SANCO/42/2008 Rev. 1

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2008

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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 foodstuffs [1], 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

Annex II to Regulation (EC) No 852/2004 is amended as follows:

1. In Chapter VII, 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.'

Deleted: The water intake must be situated in a position that avoids contamination of the water supply.

Deleted: 2. In Chapter VII, Point 4 is replaced by the following:¶
'4. Ice which comes into contact with food or which may contaminate food is to be made from potable water or, when used to chill whole fishery products, clean water. It is to be made, handled and stored under conditions that protect it from contamination.

SANCO/43/2008 Rev. 1

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2008

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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.

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.

[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).

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 exposed after removal of its packaging and/or wrapping 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 1028/2006[2].'

(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:'

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[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, Chapters III, IV and V are amended as follows:

(a) In Chapter III, Points 2 to 4 of Part A are 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 with potable water or clean water immediately after these operations.

3. Operations such as filleting and cutting must be carried out so as to avoid contamination or spoilage of fillets and slices. Where necessary, the products must be washed with potable water or clean water. Fillets and slices must not remain on the worktables beyond the time necessary for their preparation. Fillets and slices must be wrapped and, where necessary, packaged and must be chilled as quickly as possible after their preparation.

4. Ice used to chill fishery products must be made from potable water or clean water. Containers used for the dispatch or storage of unpackaged prepared fresh fishery products stored under ice must ensure that melt water does not remain in contact with the products.'

(b) In Chapter IV, Point 1 is replaced by the following:

'1. Rapid cooling must follow cooking. Water used for this purpose must be potable water or clean water. If no other method of preservation is used, cooling must continue until a temperature approaching that of melting ice is reached.'

(c) 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. (a) Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

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

and

(ii) processed cows' milk used to prepare dairy products has a plate count at 30ºC of less than 100 000 per ml.

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(b) 'Food business operators need not initiate the procedures laid down in point (a) if the competent authorities authorise so for technological reasons related to the manufacture of certain dairy products.'

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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.'

ANNEX I (SANCO/43/2008 Rev. 1 – Danish proposal)

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. However, when a product is handled in another establishment in a way that alters the product, i.e. has its packaging and/or wrapping removed and/or is treated in some way, whether the treatment results in an unprocessed or processed product, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place. Freezing or quick freezing of a product does not require a new mark on an already marked product.

3. An identification mark is not necessary on packs of eggs when a packing centre code is applied in accordance with Regulation (EC) No 1028/2006[1].'

(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:'

Deleted: A new mark must only be applied to a product when it is handled exposed after removal of its packaging and/or wrapping is removed or when it is further processed in another establishment

Deleted: on packs of eggs

[1] OJ L 186, 7.7.2006, p. 1.

SANCO/44/2008 Rev. 1

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2008 Deleted: 8.1

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 consumption [1], 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.*

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

[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).

Done at Brussels, […]

For the Commission
[…]
Member of the Commission

ANNEX

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

1. In Chapter III of Section III to Annex I, 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 tasks 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 shall 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.]'

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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.'

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

'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;

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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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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2008

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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 origin[1], 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 intial 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 foodstuffs[2] 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 and to amend Regulation (EC) No 853/2004 accordingly.

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

[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

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 handling which requires it to be thawed, food business operators must ensure that frozen food of animal origin intended for human consumption meets the following requirements.

1. (a) Relevant information must be made available in an appropriate form to the food business operator to whom food is supplied and, upon request, to the competent authority.

   (b) In the case of carcases of all animals and half carcases, half carcases cut into no more than three wholesale cuts, and quarters of domestic ungulates and wild game, the relevant information must be borne directly on the food.

2. The relevant information referred to in point 1 must comprise:

   (a) The date of production or, in the case of the food referred to in point 1(b), the date of slaughter,

   (b) The date of freezing, if different from the date of production. However, where the food is thawed and refrozen, information on the date on which it was initially frozen and subsequent dates of refreezing must be made available.

   (c) The date of minimum durability.

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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Deleted: Food

Deleted: Until the stage at which a food is labelled in accordance with Directive 2000/13/EC or used for further processing, relevant

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ANNEX (SANCO/1489/2007 Rev. 5, Danish proposal)

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 handling which requires it to be thawed, 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 food is supplied and, upon request, to the competent authority. The relevant information must contain a reference enabling the lot or batch to be identified.

2. The relevant information referred to in point 1 must comprise:

   (a) The date of production or, in the case of fresh meat, minced meat, mechanically separated meat or meat preparations, the date of slaughter. If a lot or batch consists of different production dates, the oldest date must be given.

   (b) The date of freezing, if different from the date of production. However, where the food is thawed and refrozen, information on the date on which it was initially frozen and subsequent dates of refreezing must be made available.

   (c) The date of minimum durability.

3. The dates referred to in point 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."

Deleted: products

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Deleted: (a)

Deleted: Until the stage at which a food is labelled in accordance with Directive 2000/13/EC or used for further processing, relevant

Deleted: (b) . In the case of carcases of all animals, and half carcases, half carcases cut into no more than three wholesale cuts, and quarters of domestic ungulates and wild game, the relevant information must be borne directly on the food.

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COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 14.04.2008

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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 safety[1], 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.

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(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 belongs[2], Council Regulation (EEC) No 1906/90 on certain marketing standards for poultry[3], Commission Regulation (EEC) No 1538/91 introducing detailed rules for implementing Regulation (EEC) No 1906/90 on certain marketing standards for poultrymeat[4] 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 820/97[5].

(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 852/2004[6], (EC) No 853/2004[7] and (EC) No 854/2004[8] 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.

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(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.

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[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 L320, 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 consignor if different from the food business operator supplying the food,

(d) The name and address of the consignee if different from the food business operator to whom the food is being sent,

(e) A reference enabling the lot or batch to be identified, and

(f) The date of dispatch.

Deleted: The lot or batch number, as referred to in Article 1(2) of Directive 89/396/EEC or in Article 1 a of Regulation (EEC) No 1538/91

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

03/04/2008

MICROBIOLOGICAL MONITORING OF BIVALVE MOLLUSCS AREAS: DRAFT DOCUMENT SUBMITTED BY THE COMMUNITY REFERENCE LABORATORY FOR BACTERIOLOGICAL AND VIRAL MONITORING OF BIVALVE MOLLUSCS

Microbiological monitoring of bivalve molluscs areas:
Draft document submitted by the Community Reference Laboratory for Bacteriological and Viral Monitoring of Bivalve Molluscs

The Community Reference Laboratory (CRL) for bacteriological and viral monitoring of bivalve molluscs has submitted the enclosed document to the Commission. The document has been titled "Community Guide to the Principles of Good Practice for the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas with regard to Regulation 854/2004".

The document is a compressed and simplified version of the more extensive document called "Microbiological Monitoring of Bivalve Mollusc Harvesting Areas - Guide to Good Practice: Technical Application" which is available at www.crlcefas.org for those being registered for the information centre part of this web-site. This document is already used as guidance by competent authorities.

The Commission seeks the opinion of the Member States for how the draft document should be handled. Some alternatives are listed below. It should be noted that, whatever alternative is chosen, the document will not have the status as Community Legislation.

(I) Develop the document into a **"Community Guide"** as referred to in Article 9 of Regulation (EC) No 852/2004

(II) Develop the document into a **"Guidance Document"** in line with other Commission Guidance Documents to the Hygiene Regulations

(III) Publish the document on the SANCO website as a **"Guideline developed by the CRL"**

(IV) Leave it to the CRL to publish the document on its own website

"Community Guide"

Article 9 of Regulation (EC) No 852/2004 provides requirements for development of Community Guides to good practice for hygiene, which food business operators may use as an aid to compliance with their obligations under the hygiene regulations. These requirements are further elaborated on in the "Guidelines for the development of Community guides".

http://ec.europa.eu/food/food/biosafety/hygienelegislation/guidelines_good_practice_en.pdf

The enclosed document has not been developed according to these procedures. Inter alia, it has not been developed by or in consultation with appropriate representatives of European food business sectors and other interested parties. Furthermore, the document targets Competent Authorities, not food business operators.

"Guidance document"

The Commission has issued several Guidance Documents that aim to give guidance on the implementation of the food hygiene requirements and on related subjects. Guidance Documents are both directed at food business operators and competent authorities. They have been established for information purposes only, and have not been adopted or in any way approved by the European Commission.

The content of the enclosed document would fit in a Commission guidance document. However, the layout has to be modified if this alternative is chosen.

"Guideline developed by the CRL published on DG SANCOs webpage"

The Community Reference Laboratory for Parasites has developed two similar documents:

- Guideline for the detection of Trichinella larvae at the slaughterhouse or connected laboratory in a Quality Assurance System.

- Guideline for the identification and development of sampling methods and design of suitable protocols for monitoring of Trichinella infection in indicator species.

These have been published at DG SANCO's website:
http://ec.europa.eu/food/food/biosafety/hygienelegislation/trichinella_en.htm

Enclosure: Document "Community Guide to the Principles of Good Practice for the Microbiological Monitoring of Bivalve Mollusc Harvesting Areas with regard to Regulation 854/2004, Issue 1, October 2007"

Adobe Acrobat Document

03/04/2008

Elements of a draft Proposal as regards Fish Oil for Human Consumption

Elements of a Draft Proposal as regards Fish Oil for Human Consumption

Following the discussions in the meeting 6 March 2008 of the Working Group on Implementing Measures of the Hygiene Regulations several Member States have provided written comments as requested in the meeting.

Furthermore, the following organisations have provided the enclosed a coordinated input on the issue: (the document which was attached below is available as an annex)

- AIPCE-CEN (European Fish Processors Association and the Federation of National Organisations of Importers and Exporters of Fish)
- EHPM (European Federation of Associations of Health Product Manufacturers)
- GOED (Global Organisation for EPA and DHA Omega-3s)
- IFFO (International Fishmeal and Fish Oil Organisation)

An updated draft proposal on fish oil for human consumption has been prepared for the meeting 14 April 2008. The main features of the proposal are explained below.

The draft contains a proposal for a time-limit of up to 36 hours on certain conditions before processing for material from vessels not designed and equipped to preserve fishery products at the temperatures laid down in Chapter VII, Section VIII of Annex III to Regulation (EC) No 853/2004.

Such vessels may today deliver their catch for human consumption up to 24 hours without chilling after being loaded on the boat, provided that certain criteria are met. One of the requirements is that raw material must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

Such raw material is processed continuously upon arrival at establishments producing fish oil for human consumption. However, due to the structure of some fisheries queuing of boats may prevent that the raw material is processed immediately. Fish oil from such establishment has up to now been accepted for human consumption.

Some of the contributions from Member States conclude that the proposed 36 hours time-limit are less strict compared to requirements for animal by-products. According to the provisions of Regulation (EC) No 1774/2002 category 3 materials for pet food etc. does not need to be chilled if processed within 24 hours after leaving the establishment where it is collected.

The proposed 36 hours time-limit is, however, stricter. If a food business operator for some reason wants to pass on not chilled fish immediately to a category 3 material establishment he may do so. The material then has to be processed as category 3 material within 24+24=48 hours after the catch, if it is not refrigerated.

To ensure the freshness of raw fish for the production of fish oil for human consumption it is proposed to introduce a limit of total viable nitrogen (TVB-N) for material used directly for the preparation of fish oil, involving changes in Annex II to Commission Regulation (EC) No 2074/2005. See Annex II of the draft proposal.

Raw materials from vessels that are not equipped to chill fresh fishery products, and which are not chilled immediately after landing can only be processed up to 36 hours after the catch provided that the total viable basic nitrogen (TVB-N) is below 100 mg nitrogen/100 g. The basis for proposing this level can be found in the coordinated input from the stakeholder organisations. Based on studies of raw material used to produce high quality crude oil AIPCE-CEN, EHPM, GOED and IFFO propose a value of TVN in fish of between 100 to 110 mg of N/100 g.

Various levels of TVB-N have already been accepted in Chapter II, Section II of Annex II to Commission Regulation (EC) No 2074/2005 depending on the raw material. Furthermore, for species having a higher TVB-N in the fresh fish a TVB-N limit has not been established.

Chapter V, Section VIII of Annex III to Regulation (EC) No 853/2004 lists health standards for fishery products. Point B (Histamine) and D (Parasites) are not applicable for fish that are used directly for the preparation of fish oil intended for human consumption.

Point 3 in Annex 1 of the draft proposal has been modified to clarify that food grade fish oil and fish meal may also be used as raw material for products not intended for human consumption. Guidance has to be provided in an appropriate form on the question of multiple approvals after various Regulations.

In the previous draft criteria were indicated for parameters for crude oil and for oil put on the market for the final consumer to ensure food safety. The stakeholder organisations have at all the times pointed out that there are little or no correlations between these parameters and the hygienic status of the raw material and that these parameters are quality parameters. An introduction of the TVB-N for fish used directly for the production of fish oil under the 36 hours-regime reduces the need for end product criteria.

Only parameters for fish oil put on the market for the final consumer are now included in the draft. Though the peroxide value, anisidine value and totox may be related to rancidity issues, more knowledge on food safety related to rancidity is needed before rancidity parameters can be fixed. Total insoluble impurities have also been excluded as there is no harmonised definition of and method for this parameter.

Parameters are proposed for free fatty acid in triglycerides and ethyl esters and water content in fish oil to be put on the market for the final consumer. The footnote "Chemical bonded water is not included as part of the water content" has been added as certain fish oils, such as krill oil, the water content may be higher as water is bound to phospholipids.

AIPCE - CEP

Association des Industries du Poisson de l'U.E./E.U. Fish Processors Association
Comité des Organisations Nationales des Importateurs et Exportateurs de Poisson de l'U.E./E.U. Federation of National Organisations of Importers and Exporters of Fish

AIPCE/2008/8 Brussels, April 2nd, 2008

M. Lennart Johanson
European Commission
DG SANCO-E2
Rue Belliard 232, B232 04/08
1040 Brussels
Belgium

Joint position paper on a limit of TVN as a parameter for the freshness of raw fish for the production of fish oil for human consumption and on minimal requirements for refined products placed on the market for the final consumer.

Dear Mr. Johanson,

AIPCE-CEP, EHPM, GOED and IFFO appreciate the discussion within the Working Group regarding the hygiene regulation applicable to fish oil for human consumption. We would like the Commission and Member States to consider the following joint position, addressing the use of TVN as a parameter for the freshness of raw fish for the production of fish oil for human consumption. In addition, we will contribute to the process of adopting the minimum requirements, based on a few parameters, of fish oil placed on the market for the final consumer.

As far as we have understood, the aim of the Commission is, by these parameters to secure, within the framework of the hygiene regulations, sufficient *freshness* of the raw material to be used in the crude oil production as well as securing satisfactory minimum standard of the end products placed on the market for the final consumer.

The freshness requirement and TVN-B as a measurable parameter

Our position is still to support the '36 hours' criteria in order to simplify the system well within the objective of securing safe fish oil. This opinion is based on current practice, pragmatic reality - that will not change as the sourcing of the fish oil for human consumption sector is a derivate of more lucrative productions -, and also taking into account the TVN parameters, among other elements, but not naming them specifically as they are non-accurate quality criteria.

Firstly, we would like to stress that TVN parameters are a quality criteria, but recognising the use of TVN as an indicator of freshness used elsewhere in the hygiene package, we

consider TVN as a proper choice also for the fish caught for direct use in crude oil production. However, it has to be underlined that the TVN is only a parameter showing compliance with the *freshness requirement* according to Regulation (EC) No 853/2004 and not a predictive value of the quality of the crude oil.

It must be stressed that there is no or very little consistent correlation between the TVB-N value of a given batch of raw material and the chemical characteristics for the oil, like FFA (free fatty acid), peroxide values and anisidin numbers in the crude oil produced from that batch. The variation in the amount of stomach content in the fish will contribute to this lack of correlation.

In addition the TVN parameters cannot be generalised as they are specific for each species at the same level of freshness, and there are also no harmonised or accurate method for evaluation.

The current common position has been developed on the basis of a report made by FHL-MARING and of the experience of our different associations covering almost the entire sector of fish oil. Concerning information on conditions in Peru, we refer to the documents from FHL already submitted to the Commission.

TVN-data from Peru

Additional information to the table below.

Of the 13 fishmeal and fish oil establishments that were visited by FHL-MARING, each establishment had several numbered storage bins for the raw material. At most 8 bins were counted. The storage was usually concrete covered by a roof, with open lateral gaps between the top of the bin and the roof.

Each bin had records showing the elapsed time from when the fish was caught to when the raw material is processed. This record is updated on an hourly basis. Also recorded is which vessels delivered the fish in each specific storage bin. At some establishments those records are also computerised.

The material is as a general rule processed within 24 hours of the catch. But if there are many landings at the same time the storage time can be longer, as was found during the visit. The time from the catch (TDC) to processing was on average 20 hours, the longest TDC was said to be 20 hours at one establishment, and between 35 - 40 hours in others. One establishment reported that 60 hours was the longest recorded TDC to processing.

As an indication, some TDC and corresponding TVN values are listed. It must be noted that different establishments provide these values and FHL-MARING did not check whether the methods used are directly comparable. These numbers can only give a general indication on the levels of TVN.

Table 1: TDC and corresponding TVN values

TDC (hours from catch)	TVN (mg/100g)
8	24
12	30 -36
17	31
29	46
32	50 - 60
40	100

Because the evolution of TVN value is different from one species to another, and as it is impossible to discriminate the fish during or after the catch, the level set should be high enough to cover the species used as raw material for the current production of fish oil for human consumption.

TVN parameter - 100 to 110 mg of N/100g

Based on the above-mentioned assumptions and focusing on documented experiences of raw material used to produce high quality crude oil, the industry **(AIPCE-CEN, EHPM, GOED and IFFO) suggests a value of TVN in raw material (fish) of between 100 to 110 mg of N/100 g.**

Compared to other fish products placed on the market intended for human consumption, a TVN at the proposed level is not significantly higher in spite of the values adopted for fresh fish at the time of landing meant for human consumption at a later stage (Cf. Commission Regulation 2074/2005, annex II, section II).

Iced ling and tusk intended for drying and treating with lye before they are ready for the consumers, have values of TVB-N between 70 and 93 mg N / 100 g at the time of landing.

Dried fish (stockfish) have values around 220 mg N / 100 g, and after steeping the values will be approx. 50-60 depending of the steeping process.

Sugar-salted herring have values around 75 mg N / 100 g when placed on the market as a ready to eat product.

All these products are safe food produced within the framework of the hygiene regulations.

Regarding fish oil, our data and experience show that high quality and safe refined oils for human consumption can be produced from crude oils with TVN values up to the suggested level at 100 to 110 mg of N/100 g in the raw material.

It is important to bear in mind that this raw material is not intended for direct human consumption. Within the framework of the hygiene regulations, the assessment of the freshness of the raw material - based on a quality criteria - has to be **adjusted to the characteristics of the process the material will be subject to**, in order for the product to be ready for human consumption**,**

Raw fish for the production of fish oil for human consumption passes through two rough processes including one refining of the raw oil. It is therefore relevant to have limits of TVB-N for raw fish oil at a **significant higher level to those adopted for some fish raw material that does not undergo these processes**, before going to the final consumer (Cf. Commission Regulation 2074/2005, annex II, section II).

Having a **TVN limit of 100 to 110 mg of N/100 g** in the specific case of fish oil for human consumption production is therefore **based on science and concrete reality of the sector**.

This TVN limit would be applicable to crude fish oils extracted from fish within the EEA, and also to crude fish oils extracted in Third Countries. This will ensure a level playing field for all global producers of crude fish oil outside the EEA**. This will also ensure the sourcing of the European production of food supplements.**

Minimum requirements for the refined fish oil to be placed on the market for the final consumer

We support the current aim of the Commission not to propose standard requirements for intermediate products between crude fish oil and the final products to be placed on the market for the final consumer.

We also agree with the proposal put forward by the UK concerning the five different parameters listed in the table below. It is important to note that the UK proposal misquotes acid value (Acid value is expressed at mgKOH/g and not as %) instead of the free fatty acid proposed by the commission, we believe the intention was to set a Free Fatty Acid value of 2% consistent with the Commission's original proposal for the table.

Table 2: Minimum requirements for fish oil placed on the market for the final consumer

	Fish oil to be placed on the market for the final consumer Minimum requirements
Peroxide value (PV)	≤20 meq/kg
Anisidine value (AnV)	≤50
Free Fatty Acid content	≤ 2 %[1]
Total insoluble impurities[2]	≤0,2 %
Water content[3]	≤0,3 %

[1] Should only applies to triglycerides and ethyl esters

[2] Method for determination must be provided by the Commission prior to this parameter being accepted/included

[3] Limits proposed need to be verified as broad enough to cover the range of commercial materials available (or if this is not possible should be deleted.

However, for the sake of clarification and consistency of the implementation and enforcement we will stress the need to explicitly express in the regulation that the values listed in the table, shall apply *at the time of the placing on the market* by the producer and without prejudice to labeling requirements including assessment of shelf-life.

In addition, the methods to be used by the competent authorities to assess compliance have to be specified.

Yours Sincerely,

AIPCE-CEP / EHPM / GOED / IFFO

- AIPCE-CEP (European Fish Processors Association and the Federation of National Organisations of Importers and Exporters of Fish)
- EHPM (European Federation of Associations of Health Product Manufacturers)
- GOED (Global Organisation for EPA and DHA Omega-3s)
- IFFO (International Fishmeal and Fish Oil Organisation)

SANCO/XX/2008 rev1

WORKING DOCUMENT

DOES NOT NECESSARILY REPRESENT THE OPINION OF THE COMMISSION SERVICES

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.4.2008

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

Deleted: *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

ANNEX I

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

1 In Chapter III, Part E is hereby deleted;

2 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.

Deleted: (a) . in the case of fish that are directly used for that purpose:

Deleted: (i) . come from vessels registered pursuant to Regulation (EC) No 852/2004;¶
(ii) be transported and stored in hygienic conditions and chilled as soon as possible, unless they are processed within 36 hours after loading.¶

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Deleted: in the case of other raw materials:

Deleted: and remain at the temperatures specified in Chapter VII.

(b) By way of derogation from the provisions of Point 1 (a)(iv), when fish 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. Fish oil to be placed on the market for the final consumer must not exceed the following requirements:

Free Fatty Acid content	≤ 2 %[1]
Water content	≤0,3 %[2]

[1] Does only apply to triglycerides and ethyl esters

[2] Chemical bonded water is not included as part of the water content.

3 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:

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Formatted: Point 2

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Deleted: (b) . the crude oil obtained in accordance with point (a) is subject, where appropriate, to further processing, refining and purification steps in order to improve its physico-chemical quality before being placed on the market for the final consumer.¶

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Deleted: provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption.

Deleted: depending on the type

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Formatted: Point 3

Deleted: 4. Fish oil, depending on the type, must comply with the following requirements: ... [1]

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Deleted: , C

'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) 100 mg of nitrogen/100 g of whole fish for fish 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.

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.'

Deleted: belonging to the species categories listed in Chapter II

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4. Fish oil, depending on the type, must comply with the following requirements:	Crude fish oil for further processing	Fish oil to be placed on the market for the final consumer
Peroxide value (AV)	[10 meq/kg]	[10 meq/kg]
Anisidine value (PV)	[30 meq/kg]	[30 meq/kg]
Totox (AV + 2 x PV)	[ ]	[ ]
Free fatty acid	[5 %]	[2 %]
Total insoluble impurities	[0,5 %]	[0,2 %]
Stability test (acceleration test) for oxidation	[ ]	[ ]
Water content	[1 %]	[0,3 %]

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Brussels, 14 April 2008

Draft

Guidelines on the registration of national guides to good practice

regarding Regulation (EC) No 852/2004

Introduction

Regulation (EC) No 852/2004 on the hygiene of foodstuffs[1] was adopted on 29 April 2004. It lays down general hygiene requirements to be respected by food businesses at all stages of the food chain.

Articles 7-9 of the Regulation provide for the development of guides to good practice for hygiene.

Such guides enable food business sectors to describe in more detail how operators can comply with the legal requirements which are expressed in more general terms in the Regulation and help them to implement good hygiene practices tailored to the characteristics of their production.

According to Regulation (EC) No 852/2004, two types of guides may be developed depending on the level at which they are established: national and Community levels. When national guides are developed, they have to be assessed by national authorities in order to ensure suitability of their contents with Community legislation and their practicability for the sectors to which they refer. Member States must thereafter forward to the Commission the national guides they agreed upon.

On several occasions, the Commission indicated its intention to examine how to improve the availability to the list of national guides to good practice developed in the different Member States.

In the interest of transparency and in accordance with Article 8 (4) of Regulation (EC) No 852/2004, the Commission created a register on its website which is available at the following address:

http://ec.europa.eu/foog/food/biosafety/hygienelegislation/good_practice_en.htm

http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

Based on experience, it was noted that Member States use different ways when communicating national guides to good practice to the Commission: a paper version in the national language, a translation into English, an electronic version, an updated list of national guides or a simple link to the website where such information can be found. This does not facilitate the management of the register at Community level and might lead to confusion or involuntary mistakes.

The present document aims to assist the competent authorities of the Member States in sending their national guides to the Commission in a uniform way.

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[1] OJ No L 226, 25.6.2004, p. 3

[1] OJ No L 226, 25.6.2004, p. 3

Scope

These guidelines apply to the registration system for national guides, as defined in Article 8 (4) of the above referred Regulation regarding rules concerning hygiene of foodstuffs.

It is intended for each competent authority which is responsible for forwarding the national guides to good practice to the Commission.

Although the Regulation requires Member States to forward physical copies of national guides to the Commission, it is proposed now to enable Member States to initially submit only certain information concerning their guides, provided that they ensure that copies of such guides can be sent to the Commission on request.

In order to manage the register efficiently and to reduce the administrative burden, it is therefore proposed to codify the procedure and the information that should be submitted by Member States when informing the Commission about national guides.

A similar approach will be used for guides to good practice developed in the feed sector. A specific register will be created to that end. This register will include all guides based on Article 21 of Regulation (EC) No 183/2005.

Information to be transmitted

The relevant information shall comprise:

Original title

The original title of the guide is to be given in the official language of the Member State.

Title in English

The original title of the guide is to be given in its English translation.

Country

The name of the country (Member State) of origin is to be given as a two-letter code in accordance with the relevant ISO standard. These codes are AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK and UK.

Language

The language or languages in which the guide is available is to be given as the abbreviation: AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK and UK.

Publisher / Author

The author is the sector which is responsible for the respective guide to good practice. It should to be given in the official language of the Member State; e.g. an association or a working group.

Edition

The edition should to be given as the date of publishing. If a national guide has been changed, the date of the last up-date is to be provided.

ISBN / ISSN

If the national guide to good practice is published with an ISBN/ISSN number, this should be provided.

Contact

Internet or other contact details should be provided indicating where the guides can be assessed.

Key-words

Relevant key-words should to be used and given in English in order to ease the search for a relevant guide. Relevant key-words are listed in Annex I. The list might be updated after discussion with all Member States.

Procedure

The relevant information should be communicated preferably electronically to the Commission using the table in Annex II which can also to be found at the following address:

http://ec.europa.eu/food/food/biosafety/hygienelegislation/register_national_guides_en.pdf

The relevant information should to be sent electronically to the following mailbox:

Sanco-NationalguidesGHP@ec.europa.eu

Annex I

Key words used in the register on national guides to good practice

I- Food sector

Category	Special subcategory used
Bakery	Bred
	Cake
Beverages	Beverages (alcoholic)
	Beverages (soft)
	Beverage dispensing systems
	Beer
	Spirits drinks
	Wine
Brewery	Malt
Catering	Canteen (sport)
	Catering (agritourism)
	Catering (collective nourishment)
	Catering (ferry boat)
	Catering (hospital)
	Catering (hotel)
	Catering (kindergarten)
	Catering (restaurant)
	Catering (school)
	Catering (social centre)
Cereals	Rice
Chocolate	
Cleaning and disinfection	
Coffee	
Confectionery	
Dispensing	Dispensing and vending
	Mail Order
Distribution	Distribution (automatic)
	Distribution (beer)
	Distribution (cold store)
	Distribution (dried mushrooms)
	Distribution (food additives, flavourings)
	Distribution (large-scale)
	Distribution (quick-frozen food)
	Distribution (wholesale)

Category	Special subcategory used
Eggs	
Egg products	
Fats and oil	Fats
	Margarine
	Oil
	Olive oil
Fishery	Fishing vessels
	Fish products
	Fish products, Aquaculture
Food industry	
Food packaging	
Food processing	
Food processing (at farm level)	
Food supplements	
Food for special health purposes	
Fresh products	
Fruit	
Fruit and Vegetables	
Fruit juices	
Gastronomy	
HACCP	
Honey	
Ice-cream	
Local markets	
Management	
Markets and Fairs	Open air fairs and Exhibitions
Meat	Meat (poultry)
	Butchers shop
	Slaughterhouse
Meat products	Meat products (poultry)
Microbiology	
Milk	Automatic milking system
Milk products	Cheese
Milling industry	Flour mills
	Milling products
	Milling products (mais)
	Milling products (wind-water mills)

Category	Special subcategory used
Pasta	
Pastry industry	
Personal hygiene	
Pest control	
Pizza	
Prepared meals	
Retail	Petrol-station stores
	Retail (beverages)
	Retail (cheese)
	Retail (delicatessen)
	Retail (fishery products)
	Retail (fruit, vegetables)
	Retail (mobile establishments)
	Retail (self-control)
	Retail (small foodstuffs)
	Retail (traceability)
	Retail (wholesale)
	Retail (supermarkets)
	Supermarket
	Supermarket (meat)
Salt	
Seeds	
Self Service, unpacked food	
Soups, Bouillon	
Storage	
Sugar	
Temperature	
Training	Hygiene training
Transport	Shipping
	Transport (barge)
	Transport (small boats)
	Transport and distribution
Vegetables	Mushrooms
	Potatoes
	Preserved vegetables
	Processed tomatoes
	Vegetables (heat treatment)
Vinegar	
Water	Bottled water
	Mineral water

Category	Special subcategory used
Wholesale	Wholesale (fruit, vegetables)
Working clothes	

Feed sector and primary production

Category	Special subcategory used
Chicken Primary Production	
Compound feedingstuffs	
Farm	
Feed	
Laying hens	
Medicated feedingstuffs	
Pesticides	
Plant Primary production	
Premixtures	
Raw milk	

Annex II

REGISTER OF NATIONAL GUIDES TO GOOD HYGIENE PRACTICE
REGISTRE DES GUIDES NATIONAUX DE BONNES PRATIQUES HYGIENIQUES
REGISTER FÜR EINZELSTAATLICHE LEITLINIEN FÜR DIE GUTE HYGIENEPRAXIS

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