Fish Oil

Handling/Processing

Identification of Petitioned Substance

Chemical Names:
Two omega-3 fatty acid components of fish oil: eicosapentaenoic acid (EPA), docosahexaenoic acid (DHA)

Other Names:
Cod liver oil, EPA/DHA ethyl ester, fish body oil, herring oil, marine lipid concentrate, marine fish oil, marine lipid oil, marine lipids, marine oil, marine triglyceride, menhaden oil, n-3 fatty acids, n-3 polyunsaturated fatty acids (PUFAs), omega-3, omega-3 fatty acid ethyl ester, omega-3 fatty acids, omega-3 marine triglycerides, salmon oil, tuna fish oil, tuna oil, ω-3 fatty acids (NLM, 2014)

Trade Names:
None

CAS Numbers:
Fish oil (Fatty acid CAS #'s: 10417-94-4, and 25167-62-8)—stabilized with organic ingredients or only with ingredients on the National List, §§205.605 and 205.606.

Summary of Petitioned Use

Fish oil is currently included on the National List of Allowed and Prohibited Substances (hereafter referred to as the National List) as a nonorganically-produced ingredient in or on processed products labeled as "organic" when the substance is not commercially available in organic form (7 CFR 205.606) and is stabilized with organic ingredients or with ingredients on the National List, §§205.605 and 205.606 (7 CFR 205.606[f]). Fish oil is used in organic processing and handling as an ingredient to increase the content of omega-3 fatty acids—primarily, eicosapentaenoic acid (EPA) and docosahexaenoic acid (DHA)—in foods to benefit human health by contributing to healthy brain development and reducing risks of cardiovascular disease, diabetes, inflammation, atherosclerosis (Chang et al., 2009; Lee et al., 2014). Fish oil is used in a variety of food products, including breads, pies, cereals, yogurt, cheese products, frozen dairy products, meat products, cookies, crackers, snack foods, condiments, sauces, and soup mixes (Rizliya and Mendis, 2014).

Characterization of Petitioned Substance

<u>**Composition of the Substance**</u>**:**
Unrefined fish oil is approximately 90 percent long chain fatty acids (EPA, DHA, and others) (Farooqui, 2009; U.S. FDA, 2004a). Two to five percent of fish oil consists of sterols (including cholesterol), fatty acid-esterified cholesterol, and free fatty acids (Farooqui, 2009; U.S. FDA, 2004a). Other minor components in the raw, unrefined fish material include vitamins A, D, E, and some water-soluble amino acids, peptides, and minerals (Farooqui, 2009). Hydrocarbons such as squalene can be found in relatively high amounts in shark liver oil, but commercial fish oil usually contains less than 0.2 percent hydrocarbons (Rizliya and Mendis, 2014).

Long-chain fatty acids such as those in fish oil are carbon chains ranging from 14 to 22 carbon atoms. The structures of several long-chain saturated and unsaturated fatty acids are presented in Figure 1. Saturated fatty acids do not have double bonds in the carbon chain because all bonding sites on the carbon chain are saturated with hydrogen atoms. A monounsaturated long-chain fatty acid, such as oleic acid, contains one double bond on the carbon chain. Polyunsaturated fatty acids, such as linoleic acid, DHA, and EPA, have multiple double bonds on the carbon chain.

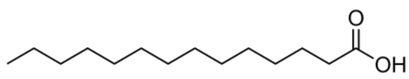
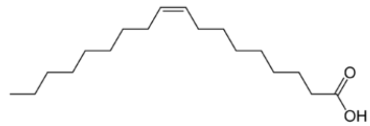
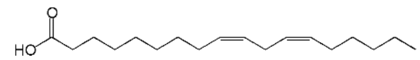
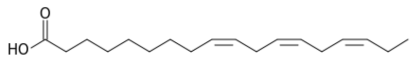
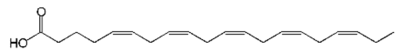
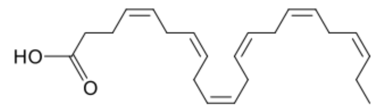
		
Myristic acid	**Oleic acid**	**Linoleic acid**
Saturated long-chain fatty acid	Monounsaturated long-chain fatty acid	Polyunsaturated long-chain omega-6 fatty acid
		
Alpha-linolenic acid (ALA)	**EPA**	**DHA**
Polyunsaturated long-chain omega-3 fatty acid	Polyunsaturated long-chain omega-3 fatty acid	Polyunsaturated long-chain omega-3 fatty acid

Figure 1: Chemical Structures of Selected Long-Chain Fatty Acids Found in Fish Oil

Approximately one-third of the fatty acids present in fish oil are omega-3 long-chain polyunsaturated fatty acids (LC-PUFAs), and it is these fatty acids that have been linked to potential health benefits (Harris, 2004; Kidd, 2013; Rizliya and Mendis, 2014). Omega-3 fatty acids have carbon chains ranging from 18 to 22 carbon atoms, depending on the type of fish oil, with a double bond located at the third carbon atom from the end of the carbon chain (i.e., the methyl or omega [ω] end) (Harris, 2004). EPA has a 20-atom carbon chain; DHA has a 22-atom carbon chain (Harris, 2004; Rizliya and Mendis, 2014).

Purified fish oil contains only the fatty acids naturally present in fish although oils used in pharmaceutical applications are usually formulated with antioxidants such as tocopherols and vitamin E and then packaged in a protective capsule (usually made of gelatin) to protect the oils from oxidation (Rizliya and Mendis, 2014). The composition of fatty acids in fish oil varies widely by species of fish (see Table 1) and location where the fish are caught. Generally, fish oil contains the following omega-3 fatty acids: EPA, DHA, ALA, stearidonic acid, docosapentaenoic acid (DPA), and arachidonic acid. The omega-3 LC-PUFAs in fish oil are mostly EPA and DHA with some DPA (NLM, 2014; Pike and Jackson, 2010).

The distribution of fatty acid types in fish oil along with lipid numbers obtained from three studies are presented in Table 1. The lipid number takes the form *C:D(n-x)*, where *C* is the number of carbon atoms, *D* is the number double bonds, and *n-x* represents the location of the last (or ω) double-bond. A lipid number ending in *n-3* indicates an omega-3 fatty acid.

<u>Source or Origin of the Substance</u>:
Fish oil accumulates in fish via transfer of fatty acids (obtained from algae and phytoplankton) up through the food chain. Photosynthesis by algae and phytoplankton leads to production of these polyunsaturated fatty acids (PUFAs), which directly or indirectly are consumed by fish and become fish lipids (Moffat and McGill, 1993). The types of finfish species used for fish oil production vary by manufacturer and region, but may include: menhaden (*Brevoortia* sp., *Ethmidium maculatum*); tuna and mackerel (*Scombridae* family); sardine and herring (*Clupeidae* family); anchovy (*Engraulidae* family); halibut (*Hippoglossus* sp.); salmon (*Oncorhynchus* sp. and *Salmo* sp.); and cod (*Gadus* sp.) (Boxshall et al., 2014; NLM, 2014). Whale (order *Cetacea*) blubber, seal (clade *Pinnipedia*) blubber, and shark liver oil are also used in fish oil production (Boxshall et al., 2014; NLM, 2014; Rizliya and Mendis, 2014). Although many species of fish are used to produce fish oil, a single species is typically used for any single production run of fish oil (Rizliya and Mendis, 2014).

Table 1: Fish Oil Components with their Relative Abundance

Fish Oil Fatty Acid	Lipid Number	% by Weight in Fish Oil[a]	% Total Lipids (range of 6 fish species)[b]	% Total Fatty Acids (range of 15 fish species)[c]
Polyunsaturated Fatty Acids				
Omega-3 Fatty Acids				
α-Linolenic acid/ALA	C18:3 (n-3)	6.0%	NR	ND–14%
Stearidonic acid	C18:4 (n-3)	NR	NR	ND–18.5%
Arachidonic acid	C20:4 (n-3)	NR	NR	0.5–16.5%
Eicosapentaenoic acid/EPA	C20:5 (n-3)	27.5%	6–13%	4–26%
Docosapentaenoic acid/DPA	C22:5 (n-3)	2.2%	NR	ND–5%
Docosahexaenoic acid/DHA	C22:6 (n-3)	8.9%	7–18%	2.5–42.5%
Omega-6 Fatty Acids				
Linoleic acid	C18:2 (n-6)	NR	NR	ND–11%
γ-Linolenic acid/GLA	C18:3 (n-6)	1.6%	NR	ND–5.5%
Eicosatetraenoic acid	C20:4 (n-6)	1.2%	NR	ND–16.5%
Monounsaturated Fatty Acids				
Palmitoleic acid	C16:1 (n-7)	11.3%	5–10%	ND–17.5%
Vaccenic acid	C18:1 (n-7)	2.8%	NR	2.0–7.0%*
Oleic acid	C18:1 (n-9)	7.8%	11–14%	2.3–40%
Eicosenoic acid	C20:1 (n-9)	NR	4–17%	ND–20%
Cetoleic acid	C22:1 (n-11)	NR	2–15%	ND–27%
Saturated Fatty Acids				
Myristic acid	C14:0	6.1%	6-9%	2–21.5%
Palmitic acid	C16:0	7.6%	10–19%	4–23.0%
Heptadecanoic acid	C17:0	2.0%	NR	ND–2.5%
Stearic acid	C18:0	6.2%	NR	0.5–9.0%

[a]Garg et al., 1988
[b]Pike and Jackson, 2010
[c]CODEX, 2013b
NR = not reported; ND = not detected
*Tuna Only

Based on 2009 data from the 2010 International Fishmeal and Fish Oil Organization (IFFO) Fishmeal and Fish Oil Statistical Yearbook, Peru produces the most fish oil worldwide and is responsible for one-third of the global production of fish oil, followed by Chile and the United States (Fréon et al., 2014; SEAFISH, 2011). Denmark, Japan, and Iceland are also prominent producers of fish oil. Overall, Peru is the world's largest exporter of fish oil; together, Peru and Chile are responsible for 39% of global fish oil exports (Freon et al., 2014; Rizliya and Mendis, 2014). Most of the fish oil produced in Peru and Chile is refined by companies in Norway, the United States, and Canada although domestic refineries for fish oil are emerging in Peru, Chile, and other South American countries (Dowling, 2012; GOED, 2014). Predominant types of fish used to produce fish oil and fish oil production volumes based on 2009 data are provided in Table 2.

Approximately 90 percent of the fish species used to make fish oil are unmarketable for human food, at least in large quantities (Rizliya and Mendis, 2014). In Peru, anchovies are used almost exclusively (>98%) for the production of fish meal and fish oil (Freon et al., 2014). Peru, Chile, Iceland, and the United States consistently report fish species used for fish oil, whereas other countries do not. The U.N. Food and Agriculture Organization (FAO) estimates that 58% of total fish oil production is nonspecies-specific, so tracking the specific species used in fish oil production can be difficult (FAO, 2008 as cited in Rizliya and Mendis, 2014).

Table 2: Relative Fish Oil Production by Country and Species Used for Oil Production[a]

Country of Production	Species Reportedly Used for Fish Oil	2009 Fish Oil Production (× 1,000 metric tons)
Peru	Anchovy	282
Chile	Jack mackerel, anchovy, sardines	152
United States	Menhaden, Alaska pollock	75
Denmark	Various species, anchovy	72
Japan	Sardine, pilchard, various species	64
Iceland	Blue whiting, herring, sprat	62
Morocco	Not available	44
Norway	Blue whiting, capelin, herring, sand eel	42
China	Various species, anchovy	14

[a]Rizliya and Mendis, 2014; SEAFISH, 2011

Humans do not metabolically generate omega-3 fatty acids and so must consume them from plant or animal sources in the diet (Harris, 2004). Omega-3 fatty acids in fish oil are targeted as dietary supplements due to the health benefits attributed to fish oil (NLM, 2014). Some recent research reviews, however, have challenged the association between fish oil and cardiovascular health benefits (Baum et al., 2012; Rizos et al., 2012). Two omega-3 fatty acids, EPA and DHA, are considered the most important components of fish oil from a human health standpoint and, as a result, those two fatty acids have been researched most thoroughly (Baum et al., 2012; NLM, 2014).

Properties of the Substance:

Refined fish oil is liquid at room temperature (20 °C) although it may be partially solid if there are any remaining triglycerides in the mixture because triglycerides have a higher melting point than fish oil (Rizliya and Mendis, 2014). The triglycerides can be removed from the mixture through fractionation by crystallization in which the oil slowly cools and the triglycerides crystallize, permitting separation of the two (Moffat and McGill, 1993; Rizliya and Mendis, 2014). Manufacturers of fish oil supplements may also remove triglycerides to increase EPA and DHA concentrations in the fish oil products (Moffat and McGill, 1993). Physical properties of fish oil are provided in Table 3.

Table 3: Physical Properties of Fish Oil[a]

Property	Value
Appearance	Amber colored oil
Odor	Characteristic fish odor
Molecular weight	EPA: 302.45, DHA: 328.49; other oils vary
Melting point	10–15 °C
Flash point (fatty acids)	Approximately 220 °C
Boiling point	>250 °C
Specific gravity (30 °C)	0.91 (s.g. of water at 30 °C is 0.996)

[a]Rizliya and Mendis, 2014

<u>Specific Uses of the Substance</u>:

Fish oil is used as a nutritional supplement and functional food ingredient to increase the amount of omega-3 fatty acids in the diet (Harris, 2004; Moffat and McGill, 1993; Rizliya and Mendis, 2014). Edible fish oil also is used as a commodity ingredient for its physical properties (e.g., unsaturated fish oils provide creaming properties, as well as smoothing and plasticity) in food products such as margarine, salad dressing, and mayonnaise (Irianto et al., 2014; Rizliya and Mendis, 2014). Early research suggested a link between EPA and decreased cardiovascular risk (Bang et al., 1971; Dyerberg et al., 1978), but current research on the subject is contradictory. Some research has shown that omega-3 fatty acids, specifically EPA and DHA, can decrease the risk of cardiovascular disease, diabetes, depression, and cancer and can improve brain development (Harris, 2004; Ruxton et al., 2004). A recent systematic review and meta-analysis, however, indicated that omega-3 fatty acid supplementation was not associated with lower cardiovascular risks (Rizos et al., 2012). Another large, recent study reported that daily treatment with omega-3 fatty acids did not reduce cardiovascular mortality and morbidity (Roncaglioni et al., 2013). These studies are discussed further under Evaluation Question #10.

Fish oil is also used in aquaculture as a feed supplement for farmed fish (Naylor et al., 2001). The farmed fish are fed fish oil because their diets are typically deficient in plants and animals that lead to the inherent production of fish oil (Naylor et al., 2001). Farmed carnivorous fish and other fish such as tilapia are often fed fish oil from smaller, wild-caught fish (Greene et al., 2013). Data from 2010 indicated that more than 16 percent of wild-caught fish (approximately 15 million metric tons) were processed into fish meal and fish oil, with the majority used in feed for aquaculture (FAO/UN, 2012; Fry and Love, 2013).

In addition to aquaculture—estimated to use about 81% of the fish oil produced worldwide—fish oil is used in feed for livestock such as pigs, cattle, poultry, and sheep. Industrial applications of fish oil include paint production, leather making, and biodiesel manufacture. Historically, fish oil was used as lamp oil, among other uses (Rizliya and Mendis, 2014).

<u>Approved Legal Uses of the Substance</u>:

Fish oil is currently included on the National List as a nonorganically produced ingredient in or on processed products labeled as ”organic” when the substance is not commercially available in organic form (7 CFR 205.606). FDA GRAS notices exist for several variations of the term fish oil.

- fish oil concentrate (GRN 105)
- fish oil (GRN 138)
- fish oil (predominantly sardine and anchovy); tuna oil (GRN 193)
- tailored triglycerides enriched in omega-3 fatty acids from fish oil (GRN 200)

FDA issued a letter in response to each GRAS notice, and the conclusion for GRNs 105, 138, 193, and 200 was that FDA has no questions about those fish oil variations. Another GRAS notice for fish oil (GRN 539) is currently pending. Further information about the FDA GRAS notices is provided in the response to Evaluation Question #4.

Action of the Substance:

As described in the Specific Uses of the Substance section, fish oil is used as a nutritional supplement and ingredient in various food products to increase the amount of omega-3 fatty acids in the diet (Harris, 2004; Irianto et al., 2014; Moffat and McGill, 1993; Rizliya and Mendis, 2014). Omega-3 fatty acids are reported to provide health benefits (e.g., reduce the risks for cardiovascular disease) and they do so through both direct and indirect mechanisms (Calder, 2012; Harris, 2004).

Increased intake of omega-3 fatty acids from fish oil can increase the ratio of omega-3 to omega-6 fatty acids in the body, displacing omega-6 fatty acids in the process (Calder, 2012; Lenihan-Geels et al., 2013). Omega-6 fatty acids such as arachidonic acid are much more common in the Western diet, and high amounts relative to amounts of omega-3 fatty acids in the body can contribute to inflammatory diseases such as heart disease (Simopoulos, 2002). Omega-3 fatty acids work by affecting cell membrane fatty acid composition, causing the omega-3 fatty acids to replace the omega-6 fatty acids (Calder, 2012; Lenihan-Lenihan-Geels et al., 2013).

When cell membrane materials are composed of omega-3 fatty acids such as DHA and EPA, anti-inflammatory lipid mediator proteins are synthesized; in contrast, when proteins are synthesized from omega-6 fatty acids, there is a pro-inflammatory response (Lenihan-Geels et al., 2013). In reducing inflammation, omega-3 fatty acids could lower the risk of cardiovascular disease, arthritis, inflammatory bowel disease, and some cancers (Lenihan-Geels et al., 2013).

Combinations of the Substance:

Fish oil rapidly oxidizes and offensive odors will form if the proper steps are not taken to prevent oxidation. Different strategies used to prevent oxidation include freezing of the oils, vacuum packaging, or the use of antioxidants. Common antioxidants are tocopherols and/or vitamin E, which help stabilize the fish oil formulation (Tahergorabi and Jaczynski, 2014). Fish oil is commonly combined with tocopherols during product formulation. Tocopherols obtained from vegetable oil are allowed for use as ingredients in or on processed products labeled as “organic” or “made with organic (specified ingredients or food group[s])” when rosemary extracts are not a suitable alternative (7 CFR 205.605[b]).Preventing oxidation of fish oil is critical because the lipid peroxides that are produced from oxidized fish oil, as well as their breakdown products, can be cytotoxic (toxic to cells) and lead to oxidative stress, cell damage, and potentially DNA damage (Moffat and McGill, 1993).

Fish oil may be microencapsulated in gelatin (included on the National List at 7 CFR 205.606) to protect the oils and make them easier to use in food applications. Microencapsulates can be stable for up to 2 years. A disadvantage to the microencapsulate process is that a large amount of encapsulate material must be used (Health Canada, 2007; Rizliya and Mendis, 2014). Another type of microencapsulation is a spray-drying process that uses casein from milk as an emulsifier and lactose as filler in the capsules (Keough et al., 2001). Casein and lactose from non-organic sources are not included on the National List.

Status

Historic Use:

Humans have eaten fish and shellfish as a normal part of the diet for centuries. There are fossilized remains of fish caught by hand that date back almost 400,000 years. The nutritional benefits of cod liver oil were known, or at least assumed, by the late 19th century (Moffat and McGill, 1993). The modern theory that fish oil might lower the rate of coronary heart disease (CHD) was suggested in the 1950s based on a population of Eskimos in Greenland that ate a diet low in fruit and vegetables and high in cholesterol and saturated fat, but had lower incidence of CHD. Because these indigenous populations consumed large amounts of fish (and fish oil) as part of their diet, researchers began investigating the role of fish oil in preventing CHD (Greene et al., 2013). U.S. FDA GRAS notices for fish oil date back to 2002.

In 1990, most of the fish oil produced (approximately 76 percent) was used in foods such as margarine and shortening. By 2002, approximately 81 percent of the fish oil produced was used in aquaculture (Rizliya and Mendis, 2014). Although aquaculture has recently been the largest market for fish oil, food uses of fish oil and fish oil supplements (so-called nutraceuticals) for human consumption represent a growing area of the market (Pike and Jackson, 2010). The annual global production of fish oil uses 25 to 30 million tons of whole fish and trimmings (Rizliya and Mendis, 2014). Total fish oil production has fluctuated in recent years ranging from nearly 1.6 million tons in 1997 to approximately 1.1 million tons in 2011 and approximately 900,000 tons in 2012. During this time, refined omega-3 oil production and demand has greatly increased in response to the published health benefits from omega-3 fatty acid supplementation (Freon et al., 2014; Pike and Jackson, 2010; Rizliya and Mendis, 2014). With this increase in demand, a concomitant increase in the price of fish oil has followed (Freon et al., 2014; Tacon and Metian, 2008).

Organic Foods Production Act, USDA Final Rule:

Fish oil is currently included (as of March 2007) on the National List as a nonorganically-produced ingredient in or on processed products labeled as "organic" when the substance is not commercially available in organic form (7 CFR 205.606) and is stabilized with organic ingredients or with ingredients on the National List, §§205.605 and 205.606 (7 CFR 205.606[f]).

International:

Canada - Canadian General Standards Board (CGSB) Permitted Substances List

Fish products are listed on the CGSB permitted substances list for use in organic production systems as soil amendments and crop nutrition. Fish oil is not listed on the Permitted Substances list for organic processing (CGSB, 2011).

CODEX Alimentarius Commission, Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods

Fish oil is not listed in the CODEX Alimentarius Commission Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (CODEX, 2013a). The CODEX guidelines discuss the use of processed fish industry products for soil fertilizing and conditioning, but their use requires recognition by a certification body or other authority (CODEX, 2013a).

At the 34th session of the Codex Alimentarius Commission in 2013, a draft standard for fish oil developed by the Codex Committee on Fats and Oils was considered. The draft standard characterizes fish oil as being from wild and farmed finfish as well as shellfish. The standard allows for whole fish and fish byproducts to be used in the production of fish oil. The standard does not address organic production methods or the use of fish oil in organic production (CODEX, 2013b).

European Economic Community (EEC) Council Regulation

The EEC Council Regulation provides rules for using fish byproducts in organic aquaculture (710/2009), but no information was provided about fish oil use in organic processing and handling.

International Federation of Organic Agriculture Movements (IFOAM)

According to the IFOAM Norms for Organic Production and Processing, fish products can be used in organic agriculture as fertilizers and soil conditioners (IFOAM, 2014). No information was available in the IFOAM Norms about the use of fish oil in processing or handling of organic food.

Japan Agricultural Standard for Organic Production

Fish oil is not specifically listed in the Japan Agricultural Standards for Organic Production.

Evaluation Questions for Substances to be used in Organic Handling

<u>Evaluation Question #1:</u> Describe the most prevalent processes used to manufacture or formulate the petitioned substance. Further, describe any chemical change that may occur during manufacture or formulation of the petitioned substance when this substance is extracted from naturally occurring plant, animal, or mineral sources (7 U.S.C. § 6502 (21)).

Fish oil is produced from fish byproducts or from fish that are caught specifically for the purpose of making fish oil (Kim and Venkatesan, 2014). Between 20 and 80 kilograms of fish oil can be extracted per ton of fish waste (Karadeniz and Kim, 2014). The steps for fish oil extraction are illustrated in Figure 2. Once the raw fish or fish parts are obtained, they are cooked in steam at 100 °C in a process called wet reduction (U.S. EPA, 1995; Kim and Venkatesan, 2014). The cooked material is then strained and sent to a press, where liquid, including the oil, is pressed from the cooked fish (U.S. EPA, 1995). The oil is decanted from the pressing liquid, and separation is accomplished using a centrifuge (U.S. EPA, 1995; Kim and Venkatesan, 2014). The oil may be further washed with hot water in a process called polishing (U.S.EPA, 1995). The oil is stored in tanks until it is used for its commercial purpose as a food ingredient or supplement, and any remaining fish solids or fish solubles from the process are dried and used as fish meal (Kim and Venkatesan, 2014). At this point in the process, the only additions to the fish oil are water, heat, and pressure. The waste streams from this process include emissions of the volatile organic compounds (VOCs) hydrogen sulfide and trimethylamine and wastewater. VOC emissions result during both the pre-cooking and drying of fish solids and fish solubles into fish meal (U.S. EPA, 1995).

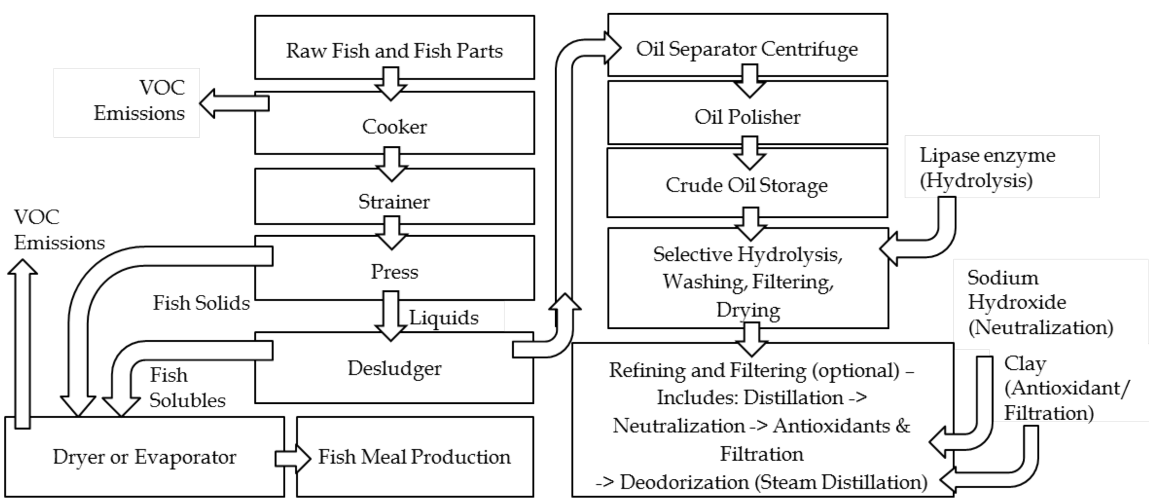


Figure 2: Diagram of Fish Oil Processing
Sources: U.S. EPA, 1995; EPAX Norway, undated; U.S. FDA, 2002

Fish oil may be further processed by hardening, which is performed to further purify the oil (U.S. EPA, 1995). Hardening involves mixing the oil with an alkaline solution (e.g., sodium hydroxide, potassium hydroxide, or other alkali metal), which reacts with free fatty acids in the oil to form soaps. The soaps are then removed from the solution by washing with hot water (U.S. EPA, 1995). Fish oil used for feed, aquaculture, supplements, or food applications is further purified using a carbon filter to reduce contaminants (e.g., dioxins/furans, polybrominated diphenyl ethers [PBDEs], polychlorinated biphenyl [PCBs], polycyclic aromatic hydrocarbons [PAHs]) that may be present in the oil (Rizliya and Mendis, 2014). Further extraction and purification of the oil can be performed by selective hydrolysis, followed by filtration, neutralization with sodium hydroxide, removal of oxidized oil by clay, and deodorization using steam distillation (EPAX Norway, undated; U.S. FDA, 2002).

Solvent extraction may also be used to produce purified fish oil, but this process is problematic because of the limited number of food-grade solvents available and the large solvent volume required for the process (Rizliya and Mendis, 2014). Another process for purifying fish oil uses supercritical fluid extraction (SFE) in which a supercritical fluid (e.g., carbon dioxide) at a temperature and pressure above its critical point is used to extract impurities from the oil or to separate out DHA and EPA. The SFE method is very costly and requires high temperatures and pressures (Rizliya and Mendis, 2014).

Evaluation Question #2: Discuss whether the petitioned substance is formulated or manufactured by a chemical process, or created by naturally occurring biological processes (7 U.S.C. § 6502 (21)). Discuss whether the petitioned substance is derived from an agricultural source.

Fish oil is created by a naturally-occurring biological process. As discussed in Evaluation Question #1, fish oil is extracted from a natural material, namely whole fish or fish waste material. Fish are an agricultural commodity as defined by the OFPA, which states that livestock includes "…animals used for food or in the production of food, fish used for food, wild or domesticated game…" (USDA, 1990). Fish oil was classified by the NOSB previously as an agricultural product and is listed at 7 CFR 205.606 for agricultural substances. Aquatic animals are not currently included in the definition for "livestock" in the USDA organic regulations, but standards are in development for the certification of organic aquaculture (farmed fish) products. Notably, farmed fish are not a source of fish oil; they are in fact often fed fish oil supplements to boost their own levels of omega-3 fatty acids (Rizliya and Mendis, 2014).

As described in the response to Evaluation Question #1, fish oil may be extracted by the physical processes of pressing and centrifugation, but further filtration of the fish oil is usually required to purify the oil and remove contaminants so that it can be used in food and/or supplements (Rizliya and Mendis, 2014; U.S. EPA, 1995). This purification is accomplished using chemical methods or an SFE system. The fish oil remains intact through the purification process and is not chemically modified. Activated carbon for filtration and solvents for purification are synthetic materials used in fish oil refining and purification (Rizliya and Mendis, 2014).

Evaluation Question #3: If the substance is a synthetic substance, provide a list of nonsynthetic or natural source(s) of the petitioned substance (7 CFR § 205.600 (b) (1)).

Fish oil is produced from a natural source and is not chemically modified during processing. EPA and DHA, the omega-3 fatty acids in fish oil that are targeted for their health benefits, are not available from sources other than fish oil, whale and seal blubber, and shark liver oil, with the exception of some species of seaweed and brown algae (Dawczynski et al., 2007; Patil et al., 2007 ; Pike and Jackson, 2010). Some small amounts of DHA may be produced by metabolism of the essential fatty acid ALA (not present in fish oil) inside the human body, but this is not a significant source (Gebauer et al., 2006). ALA is available from several plant-based sources such as chia seeds, flaxseed, and perilla seed (Ciftci et al., 2012).

Evaluation Question #4: Specify whether the petitioned substance is categorized as generally recognized as safe (GRAS) when used according to FDA's good manufacturing practices (7 CFR § 205.600 (b)(5)). If not categorized as GRAS, describe the regulatory status.

There are FDA GRAS notices for several variations of the term fish oil (see Table 4). FDA issues a letter in response to each GRAS notice, and the conclusion for GRNs 105, 138, 193, and 200 was that FDA has no questions about those fish oil variations. Another GRAS notice for fish oil (GRN 539) is currently pending. After 2002, the notices refer to use of fish oil as it relates to 21 CFR 184.1472(a)(3), which affirms menhaden oil as GRAS under the rule.

Evaluation Question #5: Describe whether the primary technical function or purpose of the petitioned substance is a preservative. If so, provide a detailed description of its mechanism as a preservative (7 CFR § 205.600 (b)(4)).

The primary technical function of fish oil is to add polyunsaturated omega-3 fatty acids, specifically EPA and DHA, to food products or supplements (Baum et al., 2012; Lenihan-Geels et al., 2013). EPA and DHA are the fatty acids in fish oil that have been linked to potential health benefits (Baum et al., 2012; NLM, 2014). These fatty acids do not serve as preservatives. In fact, preservatives must be used when packaging the fish oil to prevent oxidation (Rizliya and Mendis, 2014). Antioxidant preservatives such as tocopherols and vitamin E are used to stabilize the fish oil and protect it from oxidation (Tahergorabi and Jaczynski, 2014).

Table 4: FDA GRAS Status for Fish Oil Preparations

Substance Name	GRAS Registry Number	Date of Closure	Intended Use
Fish oil concentrate	105	10/15/2002	Use as an ingredient in foods described in FDA proposed rule for the use of menhaden oil (67 FR 8744; 02/26/2002) at a level 57% of the levels listed in the proposed rule
Fish oil	138	04/20/2004	"For use as a direct food ingredient in the food categories listed in 21 CFR 184.1472(a)(3). Two formulations are provided: an oil (to be used at a levels that are no more than 67 percent of the levels specified in 21 CFR 184.1472(a)(3)) and a microencapsulated oil (to be used at levels that are no more than 120 percent of the levels specified in 21 CFR 184.1472(a)(3))"
Fish oil (predominantly sardine and anchovy); tuna oil	193	08/03/2006	"Use as direct food ingredients in the food categories listed in 21 CFR 184.1472(a)(3) at levels that are no more than 67 percent of the levels specified in 21 CFR 184.1472(a)(3)"
Tailored triglycerides enriched in omega-3 fatty acids from fish oil	200	11/24/2006	"As a direct food ingredient in the food categories listed in 21 CFR 184.1472(a)(3) at levels that are no more than 36 percent of the levels specified in 21 CFR 184.1472(a)(3)"
Fish oil	539	Pending	"Intended for use as an ingredient in the food categories and at use levels listed in 21 CFR 184.1472(a)(3)"

<u>Evaluation Question #6:</u> Describe whether the petitioned substance will be used primarily to recreate or improve flavors, colors, textures, or nutritive values lost in processing (except when required by law) and how the substance recreates or improves any of these food/feed characteristics (7 CFR § 205.600 (b)(4)).

Fish oil is not used to improve flavors, colors, textures, or nutritive values lost in processing. Rather, fish oil is added to food to improve the nutritive value of the food in a way that would not exist otherwise. Due to the fact that DHA and EPA are only found in fish oil, seal and whale blubber, shark liver oil, and some seaweed and algae species, the only way they can exist in most food products is if oils from these sources are added to the food products (CODEX, 2013b; Garg et al., 1988; Moffat and McGill, 1993; Pike and Jackson, 2010).

<u>Evaluation Question #7:</u> Describe any effect or potential effect on the nutritional quality of the food or feed when the petitioned substance is used (7 CFR § 205.600 (b)(3)).

Fish oil is included in food to increase the content of omega-3 fatty acids, with particular emphasis on DHA and EPA. When added to food, these compounds increase the amount of fat, caloric energy, and nutrients (omega-3 fatty acids) in the food (Irianto et al., 2014; Rizliya and Mendis, 2014). Preservatives added to the fish oil, such as tocopherols and vitamin E, may also marginally increase the amount of nutrients in the food products (Tahergorabi and Jaczynski, 2014).

Evaluation Question #8: List any reported residues of heavy metals or other contaminants in excess of FDA tolerances that are present or have been reported in the petitioned substance (7 CFR § 205.600 (b)(5)).

A laboratory analysis of 31 fish oil supplements found that every product contained measurable amounts of mercury, with an average concentration of 2.9 parts per billion (ppb) across all brands (LabDoor, 2014). The highest level of mercury recorded in the supplements was 6 ppb (LabDoor, 2014). The FDA action level for methylmercury in fish is 1 part per million (ppm) (U.S. FDA, 2011). The Global Organization for EPA and DHA Omega-3 (GOED) sets voluntary standards for fish oil. GOED recommends a maximum value of 0.1 mg/kg (i.e., 0.1 ppm or 100 ppb) mercury in fish oil. The GOED has set the same 0.1-ppm voluntary standard value for lead, cadmium, and inorganic arsenic (GOED, 2012).

PCBs might also be present in fish oil. The levels of PCBs and other lipophilic organochlorine chemicals will be more concentrated in the oil fraction of the fish than in the whole fish (U.S. FDA, 2011). The FDA tolerance for PCBs is 2 ppm for all fish (U.S. FDA, 2011). An analysis of 13 over-the-counter children's fish oil dietary supplements showed that every supplement contained PCBs, with a mean concentration of 9 (± 8) ppb (Ashley et al., 2013). The GOED maximum value for PCBs in fish oil is 0.09 ppm (GOED, 2012).

Dioxins and furans are hazardous environmental compounds that may also be found in fish and fish oil. In one study, 30 samples of omega-3-enriched dietary supplements were analyzed for the presence of dioxins/furans and PBDEs. Twenty-four of the samples had dioxin levels above detection, while all samples had PBDE levels above detection. Average intake estimates for dioxins and PBDE's from the supplements were 4.3 picograms (pg) and 25,100 pg per day, respectively (Rawn et al., 2009). The GOED maximum values for dioxins; dioxin-like PCBs; and total dioxins, furans, and dioxin like PCBs are 2 pg, 3 pg, and 4 pg, respectively (GOED, 2012).

There are no FDA action levels for dioxins and PBDEs, nor are their guidance levels of these compounds in supplements. The U.S. EPA has published a noncancer reference dose (RfD) for oral exposure to dioxin of 700 pg per kilogram body weight per day, which is equivalent to 49,000 pg for a 70-kg person (U.S. EPA, 2012). This is approximately 10,000 times the estimated dose from the supplements. For reference, the EPA RfD for tetrabromodiphenyl ether, a type of PBDE, is 100,000 pg per kilogram body weight per day (U.S. EPA, 2008). This is equivalent to a dose of 7,000,000 pg per day for a 70-kg person, about 278 times greater than the estimated dose of 25,100 pg from the supplements. The GOED voluntary values do not include maximum values for PBDEs. Benzo[a] pyrene (B[a]p) can be used as a surrogate for PAH contamination in fish oil. The European Scientific Committee on Food set a maximum level of 2.0 ppb for B[a]p in oils and fats for human consumption (Maes et al., 2005). Data were not found regarding levels of PAHs in fish oil used in food or supplements.

Evaluation Question #9: Discuss and summarize findings on whether the manufacture and use of the petitioned substance may be harmful to the environment or biodiversity (7 U.S.C. § 6517 (c) (1) (A) (i) and 7 U.S.C. § 6517 (c) (2) (A) (i)).

In recent years, interest in the potential health benefits of fish oil has greatly increased as has consumption of fish oil for dietary use (Lenihan-Geels et al., 2013). At the same time, concern has grown over the state of the world's fisheries, which have been in decline since the late 1990s (Greene et al., 2013). To address the shortfall, aquaculture has been used to increase fish stocks, but up to this point aquaculture has not been to sufficient to meet the growing demand for fish for human consumption. In addition, aquaculture requires inputs derived from fisheries, including fish oil and fish meal, to supplement the diet of farmed fish (Fry and Love, 2013; Greene et al, 2013; Naylor et al., 2001). In fact, the largest use of fish oil worldwide is in aquaculture (Rizliya and Mendis, 2014; SEAFISH, 2011). Overall, demands on fisheries (from direct consumption and aquaculture) may overburden the current supply of fish (Ervin et al., 2004; Greene et al., 2013; FAO/WHO, 2011).

The average intake of omega-3 fish oil based on data from the U.S. National Health and Nutrition Examination Survey (NHANES) (Ervin et al., 2004) is about 100 mg per day, but the World Health Organization (WHO) recommends a level of 1000 mg, or 2 servings of oily fish per week (FAO/WHO, 2003). The further utilization of fish stocks to meet these dietary recommendations could contribute to the depletion of fish stocks (Greene et al., 2013; Jenkins et al., 2009). Since the 1950s, the number of collapsed fish stocks has increasing exponentially (Jenkins et al., 2009). UN/WHO data show that 8 percent of the 600 marine fish stocks monitored by the U.N. Food and Agriculture Organization (FAO) are depleted (7 percent) or recovering from depletion (1 percent), meaning that catches are well below historical levels regardless of the amount of effort exerted (FAO/WHO, 2011).

Overfishing may also lead to species extinctions and a decrease in biodiversity. There are more than 100 confirmed cases of extinctions in marine fish populations worldwide (Jenkins et al., 2009). Exploitation of fisheries is the largest contributor to marine extinctions, higher than habitat loss, climate change, invasive species, pollution, and disease (Dulvy et al., 2003).

Evaluation Question #10: Describe and summarize any reported effects upon human health from use of the petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (i), 7 U.S.C. § 6517 (c) (2) (A) (i)) and 7 U.S.C. § 6518 (m) (4)).

The health benefit from the consumption of fish oil is currently a debated topic in the scientific community (Fry and Love, 2013; Greene et al., 2013; Turchini, 2013). Research has shown that fish oil reduces the risk of cardiovascular disease, inflammatory bowel disease, arthritis, and some cancers (Bang et al., 1971; Dyerberg et al., 1978; Gebauer et al., 2006; Harris, 2004; Lenihan-Geels, 2013). Studies in which high levels of fish oil were administered as secondary prevention to populations with previous coronary heart disease have reported benefits from fish oil supplementation (Greene et al., 2013). However, a recent systematic review and meta-analysis of 20 studies involving a total of 68,680 patients showed that omega-3 PUFA supplementation is not associated with lower risk of mortality from cardiovascular diseases such as heart attack or stroke (Rizos et al., 2012). A double-blind, placebo-controlled clinical trial of 12,513 individuals with multiple cardiovascular risk factors did not observe a reduction in cardiovascular morbidity and mortality following daily treatment with omega-3 fatty acids (including DHA and EPA) for an average of 5 years (Roncaglioni et al., 2013).

The American Heart Association (AHA) Scientific Statement on fish consumption, cardiovascular disease, and omega-3 fatty acids recommends that people without coronary heart disease (CHD) should eat a variety of fish at least twice a week. In addition, individuals with documented CHD should consume about 1 gram combined of DHA and EPA per day, preferably from oily fish (Kris-Etherton et al., 2002).

There are some health risks from the consumption of fish that may outweigh the benefit of omega-3 fatty acids from fish oil. For example, women who are pregnant or may become pregnant, nursing mothers, and young children should follow U.S. EPA/FDA-recommended fish consumption levels due to the risk of exposure to mercury and methylmercury (Gebauer et al., 2006; Harris, 2004; Kidd, 2013; Mayo Clinic, 2013; Ruxton et al., 2004). The U.S. EPA/FDA provides recommendations for fish consumption for children and women of child-bearing age.

Omega-3 fatty acids may increase the risk of bleeding, especially when consumed at levels greater than 3 grams per day. People with bleeding disorders may experience an even greater risk of bleeding if they take fish oil supplements. People with fish allergies should also avoid omega-3 fatty acids derived from fish, as consumption could lead to skin rash and general allergic response. Taking fish oil supplements may lower blood pressure and may affect blood sugar levels; therefore, populations with diabetes or those taking blood pressure medications should use caution when taking fish oil supplements (Mayo Clinic, 2013).

Contamination of fish oil supplements with mercury, PCBs, dioxins/furans, and other contaminants is a concern because many fish species have elevated levels of these bioaccumulative compounds in their tissue (Kris-Etherton et al., 2002). For this reason, AHA and others recommend that children and pregnant or lactating women should avoid consuming contaminated fish or fish oil (Kris-Etherton et al., 2002). The risks from metals and other contaminants in fish are described in the response to Evaluation Question #8.

Fish oil may also be contaminated through the process of oxidation. As discussed earlier, fish oil will oxidize and offensive odors will form if steps are not taken to prevent oxidation (Tahergorabi and Jaczynski, 2014). Preventing oxidation of fish oil is critical because the lipid peroxides that are produced from oxidized fish oil and their breakdown products can be cytotoxic and lead to oxidative stress, cell damage, and possibly DNA damage (Moffat and McGill, 1993).

Evaluation Question #11: Describe any alternative practices that would make the use of the petitioned substance unnecessary (7 U.S.C. § 6518 (m) (6)).

Fish oil is added to foods to increase their omega-3 fatty acid content, specifically of EPA and DHA. EPA and DHA are found in the highest amounts in fish and other marine animals although algal sources do provide some EPA and DHA. Fish oil is a supplemental ingredient intended to enhance the nutritional value of the foods. Given the supplemental nature of fish oil, it is not strictly necessary as an ingredient in food products when used as a supplement. There is a history of using fish oil as functional oil in products like mayonnaise, but that is not the focus of this report. As such, there is no alternative practice that would make fish oil unnecessary, aside from consuming more omega-3 fatty acid-containing whole fish directly as a source of fish oil. An alternative practice for processing and handling would be to not add fish oil to food. This would omit the potential benefit of additional EPA and DHA in the food, a benefit which is currently being debated by many researchers in the medical field.

Evaluation Question #12: Describe all natural (non-synthetic) substances or products which may be used in place of a petitioned substance (7 U.S.C. § 6517 (c) (1) (A) (ii)). Provide a list of allowed substances that may be used in place of the petitioned substance (7 U.S.C. § 6518 (m) (6)).

LC-PUFAs exist in several sources other than fish oil (Ciftci et al., 2012; Dawczynski et al., 2007). However, alternate sources of LC-PUFAs contain different distributions of fatty acids compared with fish oil. Several of the seed oils (e.g., chia, perilla, and flax) do not contain EPA or DHA, the primary fatty acids of interest in fish oil for their potential health benefits. Fatty acid profiles of several different seed oils and seaweed are summarized below in Table 5 by percent composition and in Table 6 by mg/g oil.

Seaweed has a high content of LC-PUFA relative to other fatty acids and produces relatively large amounts of EPA, which can account for nearly 50 percent of the fatty acid content of these plants (Kumari et al., 2009; Rengasamy et al., 2014). The levels of fatty acids in algae will vary depending on species, geographical location, and season, among other factors (CODEX, 2013b; Garg et al., 1988; Moffat and McGill, 1993; Pike and Jackson, 2010; Rizliya and Mendis, 2014). Although the total lipid content of seaweed is relatively low (<4 g/100 g dry weight), the LC-PUFA content is equal to or greater than levels in other terrestrial vegetable sources (Kumari et al., 2009). Red seaweed contains significant amounts of EPA (10–42.4% of total fatty acids present), but DHA was not detected in samples evaluated by Dawczynski et al. (2007). Research by Kumari et al. (2009) found that species of seaweed in the order *Ulvales* contained relatively high amounts of DHA. Some seaweed species contain similar amounts of palmitic acid and oleic acid compared with fish oil, but have lower concentrations of myristic, palmitoleic, and eicosenoic acids (Dawczynski et al., 2007).

Flaxseeds are a good source of both omega-3 (linolenic) and omega-6 (linoleic) fatty acids, with both oil types combined comprising about 40 percent of the flax seed mass. The oil content will vary depending on where and how the flaxseeds were grown, but omega-3 fatty acids can make up 30–60 percent of the total oil content, while omega-6 fatty acids make up 10–20 percent of the oil content (Teneva et al., 2014).

Chia seed oil and perilla seed oil are additional sources of LC-PUFA, and their oil content distribution is very similar to that of flaxseed oil (Ciftci et al., 2012). Chia, perilla, and flax seed oils all contain ALA in relatively high amounts ranging from approximately 58 to 61 percent of the total oil (Ciftci et al., 2012). Humans can convert dietary ALA to EPA and DHA, but synthesis from ALA is inefficient in the body, and it is estimated that DHA conversion is less than 5% for men and 9% for women (Birch et al., 2010; Komaroff, 1999). Further, supplementation with ALA in humans does not result in appreciable accumulation of DHA and only moderate increases in EPA (Arterbrun et al., 2006).

There are several species of algae that contain both omega-3 and omega-6 LC-PUFA. Based on a study of rivers, lakes, and coastal waters in Norway, DHA was present at concentrations of 0.2-15.8 mg/g of algae. Total lipid content of the surveyed algae ranged from 3.5–39.9 mg (Patil et al., 2007). By comparison, levels of all LC-PUFA are much lower in algae than in herring, salmon, and cod liver oils (see last column in Table 6) (Moffat and McGill, 1993; Patil et al., 2007).

Given that none of the plant-based oils provide the same profile of fatty acids as fish oil, a combination of oils from plant-based sources would be required to replace fish oil. One study found that fish oil is the most economical source of long-chain omega-3 fatty acids based on 500-mg quantities of EPA and DHA combined, while dried seaweed in the form of nori was the most expensive by weight. All of the most economical sources of EPA and DHA were from fish sources, including finfish, mollusks, and cephalopods (squid) (Watters et al., 2012).

Table 5: Comparison of LC-PUFA Concentrations from Various Sources (by Percentage)

LC-PUFA	Lipid Number	Percent Composition				
		Fish Oil[a]	Seaweed[b]	Flaxseed Oil[c]	Chia Seed Oil[c]	Perilla Seed Oil[c]
DHA	C22:6 (n-3)	7–18%	ND	NR	NR	NR
EPA	C20:5 (n-3)	6–13%	10–42.4%	NR	NR	NR
Myristic acid/ tetradecanoic acid	C14:0	6–9%	0.3–4.07%	0.07%	0.06%	0.06%
Palmitic acid/ hexadecanoic acid	C16:0	10–19%	13.5–37.1%	5.1%	7.1%	5.9%
Palmitoleic acid/ cis-9-hexadecenoic acid	C16:1 (n-6)	5–10%	0.15–2.24%	0.09%	0.2%	0.12%
Oleic acid	C18:1 (n-9)	11–14%	5.95–15.3%	18.1%	10.5%	16.2%
Eicosenoic acid/ cis-9-eicosenoic acid	C20:1 (n-9)	4–17%	1.42–4.09%	0.2%	0.16%	0.17%
ALA/α-linolenic acid	C18:3 (n-3)	--	5.66–11.2%	58.2%	59.8%	60.9%
GLA/γ-linolenic acid	C18:3 (n-6)	--	0.31–2.04%	<1%	0.3%	0.2%
n-6 Linoleic acid	C18:2 (n-6)	--	3.56–7.41%	15.3%	20.4%	14.7%

[a]Pike and Jackson, 2010
[b]Dawczynski et al., 2007; reported as percentage of total fatty acid methyl esters for a range of seaweed plants from 4 different genera.
[c]Ciftci et al., 2012
NR = not reported; ND = not detected

Evaluation Information #13: Provide a list of organic agricultural products that could be alternatives for the petitioned substance (7 CFR § 205.600 (b) (1)).

As described in the response to Evaluation Question #12, there is not a single agricultural product that provides the same omega-3 fatty acid profile as fish oil. It is possible that a product containing oils from either flaxseed, chia seed, or perilla seed combined with oils from various seaweed or algae could be produced that would approximate the omega-3 fatty acid profile of fish oil. Perilla, flax, and chia are sources of omega-3 fatty acids that can be produced using organic agricultural practices. Certified organic flaxseed, chia seed, and perilla seed oil products exist on the market. Seaweed is not a cultivated product, but must be wild harvested and processed into oil. There is, however, a certified organic seaweed powder available on the market from the manufacturer New Directions Aromatics (New Directions Aromatics, 2011).

Table 6: Comparison of LC-PUFA Concentrations from Herring, Salmon, and Cod Liver Oil Capsules versus Algal Oil

LC-PUFA	Lipid Number	Concentration				
		Salmon Oil (mg/g FA)	Herring Oil (mg/g FA)	Cod Liver Oil (mg/g FA)	Algal Oil (mg/g DW)	Difference Between Lowest Fish and Highest Algal Conc.
DHA	C22:6 (n-3)	140	20–62	96–114	0.2–15.8	4.2
EPA	C20:5 (n-3)	194	39–88	100–104	0.8–28.4	10.6
Myristic acid	C14:0	67	46–84	40–50	0.1–16.9	23.1
Palmitic acid	C16:0	156	101–150	112–122	3.4–21.3	79.7
Palmitoleic acid	C16:1 (n-6)	82	63–120	74–91	0.4–26.0	37
Oleic acid	C18:1 (n-9)	140	93–214	238–259	0.1–31.1	61.9
Eicosenoic acid	C20:1 (n-9)	18	110–199	71–110	0.1–0.9	17.1
ALA	C18:3 (n-3)	8	2–11	12–20	0.3–12.0	-10
GLA	C18:3 (n-6)	3	NR	trace–2	NR	NC
n-6 Linoleic acid	C18:2 (n-6)	15	6–29	23–42	0.2–11.7	-5.7

[a]Moffat and McGill, 1993
[b]Patil et al., 2007
FA = fatty acid; DW = dry weight; NR = not reported; NC = not calculated

A product called Ovega-3™ is marketed as a vegetarian alternative to fish oil. The Ovega-3™ supplement contains DHA and EPA, the two LC-PUFAs that are the focus of cardiovascular health research. The supplement does not include other omega-3 or omega-6 fatty acids that are found in fish oil. Ovega-3™ contains algal oil (which includes algae, high oleic sunflower oil, sunflower lecithin, rosemary extract, tocopherols, and ascorbyl palmitate) as well as modified cornstarch, carrageenan, glycerin, sorbitol, water, and the colors beta-carotene and caramel (Ovega-3™, 2014). The *Schizochytrium* algal species used in Ovega-3™ has been allowed for use in food products in the United Kingdom (UK FSA, 2013).

Ovega-3™ contains 320 mg of DHA and 130 mg of EPA in each softgel, which is the daily dose recommended on the packaging by the manufacturer. A Daily Value has not been established for EPA or DHA. This product, marketed as a nutritional supplement, does not necessarily use the same formulation as fish oil products added directly to food in processing and handling.

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