

The EC Hygiene Regulations on Fish Oil intended for Human Consumption and Listing of Third Country Establishments

The EC Hygiene Regulations on Fish Oil intended for Human Consumption

Specific requirements for production of fish oil for human consumption can be found in:

- Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004 as amended by Commission Regulation (EC) No 1020/2008
- Annex II to Regulation (EC) No 2074/2005 as amended by Commission Regulation (EC) No 1022/2008
- Article 7 of Regulation (EC) No 2076/2005 as amended by Commission Regulation (EC) No 1023/2008

Fish oil intended for human consumption must meet the requirements for fishery products found in the hygiene Regulations. This means that the raw materials and the fish oil:

- Must come from establishments, including vessels, registered or approved pursuant to the hygiene Regulations.
- Derive from fishery products which are fit for human consumption and are handled throughout the food chain as such. Animal by-products and fishery products not fit for human consumption cannot be used as raw material for fish oil for human consumption.

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.

The raw material must be chilled as soon as possible after the catch. When chilling is not possible on board the vessel the raw material must undergo chilling as soon as possible after landing and be stored at a temperature approaching that of melting ice.

However, by way of derogation the food business operator may refrain from chilling the fishery products, when whole fishery products are used directly in the preparation of fish oil for human consumption, and the raw material is processed within 36 hours after the catch, provided that the freshness criteria laid down are met.

The freshness criteria are based on the total volatile basic nitrogen (TVB-N), which shall not exceed 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption. However, where the raw material is still fit for human consumption the competent authority may set limits at a higher level for certain species.

It is the responsibility of food business operators to carry out specific checks that the total volatile basic nitrogen (TVB-N) requirements are met through its procedures based on the HACCP principles.

Pending the establishment of specific Community legislation on hygienic parameters for fish oil to be placed on the market for the final consumer food business operators must ensure compliance with national hygiene rules where such exist, including rancidity parameters.

Additional information regarding fish oil that is to be imported from third countries into the EU

When importing fish oil as such (both crude oil and oil ready to be put on the market) for human consumption from a third country after 30 April 2009 the country must be listed in accordance with Article 11 of Regulation (EC) 854/2004 for import of fishery products.

Furthermore, the third country establishment from which that product was dispatched, and in which it was obtained or prepared must appear on the lists of establishment from which import of specific products of animal origin are permitted. (See https://sanco.ec.europa.eu/traces/output/listsPerActivity_en.htm#)

The third country's competent authority must ensure that that the whole production chain, including fishing vessels, and the raw materials comply with the EU requirements. However, establishments and vessels not exporting to the EU shall not be included on the EU lists.

A consignment of fish oil destined for human consumption that is imported into the EU shall be accompanied by the health certificate for fishery products as laid down in Commission Regulation (EC) No 2074/2005 as amended by Commission Regulations (EC) Nos 1664/2006 and 1250/2008.

Certain third countries exporting fish oil to the EU have experienced practical difficulties in adjusting the processing conditions in fish oil producing establishments in order to comply with the EU Regulations. Therefore transitional arrangements are in place to give the possibility for such establishments to adjust to the requirements.

During the transitional period, now extended until 30 April 2009, food business operators in Member States may continue to import fish oil from establishments in third countries under the regimes that were in place in that Member State prior to requirements for fish oil being included in the hygiene Regulations.

In such cases the consignment shall be accompanied by the certificate for such consignments issued in accordance with the national of rules of the Member State that existed before the EU Regulations came into force. Consignments of fish oil accompanied by such a certificate completed and signed prior to 30 April 2009 may be imported into a Member State of the Community until 30 June 2009.