling certain processed fishery products". It is therefore the responsibility of the FBO to check this parameter when the derogation is utilised.

During the discussion on the 14 April 2007 it became clear that there is not a consensus regarding parameters for fish oil to be put on the market for the final consumer.

According to FAO Fisheries Technical Paper No 142 on the Production of Fish Meal and Oil several parameters are used for contractual reasons. Free fatty acid is still the most reliable parameter for oil quality and yield assessment and moisture in oil leads to the formation of rust in storage tanks with consequent accelerated oxidation of the oil catalysed by iron. Moisture in the oil is also responsible for the increase of free fatty acid during storage.

A discussion of hygiene end product parameters in the Hygiene Regulation for fish oil to be put on the market for the final consumer should include the rancidity issue. However, this discussion is at an initial stage as there is not yet sufficient knowledge. The usefulness of free fatty acid and water content parameters as hygiene indicators should be included in the same discussion.

As the freshness of the raw material, under the derogation is now controlled by the TVB-N parameter and the term "fit for human consumption" specific end product criteria has been replaced by a text allowing Member States may keep their national requirements awaiting harmonisation of hygiene requirements for fish oil to be placed on the market for the final consumer.

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SANCO/XX/2008 rev2

WORKING DOCUMENT

**DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION
SERVICES**

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.5.2008

Draft

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

of [...]

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and amending Annex II to Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

Draft

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

of [...]

amending Annex III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and amending Annex II to Commission Regulation (EC) No 2074/2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 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 the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin ¹, and in particular Article 10(1) thereof,

Whereas:

- (1) [\[Initial capital...\]](#).
- (2) The measures provided for in this Regulation are in accordance with the opinion of the [\[...\] Committee](#),

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

Annex II to Commission Regulation (EC) No 2074/2005 is amended in accordance with the Annex II to this Regulation.

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version 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).

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*.

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

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

1 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.'

2 In Chapter III, Part E is hereby deleted;

3 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. Water used for this purpose must be potable water or, on board vessels, clean water. 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 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 fish which are fit for human consumption and comply with the provisions laid down in this Section;
 - (iii) be transported and stored in hygienic conditions;

- (iv) be chilled as soon as possible and remain at the temperatures specified in Chapter VII.
 - (b) By way of derogation from the provisions of Point 1 (a)(iv), when whole fishery products are used directly in the preparation of fish oil for human consumption, the raw material may be processed within 36 hours after loading, provided that the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products meet the requirements of Annex II of Commission Regulation (EC) No 2074/2005.
2. The production process for fish oil must ensure that:
 - all raw material intended to produce crude 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. National standards for fish oil to be placed on the market for the final consumer apply pending the establishment of specific Community legislation.
- 4 The introductory sentence of Chapter V 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 points B and D are not applicable to fish that are used directly for the preparation of fish oil intended for human consumption.'

ANNEX II

In Annex II to Commission Regulation (EC) No 2074/2005 Section II, Chapter I, Point 1 is replaced by the following:

- '1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:
 - (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II;
 - (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II;
 - (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II;
 - (d) 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption as referred to in Point B (1)(b) of chapter IV to Section VIII of Regulation (EC) No 853/2004. National authorities may set a higher limit for certain species provided that the raw material complies with Points (i) to (iii) of Part B(1)(a) of the same Chapter.

The reference method to be used for checking the TVB-N limit involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.'

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SANCO/42/2008 Rev. 2

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.05.2008

Draft

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

of [...]

**amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and the
Council on the hygiene of foodstuffs**

Draft

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

of [...]

amending Annex II to Regulation (EC) No 852/2004 of the European Parliament and the Council on the hygiene of foodstuffs

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 852/2004 of the European Parliament and the Council of 29 April 2004 on the hygiene of foodstuffs¹, and in particular Article 13(1) thereof,

Whereas:

- (1) [Initial capital...].
- (2) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 852/2004 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the [20th] day following that 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, [...]

For the Commission

[...]

Member of the Commission

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

ANNEX

In Chapter VII of Annex II to Regulation (EC) No 852/2004, Point 1(b) is replaced by the following:

,

- '(b) Clean water may be used with whole fishery products. Clean seawater may be used with live bivalve molluscs, echinoderms, tunicates and marine gastropods; clean water may also be used for external washing. When such water is used, adequate facilities are to be available for its supply to ensure that it is not a source of contamination for the foodstuff.'

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SANCO/43/2008 Rev. 2

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.05.2008

Draft

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

of [...]

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and repealing certain provisions of Commission Regulation (EC) No 2076/2005

Draft

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

of [...]

amending Annexes II and III to Regulation (EC) No 853/2004 of the European Parliament and the Council laying down specific hygiene rules for food of animal origin and repealing certain provisions of Commission Regulation (EC) No 2076/2005

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 origin ¹, and in particular Article 10(1) thereof,

Whereas:

- (1) [\[Initial capital...\]](#).
- (2) The measures provided for in this Regulation are in accordance with the opinion of the [\[...\]](#) Committee,

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

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

¹ OJ L 139, 30.4.2004, p. 55 ; corrected version 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).

Article 4

This Regulation shall enter into force on the [20th] day following that 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, [...]

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 amended as follows:
 - (a) Points 1 to 3 of Part A are replaced by the following:
 - '1. The identification mark must be applied before the product leaves the establishment of its production.
 2. A new mark must only be applied to a product when it is handled in another establishment in such a way that it is no longer protected against contamination or when it is further processed in another establishment. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.
 3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Regulation (EC) No 1028/2006².'
 - (b) Point 8 of Part B 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 abbreviation can only be included in marks applied in establishments located within the Community.'
2. In Section III:
 - (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 Point 3, the introduction is replaced by the following:
 - '3. The relevant food chain information referred to in point 1 is to cover, in particular:'

² 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, the introductory Part and Chapters I, III, IV and V are amended as follows:
 - (a) In the Introductory Part of Section VIII, a new point (c) is added to point 3 as follows:
 - '(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 all purposes, including 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 Chapter I, point 2 of Part II is replaced by the following:
 - '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.'
 - (c) In Chapter I, point 5 of Part II is hereby deleted.
 - (d) 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.'
 - (e) In Chapter III, Point 2 of Part A 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.'
 - (f) In Chapter IV, Point 1 is replaced by the following:
 - '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.'
 - (g) In Chapter V, Point 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. The scientific name must accompany the common name on the label.'
2. In Section IX, Point 1 of Part III 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 in the HACCP-based procedures is exceeded:
 - (i) raw cows' milk used to prepare dairy products has a plate count at 30°C of less than 300 000 per ml;

and
 - (ii) processed 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, Chapters I and II are amended as follows:
 - (a) In Chapter I, Point 2 is replaced by the following:
 - '2. Eggs must be stored and transported until sale to the consumer at a temperature, preferably constant, that is best suited to assure optimal conservation of their hygiene properties, unless the competent authorities impose national temperature requirements for egg storage facilities and for vehicles transporting eggs between such storage facilities.'
 - (b) In Chapter II, Point 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.'

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SANCO/44/2008 Rev. 2

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.05.2008

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

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

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 consumption¹, and in particular Article 17 thereof,

Whereas:

- (1) [Initial capital...].
- (2) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2

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

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*.

¹ 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).

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.

[Responsibilities for production and inspection in the establishment must be kept separate and any establishment wishing to use the establishment's own inspectors must be certified in accordance with international standards, such as relevant EN ISO standards on quality management or food safety.]'

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.'

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SANCO/1489/2007 Rev 6

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.05.2008

Draft

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

of [...]

**amending Regulation (EC) No 853/2004 of the European Parliament and of the Council
as regards the requirements applicable to frozen food of animal origin intended for
human consumption**

(Text with EEA relevance)

WORKING DOCUMENT

**DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION
SERVICES**

Draft

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

of [...]

**amending Regulation (EC) No 853/2004 of the European Parliament and of the Council
as regards the requirements applicable to frozen food of animal origin intended for
human consumption**

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 origin¹, and in particular Article 10(1) thereof,

Whereas:

- (1) Experience with implementation of Regulation (EC) No 853/2004 has exposed certain difficulties as regards the storage of food of animal origin. By indicating the date of initial freezing of such food the food business operators will be better able to judge the suitability of the food for human consumption and to estimate its durability.
- (2) Directive 2000/13/EC of the European Parliament and of the Council on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs² concerns the labelling of foodstuffs to be delivered as such to the final consumer and certain aspects relating to the presentation and advertising thereof. However, this Directive does not apply at present to prior stages of production.
- (3) Enforcement of Regulation (EC) No 853/2004 by the competent authorities has revealed that more detailed requirements regarding the production, freezing, and durability of food of animal origin in the stages of production prior to its delivery as such to the final consumer are necessary.
- (4) It is, therefore, appropriate to specify certain additional rules to ensure food safety while maintaining sufficient flexibility with regard to the form under which the relevant information should be made available, and to amend Regulation (EC) No 853/2004 accordingly.

¹ OJ L 139, 30.4.2004, p.55, corrected by OJ L 226, 25.6.2004, p. 22

² OJ L 109, 6.5.2000, p. 29

- (5) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

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

Article 2
Entry into force

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

[It shall apply from 1 xxx 2008]

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

The following Section IV is added to Annex II to Regulation (EC) No 853/2004:

"Section IV. Requirements applicable to frozen food of animal origin

Until the stage at which a food is labelled in accordance with Directive 2000/13/EC or used for further processing, food business operators must ensure that frozen food of animal origin intended for human consumption meets the following requirements.

1. Relevant information must be made available in an appropriate form to the food business operator to whom the food is supplied and, upon request, to the competent authority.
2. (a) The relevant information referred to in point 1 must comprise:
 - (i) The date of production or, in the case of carcasses or half carcasses, the date of slaughter,
 - (ii) The date of freezing, if different from the date of production.
 - (iii) The date of minimum durability.
- (b) Where a food is made from a prepared batch of raw materials, the oldest dates of production, or of slaughter as appropriate, and of freezing must be made available.
3. The dates referred to in points 2 shall not be changed or removed from the food until the food is labelled in accordance with Directive 2000/13/EC or used for further processing."

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SANCO/1490/2007 Rev 6

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 19.05.2008

Draft

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

of [...]

laying down implementing measures regarding the application of traceability requirements in respect of food of animal origin under Regulation (EC) No 178/2002 of the European Parliament and of the Council

(Text with EEA relevance)

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

Draft

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

of [...]

laying down implementing measures regarding the application of traceability requirements in respect of food of animal origin under Regulation (EC) No 178/2002 of the European Parliament and of the Council

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety¹, and in particular Article 18(5) thereof,

Whereas:

- (1) Article 18 of Regulation (EC) No 178/2002 establishes the general principles of traceability of food. The traceability of food must be established at all stages of production, processing and distribution. Food business operators must be able to identify persons from whom they have been supplied with food and businesses to which their products have been supplied. This information shall be made available to the competent authorities upon demand.
- (2) Traceability is indispensable to ensure food safety and the reliability of information provided to consumers. In particular, it is necessary to apply traceability to food of animal origin to assist in enabling unsafe food to be removed from the market, thereby providing for the protection of consumers.
- (3) In order to fulfil the objective of Article 18 of the Regulation the information necessary comprises the name and address of the supplying food business operator; and the name and address of the food business operator to whom the food was supplied.

¹ OJ L 31, 1.2.2002, p. 1

- (4) Other specific Community provisions apply to the traceability of certain foods, notably Council Directive 89/396/EEC on indications or marks identifying the lot to which a foodstuff belongs², Council Regulation (EEC) No 1906/90 on certain marketing standards for poultry³, Commission Regulation (EEC) No 1538/91 introducing detailed rules for implementing Regulation (EEC) No 1906/90 on certain marketing standards for poultrymeat⁴ and Regulation (EC) No 1760/2000 of the European Parliament and of the Council establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97⁵.
- (5) Food crises in the past have revealed that documentary records were not always sufficient to allow full traceability of suspect foods. Experience of the application of Regulations (EC) No 178/2002, (EC) No 852/2004⁶, (EC) No 853/2004⁷ and (EC) No 854/2004⁸ has revealed that food business operators do not regularly have available the information necessary to ensure the adequacy of their systems concerning the identity of the foods they are handling or storing.
- (6) It is, therefore, appropriate to specify certain rules for the specific sector of food of animal origin for the purpose of applying the requirements of Article 18 of Regulation (EC) No 178/2002 while maintaining sufficient flexibility with regard to the form under which the relevant information should be made available.
- (7) In particular, it is appropriate to provide additional information on the volume or quantity of the food, the lot or batch number as appropriate, a more detailed description of the product (pre-packed or bulk product, variety or type, raw or processed product) and the date of dispatch or delivery.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the [...] Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Without prejudice to other specific Community provisions concerning the traceability of food of animal origin, food business operators shall ensure that the following additional information concerning consignments of food of animal origin is made available in an appropriate form to the food business operator to whom the food is supplied and, upon request, to the competent authority.

² OJ L 186, 30.6.1989, p. 21. Directive as last amended by Directive 92/11/EEC (OJ L 65, 11.3.1992, p. 32).

³ OJ L 173, 6.7.1990, p. 1. Regulation as last amended by Regulation (EC) No 1029/2006 (OJ L 186, 7.7.2006)

⁴ OJ L 143, 7.6.1991, p. 11

⁵ OJ L 204, 11.8.2000, p. 1. Regulation as last amended by Regulation (EC) No 1791/2006 (OJ L 363, 20.12.2006, p. 1).

⁶ OJ L 139, 30.04.2007, p. 1, corrected by OJ L 226, 25.6.2004, p. 3

⁷ OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 1662/2006 (OJ L 320, 18.11.2006, p. 1)

⁸ OJ L 139, 30.4.2004, p. 206, as corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Commission Regulation (EC) No 1664/2006, OJ L 320, 18.11.2006, p. 13

- (a) An accurate description of the food,
- (b) The volume or quantity of the food,
- (c) The name and address of the food business operator supplying the food,
- (d) The name and address of the consignor if different from the food business operator supplying the food,
- (e) The name and address of the food business operator to whom the food is being sent,
- (f) The name and address of the consignee if different from the food business operator to whom the food is being sent,
- (g) A reference enabling the lot or batch to be identified, and
- (h) The date of dispatch.

Article 2

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

[It shall apply from 1 xxx 2008.]

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