

14 May 2020

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Committee on Sanitary and Phytosanitary Measures

## Original: English

## NOTIFICATION

- 1. Notifying Member: <u>THAILAND</u>
  - If applicable, name of local government involved:
- 2. Agency responsible: Food and Drug Administration (Thai FDA)
- 3. Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): Fish oils
- 4. Regions or countries likely to be affected, to the extent relevant or practicable: [X] All trading partners
  - [X] All trading partners
  - [] Specific regions or countries:
- Title of the notified document: Draft Ministry of Public Health Notification, No. ... B.E. ... (....) Issued by virtue of the Food Act B.E. 2522 entitled "Fish oils". Language(s): Thai. Number of pages: 6

https://members.wto.org/crnattachments/2020/SPS/THA/20 3178 00 x.pdf

- **6. Description of content:** The Ministry of Public Health (MOPH) considered that requirements of safety and quality for fish oils have been issued to comply with codex standard regarding fish oil leading to protect consumer health as well as to facilitate trade as follows:
  - Clause 1 Fish oils are prescribed food to have qualities or standards and definition is defined to comply with codex standard for fish oils as follows;

"Fish oils are composed of glycerides of fatty acids including fatty acids in ethyl esters form obtained from fish or shellfish that are commonly used as food. Fish oils may contain other lipids and unsaponifiable constituents naturally present. Fish oils in dried form are also included in this notification. Fish and shellfish are defined based on Section 2 of the Code of Practice for Fish and Fishery Products (CAC/RCP 52-2003) as follows:

Fish means any of the cold-blooded (ectothermic) aquatic vertebrates. Amphibians and aquatic reptiles are not included;

Shellfish means those species of aquatic molluscs and crustaceans that are commonly used as food.

- Clause 2 Fish oils are classified in 5 categories as follows:
  - 1) Named fish oil that derived from specific species of fish or shellfish;
  - 2) Unnamed fish oil that derived from mixed fish oil from more than one type or mixture of fish oil and fish liver oil;
  - Fish liver oil that 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;
  - Concentrated fish oils that derived from fish oil classified in 1) or 2) or 3) which have been subjected to processes in order to increase the concentration of specific fatty acids; and
  - 5) Concentrated fish oils ethyl esters that derived from fish oil classified in 1) or 2) or 3) and are primarily composed of fatty acids ethyl esters form.

| - | Clause 3 - The production processes of fish oil shall be refined process intended for direct human consumption that includes, but are not limited to, extraction of crude oil from raw material and refining of that crude oil by heating at high temperatures as well as alkali/ acid treatments, removing free fatty acids and may be treated for decolourization or deodorization. The refined fish oil process typically includes several   |
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|   | steps such as hydrolysis, winterization, fractionation, full hydrogenation, re-<br>esterification, or inter-esterification.   |
| _ | Clause 4- Fish oils shall be complied with the following qualities or standards;<br>1) For fish oils in liquid form   |
|   | <ul> <li>Colour, odour and flavour inherent of that specific characteristics of fish oils and<br/>free from foreign matter and rancid odour;</li> </ul>   |
|   | <ul> <li>Fatty acid composition of some fish oils shall be complied with requirements<br/>specified in Annex 1 of this notification as well as essential composition for some<br/>fish oils shall be complied with specification in Annex 2 of this notification;</li> </ul>  |
|   | <ul> <li>Acid value shall not be more than 3 mg of potassium hydroxide per 1 gm of fish<br/>oil, except for the acid value of fish oils with a high phospholipid concentration<br/>of 30% or more shall not exceed 45 mg of potassium hydroxide per 1 g of such<br/>fish oil;</li> </ul>  |
|   | <ul> <li>Peroxide value shall not be more than 5 mg equivalent per 1 kg of fish oil;</li> <li>Anisidine value shall not be more than 20 only for fish oils with phospholipid</li> </ul>   |
|   | <ul> <li>concentration lower than 30% by weight.</li> <li>Total oxidation value (ToTox) shall not be more than 26 only for fish oils with less phospholipid concentration lower than 30% by weight.</li> </ul>  |
|   | <ul> <li>Fish liver oils, except of deep-sea shark liver oil, shall comply with following:</li> <li>a) Vitamin A shall not be less than 40 μg of retinol equivalents/mL of oil; and</li> <li>b) Vitamin D shall not be less than 1.0 μg/mL of oil</li> </ul>  |
|   | 2) For fish oils in dried form  |
|   | <ul> <li>Moisture content shall not be more than 5 % by weight.</li> <li>Fish oil used as raw material shall comply with requirements for particular fish oils in liquid form mentioned in Clause 4.</li> </ul>   |
|   | • In case of other ingredients are contained, their qualities and standards shall be complied with relevant requirements approved by Thai FDA.  |
| _ | Clause 5 - Usage of food additives and containers for fish and oil shall be complied<br>with the Notification of MOPH regarding Food additives and Standard of Containers,<br>respectively.   |
| _ | Clause 6 - Contaminants, pathogens shall not exceed the maximum limits as specified in the Notification of MOPH regarding Standard of Foods contained   |
| _ | contaminants and Standards of Pathogenic Microorganisms in Food, respectively.<br>Clause 7 - Producers or importers of fish oils for sales shall follow the notification of<br>MOPH regarding Production processes, production equipment and foods storages.  |
| _ | Clause 8 - Labeling of fish oils shall follow the Notification of Ministry of Public Health regarding labeling of prepackaged foods. In addition, the following information shall   |
|   | <ul> <li>be expressed on its label as the case may be.</li> <li>1) Name of fish used as raw material shall display with name of food, for fish oils in classification of named fished oils and Cod liver oils;</li> </ul>   |
|   | <ol> <li>Source of fish used as raw material for salmon fish oils;</li> <li>Content of vitamin A and vitamin D for liver fish oils;</li> </ol>  |
|   | <ol> <li>Content of EPA and DHA for Anchovy oil, Concentrated fish oils, and<br/>Concentrated fish oils ethyl esters;</li> <li>Types of fish oil used as ingredients in descending orders shall be displayed with</li> </ol>  |
| _ | name of food for unnamed fish oils, liver fish oils, and fish oils in dried form.<br>Clause 9 - Whenever food products contained fish oils under this notification shall<br>comply with relevant notifications of MOPH for such food products (For example, food<br>supplement consisted of fish oil, the food supplement shall comply with requirements<br>for safety, qualities, labeling or warning statement as specified in the notification of<br>MOPH regarding Food supplements). |

|     | <ul> <li>Clause 10 - Producers or importers of fish oils for sales, whose permission issued prior to this notification, shall follows:         <ol> <li>Existing fish oils can be sold in the market not exceed 2 years after this notification comes into force;</li> <li>Existing fish oils shall be complied with this notification within 2 years after this notification comes into force.</li> </ol> </li> <li>Clause 11 - This notification shall come into force as from the day following date of its publication in the Government Gazette.</li> </ul>  |
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| 7.  | Objective and rationale: [X] food safety, [ ] animal health, [ ] plant protection,<br>[ ] protect humans from animal/plant pest or disease, [ ] protect territory from<br>other damage from pests.  |
| 8.  | Is there a relevant international standard? If so, identify the standard:   |
|     | [X] Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): CODEX STAN 329-2017  |
|     | [] World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):   |
|     | [] International Plant Protection Convention (e.g. ISPM number):  |
|     | [] None   |
|     | Does this proposed regulation conform to the relevant international standard?   |
|     | [X] Yes [] No   |
|     | If no, describe, whenever possible, how and why it deviates from the international standard:  |
| 9.  | Other relevant documents and language(s) in which these are available:  |
|     | <ol> <li>The notification of the Ministry of Public Health regarding Food additives;</li> <li>The notification of the Ministry of Public Health regarding Containers;</li> <li>The notification of the Ministry of Public Health regarding Standard of Foods contained contaminants and foods storages;</li> <li>The notification of the Ministry of Public Health regarding Standards for Pathogenic Microorganisms in Food;</li> <li>The notification of the Ministry of Public Health regarding Production processes, production equipment and foods storages;</li> <li>The notification of the Ministry of Public Health regarding Labeling of Prepackaged Foods, etc.</li> </ol> |
| 10. | Proposed date of adoption (dd/mm/yy): To be determined.   |
|     | Proposed date of publication (dd/mm/yy): To be determined.  |
| 11. | Proposed date of entry into force: [] Six months from date of publication, and/or ( <i>dd/mm/yy</i> ): On the date after being notified in the Official Gazette.<br>[] Trade facilitating measure   |
| ,   |   |

12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (*dd/mm/yy*): 13 July 2020

Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

National Bureau of Agricultural Commodity and Food Standards (ACFS) 50 Phaholyothin Road, Ladyao Chatuchak, Bangkok 10900 Thailand Tel: +(662) 561 4204 Fax: +(662) 561 4204 E-mail: <u>spsthailand@gmail.com</u> Websites: <u>http://www.acfs.go.th</u> <u>http://www.spsthailand.net/</u>

13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

E-mail: spsthailand@gmail.com Websites: <u>http://www.acfs.go.th</u> <u>http://www.spsthailand.net/</u>