SCIENTIFIC OPINION

Scientific Opinion on Fish Oil for Human Consumption.
Food Hygiene, including Rancidity

EFSA Panel on Biological Hazards (BIOHAZ)

European Food Safety Authority (EFSA), Parma, Italy

SUMMARY

Following a request from the European Commission for a scientific opinion on fish oil for human consumption, food hygiene including rancidity, an assessment with respect to hygiene and rancidity is carried out in this document. Based on existing knowledge this assessment was carried out until the point of the production chain for fish oil at which a product intended for human consumption is obtained as a bulk stored product.

The composition and properties of fish oil depend on the freshness and composition of the raw materials whereby by adjusting the production process, fish oil of desired properties can be obtained even from fish not meeting the current freshness criterion. However, data on the relationship between the freshness of the raw material and the level of lipid oxidation in the refined oil are missing in the literature. The refined fish oil production process typically includes several steps such as repeated heating at high temperatures (at 90-95°C and even to 180°C) as well as alkali/acid treatments and repeated removal of the water phase, which reduce the biological food safety risk to negligible. These current risk assessments relate to the bulk storage level of the fish oils and therefore hazards arising at later stages are not dealt with. The Terms of Reference (ToR) have been addressed in this document in such a way that an assessment with respect to hygiene and rancidity is carried out until the point of the production chain for fish oil at which a product intended for human consumption is obtained including bulk storage. This does not include encapsulated or other consumer packages or the final product ready to be sold to the consumer. The refined oil at bulk storage is a well defined product whereas consumer products (e.g. capsules) are complex and oil properties are influenced by numerous extrinsic factors (packaging material, other ingredients, flavourings, storage conditions and intended use).

The fish oil production was described covering raw materials, the generic crude fish oil process, the oil refining process, the production of omega-3 concentrates and antioxidant addition and other means of oxidation protection. Factors affecting fish oil properties and potential biological and chemical hazards related to oxidation were outlined and discussed. Reference was made to recently newly introduced products such as virgin fish oils or extra low oxidised fish oils where essentially lower temperatures...
appear to be used during processing and the raw materials seem to be of particular high quality. However, information is scattered and generally accepted definitions of these products seem to be lacking so far.

In the frame of the given mandate only oxidation products may represent a potential hazard in refined fish oil intended for human consumption whilst stored in bulk. Lipid oxidation in bulk stored fish oil can be prevented by cold storage in darkness, with no exposure to oxygen and addition of antioxidants. Information on the level of oxidation of fish oil (as measured by peroxide and anisidine values) and related toxicological effect in humans is lacking. Information on toxicity of individual oxidation products of fish oil in humans is also lacking. Based on the currently available information, no qualitative or quantitative risk assessment of hazards in relation to rancidity of fish oil intended for human consumption can be carried out.

Total volatile basic nitrogen (TVB-N) is a spoilage parameter, which was developed and defined for ice stored gutted fish and fish filets. It has not been investigated for the determination of the ‘freshness’ of whole fish as raw material intended to be used for production of fish oil for human consumption. The criterion of 60 mg total volatile basic nitrogen (TVB-N) /100 g for whole fish is not based on scientific evidence. Sensory evaluation gives the most reliable results for the assessment of the freshness of raw material for fish oil production for human consumption. Currently, the methods to determine the peroxide and the anisidine values are the most reliable chemical methods for rancidity measurements in bulk fish oils. However, gas chromatography methods that can measure the specific volatile oxidation products should be standardised and implemented. Current knowledge does not allow setting and recommending maximum acceptable values for these two indexes. The quantitative relationship between peroxide and anisidine values and the specific volatile oxidation products is lacking. In addition, there is no comprehensive information about the potential negative health effects of individual oxidation products originating from refined fish oil.