

To: Interested Parties

9 May 2008

Reference: FIN 06/2008

Dear Sir or Madam

FURTHER UPDATE ON THE EUROPEAN COMMISSION'S PROPOSALS TO AMEND THE HYGIENE RULES FOR FISH OIL

Further to previous letters on the Commission's proposals to amend the hygiene rules for fish oil (references FINS 12/2007, 02/2008, 03/2008 and 05/2008) I am writing to inform you that the next meeting of the Commission's Working Group on the hygiene legislation to be held on Monday 19 May, is likely to be the last detailed discussion on the proposals to amend the hygiene rules for fish oil before the current derogation expires at the end of October 2008. Once agreed the proposals will be presented to the Standing Committee on the Food Chain and Animal Health for voting.

I attach as annexes the following 2 documents:

- Revision 2 of the draft proposal as regards fish oil for human consumption. This document sets out the changes which have been made to Draft Commission Regulation.
- The latest draft Commission Regulation to amend Annex III of Regulation (EC) No 853/2004

Interested parties are asked to consider these two attachments and provide any comments to my colleague Mark Ball no later than **12 noon on Friday 16 May**. Mark's email address is Mark.Ball@foodstandards.gsi.gov.uk

I hope that this is helpful but if you need any further information please let me know. The Agency's imports section on our website can be found at <http://www.food.gov.uk/imports>

Importers may also register for the Agency's on-line Guidance and Regulatory Advice on Import Legislation system (GRAIL) by following this link: <https://grail.foodapps.co.uk/grail/general/home.aspx>

Yours sincerely

Ian Grist
Imported Food Branch
Enforcement Support Division

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 rev~~2~~

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

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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;

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3 Chapter IV is replaced by the following:

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'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 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.'

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Free Fatty Acid content ... [1]

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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.

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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.'

4. Fish oil to be placed on the market for the final consumer must not exceed the following requirements:

Free Fatty Acid content	$\leq 2\%$ ¹
Water content	$\leq 0,3\%$ ²

¹ Does only apply to triglycerides and ethyl esters

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