Guide to good practice

For establishments producing fish oil intended for human consumption

Implementing relevant EC hygiene regulations
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Introduction

Fish oil is produced worldwide and the raw material is mainly whole fishery products caught from the open sea. The raw material may also be aquaculture fish or parts from both wild and aquaculture fish. This guidance document focuses mainly on whole fish caught at the open sea as a raw material, but it is also appropriate for other raw materials.

World production of fish oil

The world production of fish oil was almost 1 million tons in 2005. South America, Chile and Peru are by far the largest producers with approx. 40% of the total production, followed by Denmark (90,000 tons), Iceland (60,000 tons) and Norway (30,000 tons). Aquaculture is a large industry worldwide and there is a great demand for fish oil for feeding purposes. Most of the world production of fish oil is destined as a feed ingredients in compound fish feed.

As marine fatty acids are valuable and healthy nutritional ingredients, some of the fish oil is also further processed to meet requirements for human consumption. The products could for example be nutritional supplements, as Omega-3 fish oils, or they could be ingredients in foodstuff, replacing animal fat.

Fish oil is often one of the two end products of the fishmeal production. As an example, out of 1000 kg wild fat fish as raw material, the end product will be approximately 250 kg fishmeal and 67 kg fish oil. As almost 100% of the fishmeal is used for feeding purposes, this document focuses on the additional basic requirements that are to be met by establishment producing fish oil for human consumption compared to when the fish oil is only intended for feeding purposes.

Fish oil intended for human consumption

Fish oil that is intended for human consumption has to come from an establishment approved by the competent authority for human consumption, and the raw material has to derive from fishery products which are fit for human consumption.

As fish oil is of animal origin there are quite detailed hygiene regulations applying to the production. Naturally, there are separate hygiene rules depended on whether the product is destined for human consumption or for feeding purposes. Fish oil produced at an establishment approved for human consumption is allowed to be used for feeding purposes. Fish oil produced at an establishment only approved according to the Regulation (EC) No 1774/2002 for animal by-products (ABP) is never allowed to be used for human consumption.

Guide to good practice

This guidance document to good practice has been developed by the industry with regard to the EU hygiene regulations for the production of fish oil intended for human consumption. The purpose is to be suitable for food businesses and competent authorities as a guide to compliance with article 3, 4, and 5 of Regulation (EC) No 852/2004 and relevant parts of Regulation (EC) No 853/2004.

This guide is aiming at to be in accordance with article 8 in Regulation (EC) No 852/2004 on the hygiene of foodstuffs, to be assessed by the competent authority in EEC countries where this would be relevant.

Regulatory framework

Feeding purposes

Regulation (EC) No 1774/2002 (ABP) is laying down health rules concerning animal by-products not intended for human consumption. Only Category 3 material as listed in article 6 is allowed for the production of processed animal proteins to be used as feed material. This includes fish or other sea animals, except sea mammals, caught in the open sea for the purposes of fishmeal production. Without being mentioned specifically, fish oil produced for feeding purposes is also a...
product of animal origin, and as such included in the definition of animal by-products. Fishmeal and fish oil produced for feeding purposes, without adding any other ingredients, has to be in line with the Regulation (EC) No 1774/2002 for animal by-products. Basic requirements are that the plant has to have a check system in place, based on HACCP principles. The establishment has to be approved by the competent authority and hygiene requirements have to be met.

**EU - legislation foodstuff**

All products intended for human consumption have to be in line with Regulation (EC) No 178/2002 General Food Law and relevant regulations on the hygiene of foodstuffs (listed below) to ensure food safety.

**Food Hygiene**

1. Regulation (EC) No 852/2004 on the hygiene of foodstuffs (H1)
2. Regulation (EC) No 853 /2004 laying down specific rules for food of animal origin (H2)
7. Commission Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of H1, H2 and H3

**Section I Objectives**

This guide for good practice provides advice for the business operator on how to implement requirements for the production of fish oil intended for human consumption according to EC regulations.

It is a step by step guide to the production process of fish oil intended for human consumption with emphasis on the main challenges and pointing out major points to consider when developing relevant HACCP based procedures.

The primary purpose of this guidance document is to ensure that fish oil for human consumption is produced according to these requirements without unnecessary obstacles for the industry, taken into account the nature and characteristics of this specific fishery product and the known risks.
Section II Scope

2.1 Scope
This guide to good practice is mainly focusing on the production of fish oil intended for human consumption, based on whole wild fish caught from the open sea for the purpose of fishmeal production as the primary raw material. The guide is applicable from the catch to the storage of the final product at the processing plant. It applies also to raw material deriving from fishery products which are fit for human consumption, such as off cuts from mackerel, herring, cod or tuna fish.

2.2 Terms and definitions
For the purpose of this guidance document the following definition of fish oil applies:

Fish oil that is processed from fresh raw fish, by the use of temperature and different processing steps to separate fish oil from the protein and water fraction. When necessary, the fish oil has to undergo further processing, refinement, and purifying before it can be placed on the market for the final consumer according to the hygiene requirements.

Processing of fish oil
Processing steps
Fish oil is produced by a continuous and carefully controlled process which involves cooking, pressing, separation by centrifugation and purification before the fish oil is stored in bulk tanks.

The production of fish oil takes place in a closed production line with tanks and pipelines, most often at specialized fish oil and fishmeal establishments. From the time when the grounded fish enters the cooker and until the fish oil reaches the storage tank, the product stays inside the closed production units, without contact and risk of contamination with the external environment.

At the first cooking step the fishmass is heated to 90 - 95°C before it enters the press where the oil and water is removed. After the pressing step the processing of fishmeal and fish oil continues in separate lines. For the purpose of this document, only the processing steps involved in the production of fish oil are focused on.

After the pressing, there are several steps usually involving a decanter, separators and a purifier where the oil phase is separated from the stickwater containing fish protein. To facilitate the separation the liquid is usually reheated to 90 - 95°C before entering the different centrifuges. The evaporated stickwater obtained at the different steps in this process is usually piped to the fishmeal production line by a pipeline.

At the end, after the purifying step the fish oil is piped to a storage tank. The end product is fish oil with a water content ≤1% (preferably 0,3% dissolved in oil phase) and containing very little impurities (≤ 0,2%).

For other raw material than whole wild fish caught from the open sea for the purpose of fishmeal and fish oil production, other processing methods like cold-press technology to extract oils from livers that is done at 70°C may apply. If so, the relevant parts of the hygiene requirements with regard to raw material, TVB-N limits, temperature and storage have to be fulfilled. The HACCP based procedures have to be in place and maintained according to the processing steps and critical control points identified.
Risk characterization

Microbiology
Fish has a natural occurring microbiological flora which mainly consists of non-pathogenic bacteria and only few organisms pathogenic for human.

During the cooking the fish is heated to 90 - 95 °C for an extended period of time (≥10 minutes), so that potential microbiological hazards are eliminated. In addition, after the cooking step the liquid is usually reheated to 90 - 95 °C one or several times before the centrifugation steps.

The risk of microbiological contamination during the process is negligible due to the fact that it takes place in a closed process and that the temperature remains quite high through all steps. Before the fish oil enters the storage tank it is cooled to ambient temperature.

Microbiological growth in fish oil during storage:
The possibility for microbial growth would be dependant of the presence of water. This could be possible in the sediment of water and impurities in the bulk tank. Condensation could increase the possibility of microbial growth.

Histamine
Histamine is water-soluble and fish oil does therefore not constitute a risk in that regard.

Undesirable substances
With regard to undesirable substances and contaminants like dioxins, the possible content is dependent on the raw material. If the amount of undesirable substances is above regulatory limits, the fish oil has to be purified during the refining step at a processing plant before it is put on the market for human consumption. The relevant legislation is Commission Regulation (EC) No 466/2001 setting maximum levels for certain contaminants in foodstuffs.

As the production process is not affecting the amount of undesirable substances in the end product, this issue is not relevant for this document and not discussed any further.

Conclusion:
Considering the type of special product and the production process, the risk of microbiological contamination is considered to be an almost negligible. The main hygienic concern with regard to fish oil would be the quality of the raw material.

Given that the establishment has an internal risk control in place based on the HACCP principles and critical control points are established, including a documentation of the raw material to befit for human consumption this should be acceptable for the approval.
Section III Specific legislation


1) Raw materials used in the preparation of fish oils for human consumption must:
   - Come from registered or approved establishments, including vessels
   - Derive from fishery products fit for human consumption;
   - Be transported and stored in hygienic conditions;
   - Be chilled and kept at appropriate temperatures unless whole fishery products are used directly for preparing fish oil and the raw material is processed within 36 hours, and where the freshness criteria is met and the total volatile basic nitrogen (TVB-N) values do not exceed set limits.

2) The production process for fish oil must ensure that all raw material intended for the production of fish oil is subject to a treatment, including when relevant, heating, pressing, separation, centrifugation, processing, refining and purification steps before being placed on the marked for the final consumer.

3) Provided that the raw material and the production process comply with the hygiene requirements for fish oil intended for human consumption, both fish oil intended for human consumption and fish oil and fishmeal not intended for human consumption, may be stored in the same establishment.

B) Commission Regulation (EC) No 1022/2008 amends Regulation (EC) No 2074/2005, Annex II, Section II, Chapter I with regard to the total volatile basic nitrogen (TVB-N) limits, as follows:

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 limits are exceeded:
   - 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption.

For other fishery products than whole fish, other limits may apply.
**Section IV Primary production**

3.1 Catch of the wild fish at open sea

The fishing, handling and transport of fish caught from the open sea to the first establishment on land, is considered as primary production. The operator of the fishing vessel has to fulfil the hygiene requirements for primary production according to Regulation (EC) No 852/2004 Annex I, part A.

The sea-to-fork approach of the legislation includes requirements for primary producers. Fishermen, as primary producers, will need to follow good practice and manage their operations as set out in the regulations.

In practical terms, the requirements amount to fairly basic hygiene procedures. As food businesses, they will have to ensure that hazards are controlled appropriately and that the fish is protected against contamination.

It is required to keep and retain records relevant to food safety. This is for example relating to measures put in place to control hazards, like procedures for cleaning and disinfection.

Freezer and factory vessels are not considered to be primary production and they have to fulfil the hygiene requirements for establishments according to Regulation (EC) No 852/2004 Annex II. This is not elaborated any further.

### Vessels

If the raw material is intended for fish oil for human consumption, each fishing vessel has only to be registered and listed by the competent authority according to the Regulation (EC) No 852/2004 art 6 and Regulation (EC) No 853/2004 art 4. This applies to all vessels carrying out primary production including slaughter, bleeding, gutting, removing fins and refrigeration.

According to the guidance document for H1, the registration should be a simple procedure whereby the competent authority is informed about the address of the establishment and the activity carried out. Where the information is already available from other sources e.g. registration for fishing purposes, that information may also be used for hygiene purposes.

As mentioned above, vessels operating as freezer or factory vessels and where further handling like filleting, packaging and freezing takes place, are not considered to be primary production and they have to be approved by the competent authority.

3.2 Landing of the catch within 24 hours

The operator of the fishing vessel has to fulfil the requirements of Regulation (EC) No 853/2004 annex III, section VIII, chapter I, part I, A and part II.

This implies that the vessel must be designed to avoid contamination of the products. The surfaces and the equipment the fishery products come into contact with must be suitable construction to facilitate cleaning and disinfection. This does not mean stainless steel. The storage facilities have to be kept clean and maintained in good repair condition. The fish has to be protected from contamination and from the effect of sun or any other source of heat. The catch must be landed as soon as possible.

3.3. Landing of the catch after 24 hours

For vessels landing the catch after 24 hours, it is mandatory that the fish is stored at the temperature of melting ice. This is usually fulfilled by storage of the fish in cold clean seawater, in a water/ice slurry or on ice. The water used may be clean water and the ice may also be produced from clean water.
There are also more stringent requirements for the construction and the equipment of the vessel, as for the clear separation of the holds from the engine compartment and the crew quarter on board of the vessel (Regulation (EC) No 853/2004). Those requirements are not discussed any further.

**Section IV Establishment: design and facilities**

The whole production and all processing steps and transports take place in closed tanks and pipelines. This means that the fishery products after cooking are not exposed to the risk of external contamination at any time during the process.

As there is a clear separation of the units after the pressing, it is possible to only approve the part involved in the production of fish oil for human consumption. It is also possible to store both fish oil intended for human consumption and fish oil and fish meal not intended for human consumption in the same establishment. This is provided that the raw materials and the production process comply with the requirements applying to fish oil intended for human consumption.

The production and the production steps are enclosed in tanks and pipelines, with negligible risk of contamination. The production takes place according to management plans based on HACCP principles and the raw material is fish fit for human consumption. Therefore different layout of the establishment may be approved, given that the production is according to general hygienic principles and the end product is suitable for human consumption.

It has to be ensured that the basic requirements for facilities and equipments are fulfilled. Like for example, a separation between clean and unclean sector, access to lavatories, changing rooms and wash basin for the staff. There are also specific requirements with regard to the personal hygiene for the staff.

**Section V Control of operation**

**Short description of the production of fish oil intended for human consumption and flow chart**

Fish oil intended for human consumption is produced by a continuous and carefully controlled process which involves cooking, pressing, centrifugation and purification before the fish oil is stored in bulk tanks.

The following provides a step by step guide to the production process.
FLOW CHART
For the production of fish oil based on raw material from fresh fish caught from the open sea

The flow chart is for illustrative purposes only. For the implementation of the HACCP principles and the relevant legislation, a complete and comprehensive flowchart has to be drawn up for each establishment, product and their intended use.

References correspond to the steps in the following part
**Processing operations step by step**

**Step 5.1 Unloading and landing**


1) Raw materials used in the preparation of fish oil for human consumption must:
   
   a) Come from establishments, including vessels, registered or approved pursuant to Regulation (EC) No 852/2004 or in accordance with this Regulation;


All the equipment that comes into contact with the fish and is being used during the unloading and landing has to be constructed of material that is easy to clean and disinfect.

**Controls at landing**

This basic requirement is fulfilled when the whole fish for the fish oil production always is caught by vessels registered or approved according to the hygiene regulations and transported and stored according to H2 (Regulation (EC) No 853/2004).

- The management plan of the establishment should describe how this is checked upon receipt.

During landing the fish is usually pumped through a pipeline from the vessel and into a storage tank. This pumping is done with the assistance of sea water and vacuum. The fish is passing a scale where samples may be taken before they go into a storage tank at the establishment.

To avoid contamination unloading and landing should be performed rapidly and equipment causing unnecessary damage to the fish should not be used.

This has to be described in the management plan based on HACCP principles.

As there are requirements for the quality of the raw material (see 5.3.) upon landing, the management plan has to describe procedures on how to control the raw material.

**Step 5.2 Storage raw materials before processing**


1) Raw materials used in the preparation of fish oil for human consumption must:
   
   c) Be transported and stored in hygienic conditions
   
   d) Be chilled as soon as possible and remain at the temperatures set out in Chapter VII.

   By way of derogation from point 1(d) 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 loading, provided that the freshness criteria are met and the total volatile basic nitrogen (TVB-N) value of the unprocessed fishery products do not exceed the limits set out in Regulation (EC) No 2074/2005.

**Comments:**

The fish is pumped into a storage facility before processing. The storage facility may have different layout and design. It may for example be a large concrete tank (bin) with a roof over to allow air circulation.
This storage tank is necessary to keep a continuous feeding of the production. This may also be the place where the raw fish is sampled and analysed to check for freshness.

The chilling should be performed by storing the fish on ice and when necessary in a cold store. Water used for chilling purposes and for the production of ice, has to be of the quality of clean water.

If the fish is not kept at the temperature of melting ice, the fish should be taken into the production as soon as possible, at the latest within 36 hours after the loading without any chilling. This is provided the freshness criteria are met and the TVB-N value is not exceeded (see step 5.3.)

The requirement for human consumption is fulfilled if the raw fish always is stored according to the hygiene regulations.

Considering that there might be delays and stops in the production it would be a good approach to have chilled storage facilities to secure the quality of the raw material. If there is no access to chilled storage, the quality of the raw material has to be monitored to secure that it is still fit as raw material for production of fish oil intended for human consumption. If the quality is still acceptable, the fish may be processed, up to 36 hours after the catch.

This approach taken at the establishment has to be described and documented in a management plan based on HACCP principles.

Step 5.3 Quality raw material

Regulation (EC) No 853/2004 Annex III, section VIII, chapter IV, part B:

1) Raw materials used in the preparation of fish oil for human consumption must:
   
   b) Derive from fishery products which are fit for human consumption and which comply with the provisions set out in this section;

The regulatory limits for TVB-N in fishery products for human consumption are given in Regulation No. 2074/2005 amended by Regulation (EC) No 1022/2008:

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 limits are exceeded:

- 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption.

For other fishery products than whole fish, other limits may apply.

Comments:
It is important that the fish used for the production of fish oil is of an acceptable quality for human consumption and does not constitute a risk. The use of deteriorated fish is not acceptable.

For human consumption the raw material should satisfy the requirements with regard to the freshness of the product with emphasis on TVB-N. It is important that the quality of the raw material is monitored and documented.

The management plan has to describe a plan for monitoring and sampling of the raw material with regard to TVB-N. It has also to be described how the freshness criteria are met.

It has also to describe actions taken when the raw material does not meet the requirements.
Step 5.4 Cooking
The raw fish is conveyed through a steam heated continuous cooker, where it is heated to 90 - 95°C for approx 10 - 20 min. This sterilizes the fish, coagulates the proteins and disrupts the cell membranes to facilitate the separation of the soluble and the oil from the dry matter.

All unnecessary heating of the fish oil causes the product to deteriorate in quality and therefore heating is kept to a minimum. Heating is done indirectly, via heat exchangers at various stages in the process.

The cooking takes place in a closed system.

For human consumption the following requirements with regard to the equipment have to be fulfilled:

1) Regulation (EC) No 852/2004 (H1), Annex II, CHAPTER II
The most important being:

Point 1) Specific requirements in rooms where foodstuffs are prepared, treated or processed

(f) surfaces (including surfaces of equipment) in areas where foods are handled and in particular those in contact with food are to be maintained in a sound condition and be easy to clean and, where necessary, to disinfect. This will require the use of smooth, washable corrosion-resistant and non-toxic materials, unless food business operators can satisfy the competent authority that other materials used are appropriate.

Point 2) Adequate facilities are to be provided, where necessary, for the cleaning, disinfecting and storage of working utensils and equipment. These facilities are to be constructed of corrosion-resistant materials, be easy to clean and have an adequate supply of hot and cold water.

2) Regulation (EC) No 852/2004 (H1), Annex II CHAPTER V
The most important being:

1. All articles, fittings and equipment with which food comes into contact are to:

   a) be effectively cleaned and, where necessary, disinfected. Cleaning and disinfection are to take place at a frequency sufficient to avoid any risk of contamination;

   (b) be so constructed, be of such materials and be kept in such good order, repair and condition as to minimise any risk of contamination;

   (c) with the exception of non-returnable containers and packaging, be so constructed, be of such materials and be kept in such good order, repair and condition as to enable them to be kept clean and, where necessary, to be disinfected;

   (d) be installed in such a manner as to allow adequate cleaning of the equipment and the surrounding area.

Comments:
The main concern with regard to the hygiene regulation is the construction and material of the processing tank.
The requirement for corrosion resistant and non-toxic materials does not mean that the material has to be stainless steel. If other materials are used, it has to be documented that the equipment does not contaminate the product and that it does not constitute a risk.

As the process takes place in a closed tank, the risk of external contamination is low and does not need to be accounted for.

Procedures describing routines for control of operation with regard to the time and temperature for the cooking, necessary cleaning and disinfection have to be implemented and documented in a management plan based on HACCP principles.

**Step 5.5 Pressing/straining**
The cooked raw material is fed to a screw press where as much as possible of the liquid (water, dissolved dry matter and oil) is squeezed from the solid phase (the presscake). The presscake is further processed to fishmeal. The pressing takes place in a closed system and it takes approx. 30 minutes.

The pressing step is sometimes called straining.

The same comments as for step 5.4.

**Separation of press liquor**
The press liquid contains water and most of the oil from the fish, as well as suspended solids. These fractions are to be separated based on their different specific gravities. This is done by several centrifugations. An important prerequisite for efficient centrifugation is high temperature, and the press liquid is usually reheated to 90 -95°C before entering the different centrifuges. The rest of the process until the fish oil reaches the storage tank takes from 4-12 hours, depending on the throughput in the plant.

**Step 5.6 Decanter**
The decanter is a horizontal centrifuge. This is the first separation step where the suspended solids are removed and transported to be mixed in with the press cake, before the fishmeal enters the drier.

The same considerations as for step 5.4. and 5.5.

**Step 5.7 Centrifugation in separators**
The separation of stickwater from oil takes place in vertical centrifuges. Liquid from the decanter is fed to centrifuges where the oil is separated from the stickwater.

The same considerations as for step 5.4., 5.5., and 5.6.

**Step 5.8 Purification/Oil polishing**
After centrifugation the fish oil is polished in a special separator. This is a final refining step where impurities are extracted and thus ensuring stability during storage.

The same considerations as for step 5.4., 5.5., 5.6 and 5.7

**Step 5.9 Storage of fish oil**
The fish oil is subsequently stored in large tanks for placing on the market or export. This oil is allowed to cool to ambient temperature during storage.

Fish oil intended for human consumption has to be stored separate from the fish oil intended for feeding purposes. But it may be stored in the same establishment.

The same considerations as for step 5.4., 5.5., 5.6 5.7. and 5.8
Section VI Separation of the production
Fish oil intended for human consumption may be produced and stored in the same establishment producing fish oil and fishmeal not intended for human consumption. This is provided that the raw material and the production process comply with the hygiene regulations for foodstuff. This means that all fishery products accepted as raw material has to come from registered boats and have to be fit for human consumption and the processing has to take place according to the management plan for human consumption.

The management plan has to describe actions taken when the raw material does not meet the requirements. If this raw material already has entered the facility this would as a minimum be that the fish oil produced from that raw material, would be destined as feed material. The processing establishment has also to be thoroughly cleaned and properly disinfected according to written procedures.

Section VII Approval
It is acceptable only to approve the part involved in the production of fish oil for human consumption, leaving out the part only involved in the production in fishmeal. The basic requirements with regard to the facilities, equipment, water supply, personal hygiene has to be fulfilled. Management plan based on HACCP principles have to be developed for both types of production.

Section VIII Loading and transport
The clear separation of the fish oil destined for human consumption from fish oil one destined for feeding purposes, has obviously to be maintained during the loading and transport of the fish oil. This issue is not elaborated any further.