

To: Interested Parties

17 April 2008

Reference: FIN 05/2008

Dear Sir or Madam

### **FURTHER UPDATE ON EUROPEAN COMMISSION PROPOSAL TO AMEND HYGIENE RULES FOR FISH OIL**

This letter provides an update on progress of the negotiations fish oil import conditions led by the European Commission and builds on information contained in previous FIN letters on the subject which are available on the Food Standards Agency website.

Last week the European Commission provided further revised proposals for fish oil hygiene which, if agreed, will apply to fish oil for human consumption produced within the EU and imported from non-EU (third) countries. For ease of reference these are provided at Annex I. (Please note that this document is a working document and does not necessarily reflect the views of the European Commission or the Food Standards Agency).

These were presented to the main hygiene working group on Monday 18 April for discussion. This group includes representatives from all Member States, Norway and Iceland and is chaired by the European Commission.

I am very grateful to those stakeholders who provided views at very short notice ahead of that meeting to help inform the UK position.

Significant discussion points included:

- The proposed 36 hour time period (from loading to processing) derogation for raw material for production of fish oil. It is likely that this will be retained in the next version of the proposals, subject to TVB-N criteria.
- Use of TVB-N for raw material for production of fish oil and establishing the limit for this parameter. This parameter is likely to be retained with the limit being reduced to 60mgN/100g with the possibility of Member States allowing higher limits for certain species.
- Registration or approval of vessels. This is likely to be retained in the next version of the proposals. The Commission clarified that the intention is that



unless required to be approved and listed in Community law e.g. freezer or factory vessels, registration of fishing vessels is a more straightforward procedure with national lists being maintained (this includes application in third countries).

- Free fatty acid (FFA) limits. There was a proposal to reduce the allowed limit to 0.5% (from 2%). It is not clear if the revised proposal will retain the 2% limit or not. At the meeting the UK requested that FFA limits should only apply to triglycerides and ethyl esters, although this was not well supported.
- At the meeting the UK also requested that further consideration be given to the application of requirements in the production of liver oils.

The key outcomes of these discussions are:

- The Commission will refine the proposals, seek additional written comments from Member States and continue discussion at the next hygiene working group scheduled for 19 May.
- The proposals will then be finalised and presented to the Standing Committee on the Food Chain and Animal Health (SCoFCAH) in May for discussion, prior to a vote on the proposals being held at the SCoFCAH meeting in July.

When the next draft proposals are available the Agency will circulate them for your views prior to providing a response.

If you wish to discuss any issues arising from this in the interim then please do not hesitate to contact [mark.ball@foodstandards.gsi.gov.uk](mailto:mark.ball@foodstandards.gsi.gov.uk) or telephone 0207 276 8018.

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

Annex I - Draft Proposals for fish oil hygiene

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DOES NOT NECESSARILY REPRESENT THE OPINION OF THE  
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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**

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THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,  
Having regard to Regulation (EC) No 853/2004 of the European Parliament and the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin<sup>1</sup>, 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.](#)

*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*.

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<sup>1</sup> 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).

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*

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## 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.
  - (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	$\leq 2 \%^{1}$
Water content	$\leq 0,3 \%^{2}$

<sup>1</sup> Does only apply to triglycerides and ethyl esters

<sup>2</sup> 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:

- '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.'