



27 August 2020

(20-5888)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>THAILAND</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (Thai FDA) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Hemp seed, hemp seed oil, hemp seed protein, and food supplement containing hemp seed, hemp seed oil, or hemp seed protein
5.	Title, number of pages and language(s) of the notified document: Draft Ministry of Public Health Notification, No. ... B.E. (....) Issued by virtue of the Food Act B.E. 2522 entitled "Hemp seed, hemp seed oil, hemp seed protein, and food supplement containing hemp seed, hemp seed oil, or hemp seed protein"
6.	Description of content: Based on the government policy to promote hemp plant as economic crops by exemption some parts of hemp plant, mentioned in the Notification of Ministry of Public Health regarding the List of Narcotic Drug Schedule 5 under the Thai Narcotics Act B.E. 2522 (1979), especially non-viable hemp seed allowed to be used in food industries under Food Act B.E. 2522 (1979). The Ministry of Public Health (MOPH) considered the hemp seed, hemp seed oil that are allowed to be used as food ingredient must follow the food laws and fit purpose for human consumption. Therefore, the draft Notification of MOPH entitled "Hemp seed, hemp seed oil, hemp seed protein, and food supplement containing hemp seed, hemp seed oil, or hemp seed protein" has been issued as follows: <u>Clause 1</u> – Hemp seed, hemp seed oil, hemp seed protein, and food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be a specifically controlled food. <u>Clause 2</u> – Following definitions in this notification are provided; "Hemp seed" means seed from hemp plant which the scientific name is <i>Cannabis sativa</i> L. subsp. <i>sativa</i> "Hemp seed oil" means glycerides of fatty acids obtained from hemp seed. "Hemp seed protein" means organic compounds, which are large molecules made of amino acids and can provide 4 calories of energy from 1 gram obtained from dehulled hemp seed or hemp seed meal after pressing hemp seed oil extraction. "Food supplement containing hemp seed, hemp seed oil, or hemp seed protein" means products taken for consumption other than conventional foods which contain hemp seed, hemp seed oil, or hemp seed protein as ingredients. Such products are in forms of tablets, capsules, powders, flakes, liquids or others; which are not the same as the

conventional foods. The products are for consumers who expect for benefit of health promotion.

Clause 3 – Requirements for hemp seed

1) Producers, importers, or sellers of viable hemp seed shall receive license for production, import, sale, or possession under the Ministerial Regulation regarding Narcotic Drug Schedule 5 for hemp

2) Quality and standard of hemp seed used in food product shall be as follows:

2.1) Shall be non-viable seed as required under the Notification of Ministry of Public Health regarding List of Narcotic Drug Schedule 5 under the Thai Narcotics Act B.E. 2522 (1979);

2.2) Contaminants shall not exceed the maximum limits as specified in the Notification of MOPH regarding standard of foods contained contaminants and as of the following requirements;

(1) Cadmium shall not exceed 0.3 milligram per 1 kilogram of hemp seed on the dry weight basis.

(2) Lead shall not exceed 10 milligrams per 1 kilogram of hemp seed on the dry weight basis.

2.3) The following substances shall not exceed the specified limits;

(1) Total Tetrahydrocannabinols (Total THC) shall not exceed 5 milligrams per 1 kilogram of hemp seed on the dry weight basis.

(2) Cannabidiol (CBD) shall not exceed 30 milligrams per 1 kilogram of hemp seed on the dry weight basis.

The analytical method for Total THC and CBD shall comply with rules and methods as described in the annex 1 of this notification.

2.4) Pesticide residues shall not exceed the maximum limits as specified in the Notification of MOPH regarding Food Containing Pesticide Residues.

3) Hemp seed which qualities and standards complied with this notification shall be allowed to use for the production of hemp seed oil, hemp seed protein, or food supplement only. Use of hemp seed in other food shall be complied with relevant Notification issued by the Thai FDA.

Clause 4 – Requirements for food premises of hemp seed oil or hemp seed protein or food supplement containing hemp seed

1) Producers of hemp seed oil or hemp seed protein or food supplement containing hemp seed shall comply with the following requirements as the case maybe;

1.1) In case that viable hemp seed is processed to be non-viable hemp seed in the food premise, the producer shall receive license for possession under the regulations of Narcotic Drug Schedule 5 for hemp. In addition, the production of hemp seed oil or hemp seed protein shall be complied with the notification of Ministry of Public Health regarding Production Processes, Production Equipments, and Foods Storages.

1.2) In case that non-viable hemp seed is directly used in the food premise, the production of hemp seed oil or hemp seed protein shall be complied with the notification of Ministry of Public Health regarding Production Processes, Production Equipments, and Foods Storages.

Producers shall maintain records of hemp seed oil quantity used in the production of hemp seed oil or hemp seed protein or food supplement containing hemp seed.

Clause 5 – Requirements for hemp seed oil

1) The production processes of hemp seed oil shall be a mechanical process by pressing or other mechanical process approved by Thai FDA, being purified by washing with water, setting, filtering or centrifuging.

2) Quality and standard of hemp seed oil shall be as follows:

2.1) Colour, odour and flavour inherent of that specific characteristics of hemp seed oil and free from foreign matter and rancid odour;

2.2) Saponification value shall be 184-205 mg KOH/g oil;

2.3) Iodine value shall be 153-167 by Wijs;

2.4) Unsaponifiable Matter shall not exceed 15 g/ kg oil;

2.5) Acid value shall not exceed 4.0 mg KOH/g oil. In case of the acid value is expressed as percentage of free fatty acid, a conversion of percentage of free fatty acid

to acid value shall comply with this requirement;

2.6) Peroxide value shall not exceed 15 milliequivalent of active oxygen/kg oil;

2.7) Water and volatile matter at 105°C shall not exceed 0.2% m/m;

2.8) Soap content shall not exceed 0.005 % m/m;

2.9) Insoluble impurities shall not exceed 0.05% m/m;

2.10) Chemical and physical characteristics of hemp seed oil shall be complied with requirements specified in this notification;

2.11) Fatty acid composition of hemp seed oil shall be complied with requirements specified in Annex 2 of this notification. In case of different fatty acid composition with Annex 2, it shall be approved by Thai FDA;

2.12) Contaminants shall not exceed the maximum limits as specified in the Notification of MOPH regarding standard of foods contained contaminants; 2.5) Following substances shall not exceed requirements;

2.13) The following substances shall not exceed the specified limits;

(1) Total Tetrahydrocannabinols (Total THC) shall not exceed 10 milligrams per 1 kilogram of hemp seed oil.

(2) Cannabidiol (CBD) shall not exceed 75 milligrams per 1 kilogram of hemp seed oil. The analytical method for Total THC and CBD shall comply with rules and methods as described in the annex 1 of this notification

(3) Free of mineral oil

(4) Iron shall not exceed 5.0 milligrams per 1 kilogram of hemp seed oil.

(5) Copper shall not exceed 0.4 milligrams per 1 kilogram of hemp seed oil.

2.14) Pathogens shall not exceed the maximum limits as specified in the Notification of Ministry of Public Health regarding Standards of Pathogenic Microorganisms in Food;

2.15) Food additives, containers, and labelling for hemp seed oil shall be complied with the relevant Notifications of Ministry of Public Health.

3) Hemp seed oil which qualities and standards complied with this notification shall be allowed to use as an ingredient in food supplement only. Use of hemp seed oil in other food shall be approved by Thai FDA.

Clause 6 – Requirements for hemp seed protein

1) The production processes of hemp seed protein shall be a mechanical process or chemical process for separating protein from dehulled hemp seed oil or hemp seed meal as by-product of hemp seed oil production, and being milled to be powder form.

2) Quality and standard of hemp seed protein shall be as follows:

2.1) Colour, odour and flavour inherent of that specific characteristics of hemp seed protein and free from foreign matter;

2.2) Moisture not more than 10%;

2.3) Protein content shall be followed as the case maybe;

(1) not less than 30% in the case of protein from hemp seed or hemp seed meal

(2) not less than 65% in the case of hemp seed protein concentrate

(3) More than 90% in the case of hemp seed protein isolate

2.4) Contaminants shall not exceed the maximum limits as specified in the Notification of MOPH regarding standard of foods contained contaminants;

2.5) Following substances shall not exceed requirements;

(1) Total Tetrahydrocannabinols (Total THC) shall not exceed 5 milligrams per 1 kilogram and Cannabidiol (CBD) shall not exceed 30 milligrams per 1 kilogram of hemp seed protein in the case of protein from hemp seed or hemp seed meal.

(2) Total Tetrahydrocannabinols (Total THC) and Cannabidiol (CBD) shall not detect in the case of hemp seed protein concentrate and hemp seed protein isolate; The analytical method for Total THC and CBD shall comply with rules and methods as described in the annex 1 of this notification

2.6) Pathogens shall not exceed the maximum limits as specified in the Notification of Ministry of Public Health regarding Standards of Pathogenic Microorganisms in Food;

2.7) Food additives, containers, and labelling for hemp seed protein shall be complied with the relevant Notifications of Ministry of Public Health

3) Hemp seed protein which qualities and standards complied with this notification shall be allowed to use as an ingredient in food supplement only. Use of hemp seed protein in other food shall be approved by Thai FDA.

Clause 7 – Requirements for food supplement containing hemp seed, hemp seed oil, or hemp seed protein.

1) Quality and standard of food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be as follows:

1.1) Active ingredient shall be followed as the case maybe;

(1) Hemp seed shall comply with quality and standard specified in this notification; and the quantity present in the food supplement shall be according to the permitted of the authority

(2) Hemp seed oil shall comply with quality and standard specified in this notification; and the quantity present in the food supplement shall be according to the permitted of the authority

(3) Hemp seed protein shall comply with quality and standard specified in this notification; and the quantity present in the food supplement shall be according to the permitted of the authority

1.2) Contaminants shall not exceed the maximum limits as specified in the Notification of MOPH regarding standard of foods contained contaminants;

1.3) Following substances shall not exceed requirements;

(1) Total Tetrahydrocannabinols (Total THC) shall not exceed 5 milligrams per 1 kilogram of food.

(2) Cannabidiol (CBD) shall not exceed 30 milligrams per 1 kilogram of food.

The analytical method for Total THC and CBD shall comply with rules and methods as described in the annex 1 of this notification.

1.4) Pathogen shall be detected not more than following limits;

(1) *Staphylococcus aureus* shall not be detected in 0.1 gram of food

(2) *Clostridium* spp. shall not be detected in 0.1 gram of food

(3) *Escherichia coli* shall be detected less than 3 per 1 gram of food by Most Probable Number method.1

1.5) Production, food additive and package for food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be complied with relevant Notifications of Ministry of Public Health;

2) Labelling of food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be complied with the Notification of Ministry of Public Health regarding labelling of prepackaged foods, and the following requirements as the case maybe:

2.1) Names of food, "food supplements" shall be displayed as a part of, or accompanying with the name.

2.2) Food supplement quantities shall be expressed as the case may be, as follows:

(1) Food supplement in form of tablets or capsules expressed as the number per pack.

(2) Food supplement in form of liquid expressed as net volume.

(3) Food supplement in form of solid or others expressed as net weight.

2.3) Name and quantity of main ingredients of food supplement in descending orders;

2.4) Following statements with obvious letters shall be declared;

(1) "This product provides omega-6 fatty acid, namely Linoleic acid and omega-3 fatty acid, namely Gamma-Linolenic Acid. One capsule contains hemp seed oil...(specify).. milligrams consisting of Linoleic acid ...(specify).. milligrams, Gamma-Linolenic Acid ...(specify).. milligrams" in the case that hemp seed or hemp seed oil is used as the active ingredient. (2) "Should eat varieties of five categories food in appropriate proportion"

(2) "Should eat varieties of five categories of food in an appropriate proportion"

(3) "Warning" by letters not less than 1.5 mm in a rectangular frame, with the frame colour in contrast to the label background

(4) "Children, pregnant women, and breastfeeding women should not consume".

(5) "If getting irregular symptoms, stop eating immediately"

(6) "May contain THC and CBD substance, allergic person or person with hypersensitivity to these substances shall be aware"

(7) "No effect for prevention or cure of diseases" with bold letter which colour of the letters contrast with background frame.

(8) "Information for food allergy: contain protein from hemp seed" in the case that hemp seed or hemp seed protein is an ingredient in the food.

(9) Other statements specified by Thai FDA

<p>3) Nutrition claims for food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be complied with the Notification of Ministry of Public Health regarding nutrition labelling.</p> <p>4) Health claim for food supplement containing hemp seed, hemp seed oil, or hemp seed protein shall be complied with the Notification of Ministry of Public Health regarding health claim.</p> <p><u>Clause 8</u> – Any claim regarding type or quantity of total THC and CBD substances including health claims related to total THC and CDB substances in food shall be prohibited.</p> <p><u>Clause 9</u> – This notification shall come into force as from the day following date of its publication in the Government Gazette.</p> <p>This draft Ministry of Public Health Notification was also notified under the SPS Notification.</p>	<p>7. Objective and rationale, including the nature of urgent problems where applicable: Consumer protection</p>
	<p>8. Relevant documents: Attached file</p>
<p>9. Proposed date of adoption: -</p> <p>Proposed date of entry into force: On the date after being notified in the Official Gazette.</p>	
	<p>10. Final date for comments: 60 days from notification</p>
<p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body:</p> <p>National Bureau of Agricultural Commodity and Food Standards (ACFS) 50 Phaholyothin Road, Ladyao Chatuchak, Bangkok 10900 Thailand Tel: +(662) 561 4204 Fax: +(662) 561 4034 E-mail: spsthailand@gmail.com Websites: http://www.acfs.go.th http://www.spsthailand.net/</p> <p>https://members.wto.org/crnattachments/2020/TBT/THA/20_5178_00_x.pdf</p>	