

(Unofficial)

Notification of the Ministry of Public Health

(No.422) B.E 2564 (2021)

Issued by virtue of the Food Act B.E. 2522

Re: Fish oils

It deems appropriate to prescribe specific quality and standard for fish oils in order to comply with international standards and current development of production technology.

By the virtue of the provisions in the first phase of Section 5 and Section 6 (3)(4)(5)(6)(7) and (10) of the Food Act B.E. 2522 (1979), the Minister of Public Health hereby issues the notification as follows:

Clause 1 Fish oils is prescribed food to have qualities and standards.

Clause 2 In this notification,

“Fish oils” means glycerides of fatty acids including fatty acids in ethyl ester forms derived from fish and shellfish used for human consumption. It may contain other lipids and unsaponifiable constituents naturally present. This includes fish oils in powder form.

“Fish” means any of the cold-blooded (ectothermic) aquatic vertebrates, not includes amphibians and aquatic reptiles.

“Shell fish” means those species of aquatic mollusca and crustaceans.

Clause 3 Fish oils can be classified to 5 types as follows;

(1) Named fish oils means fish oils are derived from specific raw materials which are characteristic of the major fish or shellfish taxon from which the oil is extracted. It can be categorized as follows;

(1.1) Anchovy oil is derived from *Engraulis ringens* and other species of the genus *Engraulis* (family *Engraulidae*)

(1.2) Tuna oil is derived from the species of the genus *Thunnus* and from the species *Katsuwonus pelamis* (family *Scombridae*)

(1.3) Menhaden oil is derived from the genera *Brevortia* and *Ethmidium* (family *Clupeidae*)

(1.4) Salmon oil is derived from the family *Salmonidae*

(1.5) Krill oil is derived from *Euphausia superba*

(2) Unnamed fish oils means fish oils are derived from one or more species of fish or shellfish. This includes also mixtures with fish liver oils.

(3) Fish liver oils means oils are derived from the livers of fish and are composed of fatty acids, vitamins or other components that are representative of the livers from the species from which the oil is extracted. It can be categorized as follows;

(3.1) Cod liver oil is derived from the livers of wild cod, *Gadus morhua L* and other species of *Gadidae*

(3.2) Unnamed fish liver oil is derived from the livers of one or more species of fish.

(4) Concentrated fish oils are derived from fish oils described in (1) (2) or (3) which have been subjected to processes that may involve, but not limited to, hydrolysis, fractionation, winterization and/or re-esterification to increase the concentration of specific fatty acids. It can be categorized as follows;

(4.1) Concentrated fish oil means fish oil that contains 35 to 50 % w/w fatty acids as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA). In addition, not less than 50 % w/w fatty acid of EPA and DHA shall be in triglyceride and/or phospholipid forms.

(4.2) Highly concentrated fish oil means fish oil that contains more than 50 % w/w fatty acids as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA). In addition, not less than 50 % w/w fatty acid of EPA and DHA shall be in triglyceride and/or phospholipid forms.

(5) Concentrated fish oils ethyl esters are derived from fish oils described in (1) (2) or (3) and are primarily composed of fatty acid ethyl esters. It can be categorized as follows;

(5.1) Concentrated fish oil ethyl esters mean fish oil that contains fatty acids as esters of ethanol of which 40 to 60% w/w are as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA).

(5.2) highly concentrated fish oil ethyl esters mean fish oil that contains fatty acids as esters of ethanol of which more than 60% w/w are as sum of C20:5 (n-3) eicosapentaenoic acid (EPA) and C22:6 (n-3) docosahexaenoic acid (DHA).

Clause 4 Fish oil production process is by taking crude fish oil or crude liver fish oil extracted from raw materials to further refining steps such as heating, alkali/acid treatments, removal of the water phase, removal of free fatty acids, bleaching, or deodorization. The process includes hydrolysis, winterization, fractionation, full hydrogenation, re-esterification, or inter-esterification.

Clause 5 Fish oils shall have qualities or standards as follows;

(1) Color shall be inherent of that specific characteristic of fish oil.

(2) Odor and taste shall be inherent of that specific characteristics of fish oil with free from foreign substances, and rancidity.

(3) Fatty acid composition of different types of fish oils shall be complied with annex 1 and other essential compositions of some particular fish oils shall be complied with annex 2.

(4) Acid value shall not be more than 3 milligram of potassium hydroxide per 1 gram of oil. Except for fish oils with a high phospholipid concentration of 30% w/w or more, their acid value shall not more than 45 milligram of potassium hydroxide per 1 gram of oil.

(5) Peroxide value shall not be more than 5 milliequivalent of active oxygen per 1 kilogram of oil.

(6) Anisidine value shall not be more than 20, especially for fish oils with phospholipid concentration less than 30% w/w.

(7) Total oxidation value (ToTox) shall not be more than 26, especially for fish oils with phospholipid concentration less than 30% w/w.

(8) Vitamin A shall not be less than 40 microgram of retinol equivalents (RE) per 1 milliliter of oil, especially for fish liver oils.

(9) Vitamin D shall not be less than 1.0 microgram per 1 milliliter of oil, especially for fish liver oils.

However, content of vitamins in (8) and (9) shall not apply to deep sea shark liver oil.

Clause 6 Fish oil in powder form shall have qualities or standards as follows;

(1) Shall be in powder, not agglomerated or shall be in such characteristics.

(2) Moisture shall not be more than 5% w/w.

(3) Fish oils that used as raw material shall have qualities or standards complied with clause 5.

(4) Other compositions or other qualities or other standards shall be approved by the Food and Drug Administration.

Clause 7 Usage of food additives shall follow the notification of Ministry of Public Health regarding food additives.

Clause 8 Level of contaminants shall not exceed the maximum levels specified in the notification of Ministry of Public Health regarding standard for contaminants in food.

Clause 9 Pathogenic microorganisms shall follow the notification of Ministry of Public Health regarding prescribing the quality or standard, principles, conditions and methods of analysis for pathogenic microorganisms in foods.

Clause 10 Producers or importers of fish oil for sale shall follow the notification of Ministry of Public Health regarding production processes, production equipment and food storages

Clause 11 Usage of fish oil containers shall follow the notification of Ministry of Public Health regarding containers.

Clause 12 Labeling of fish oils shall follow the notification of the Ministry of Public Health regarding Labeling of Prepackaged Foods and shall display additional information as a case may as follows;

(1) Name of fish or shell fish used as raw material extracted for such fish oil in the name of food, for fish oil under clause 3 (1) and clause 3 (3) (3.1).

(2) Source of raw material, for salmon oil under clause 3 (1) (1.4)

(3) Content of vitamin A and vitamin D, for fish liver oils under clause 3 (3)

(4) Content of EPA and DHA, for anchovy oil under clause 3 (1) (1.1), concentrated fish oils under clause 3 (4), and concentrated fish oils ethyl esters under clause 3 (5)

(5) Type of fish oil ingredients in descending orders followed by the name of food, for fish oils under clause 3 (2), clause 3 (3) (3.2), and fish oils in powder form.

Clause 13 Using fish oils under this notification as ingredients in another food product, the food product shall have qualities, standards, condition of use, labelling complied with notifications of Ministry of Public Health regarding such particular food product.

Clause 14 Producers or importers of fish oils, whose permits issued prior to the date of this notification come into force, that fish oils can be continuously sold but not exceed two years from the date of this notification come into force.

Producers or importers of fish oils in the first phase shall follow this notification within two years from the date of this notification come into force.

Clause 15 This Notification shall come into force as from the day following date of its publication in the Government Gazette onwards.

Notified on 11th January B.E. 2564 (2021)

(Signed) Anutin Charnvirakul

(Mr. Anutin Charnvirakul)

Minister of Public Health

(Published in the Government Gazette Vol. 138, Special Part 31 Ngor, dated 9th January 2021.)

Note: This English version of the notification is translated to meet the need of the non-Thai speaking people. In case of any discrepancy between the Thai original and the English translation, the former will take priority.

Annex 1

Attachment to the Notification of the Ministry of Public Health (No.422) B.E 2564 (2021) Issued by virtue of the Food Act B.E. 2522

Re: Fish oils

Fatty acid compositions of specific types of fish oils as determined by gas liquid chromatography (GLC), expressed as percentage of total fatty acids

Fatty acids	anchovy oil	tuna oil	krill oil	menhaden oil	salmon oil		cod liver
					wild	farmed	
C14:0 myristic acid	2.7-11.5	ND-5.0	5.0-13.0	8.0-11.0	2.0-5.0	1.5-5.5	2.0-6.0
C15:0 pentadecanoic acid	ND-1.5	ND-2.0	NA	ND-1.0	ND-1.0	ND-0.5	ND-0.5
C16:0 palmitic acid	13.0-22.0	14.0-24.0	17.0-24.6	18.0-20.0	10.0-16.0	6.5-12.0	7.0-14.0
C16:1 (n-7) palmitoleic acid	4.0-12.6	ND-12.5	2.5-9.0	9.0-13.0	4.0-6.0	2.0-5.0	4.5-11.5
C17:0 heptadecanoic acid	ND-2.0	ND-3.0	NA	ND-1.0	ND-1.0	ND-0.5	NA
C18:0 stearic acid	1.0-7.0	ND-7.5	NA	2.5-4.0	2.0-5.0	2.0-5.0	1.0-4.0
C18:1 (n-7) vaccenic acid	1.7-3.7	ND- 7.0	4.7-8.1	2.5-3.5	1.5-2.5	NA	2.0-7.0
C18:1 (n-9) oleic acid	3.6-17.0	10.0-25.0	6.0-14.5	5.5-8.5	8.0-16.0	30.0-47.0	12.0-21.0
C18:2 (n-6) linoleic acid	ND-3.5	ND-3.0	ND-3.0	2.0-3.5	1.5-2.5	8.0-15.0	0.5-3.0
C18:3 (n-3) linolenic acid	ND-7.0	ND-2.0	0.1-4.7	ND-2.0	ND-2.0	3.0-6.0	ND-2.0
C18:3 (n-6) γ -linolenic acid	ND-5.0	ND-4.0	NA	ND-2.5	ND-2.0	ND-0.5	NA
C18:4 (n-3) stearidonic acid	ND-5.0	ND-2.0	1.0-8.1	1.5-3.0	1.0-4.0	0.5-1.5	0.5-4.5
C20:0 arachidic acid	ND-1.8	ND-2.5	NA	0.1-0.5	ND-0.5	0.1-0.5	NA
C20:1 (n-9) eicosenoic acid or gondoic acid	ND-4.0	ND-2.5	NA	ND-0.5	2.0-10.0	1.5-7.0	5.0-17.0
C20:1 (n-11) eicosenoic acid or gadoleic acid	ND-4.0	ND-3.0	NA	0.5-2.0	NA	NA	1.0-5.5
C20:4 (n-6) arachidonic acid	ND-2.5	ND-3.0	NA	ND-2.0	0.5-2.5	ND-1.2	ND-1.5

Fatty acids	anchovy oil	tuna oil	krill oil	menhaden oil	salmon oil		cod liver
					wild	farmed	
C20:4 (n-3) eicosatetraenoic acid	ND-2.0	ND-1.0	NA	NA	1.0-3.0	0.5-1.0	ND-2.0
C20:5 (n-3) eicosapentaenoic acid	5.0-26.0	2.5-9.0	14.3-28.0	12.5-19.0	6.5-11.5	2.0-6.0	7.0-16.0
C21:5 (n-3) heneicosapentaenoic acid	ND-4.0	ND-1.0	NA	0.5-1.0	ND-4.0	NA	ND-1.5
C22:1 (n-9) erucic acid	ND-2.3	ND-2.0	ND-1.5	0.1-0.5	ND-1.5	3.0-7.0	ND-1.5
C22:1 (n-11) cetoleic acid	ND-5.6	ND-1.0	NA	ND-0.1	1.0-1.5	NA	5.0-12.0
C22:5 (n-3) docosapentaenoic acid	ND-4.0	ND-3.0	ND-0.7	2.0-3.0	1.5-3.0	1.0-2.5	0.5-3.0
C22:6 (n-3) docosahexaenoic acid	4.0-26.5	21.0-42.5	7.1-15.7	5.0-11.5	6.0-14.0	3.0-10.0	6.0-18.0

Remark: ND = Non-detect (limit of detection, LOD) \leq 0.05%

NA = Not applicable or available

Annex 2

Attachment to the Notification of the Ministry of Public Health (No.422) B.E 2564 (2021)

Issued by virtue of the Food Act B.E. 2522

Re: Fish oils

Other essential compositions of some particular fish oils

Type of fish oil	other essential compositions
1. anchovy oil	The sum of EPA and DHA shall be at least 27% expressed as percentage of total fatty acids.
2. krill oil	Main compositions shall be triglycerides and phospholipids and the content of phospholipids shall be at least 30 % w/w.
3. concentrated fish oils and highly concentrated fish oils	Shall contain at least 50% w/w of fatty acid as sum of EPA and DHA in the form of triglycerides and/or phospholipids.