(Unofficial)

Notification of the Ministry of Public Health
(No.376) B.E 2559 (2016)
Re: Novel food

At present, there is substance which has never been consumed as food or used as food ingredient as well as developing innovative process that has never been used for food production. It deems to provide measure for safety assessment in order to protect consumer.

By the virtue of provisions of Section 5 in the first phrase, and 6(3) (9) and (10) of the Food Act B.E.2522 (1979), the Minister of Public Health hereby issues the notification as follows:

Clause 1. Novel food in this notification means;

(1) Any substance used as food or food ingredients which has been significantly used for human consumption less than fifteen years based on scientific or reliable evidence or;

(2) Any substance used as food or food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of such food which affect their nutritional value, metabolism or level of undesirable substances or;

(3) Any food product contains either (1) or (2) as an ingredient.

However, food additives and food obtained through certain techniques of Genetic Modification are not included in this notification.

Clause 2. Novel food shall be evaluated on safety assessment prior to submit its label to Food and Drug Administration for approval before use.

Clause 3. To evaluate safety assessment of such novel food, results of safety assessment by a risk assessment center recognized by Food and Drug Administration together with other relevant information described in the annex of this notification shall be submitted to Food and Drug Administration.

Clause 4. Novel food shall have quality or standard as well as specification and condition of use as approved by Food and Drug Administration.

Clause 5. Producers or Importers of novel food shall follow this notification, a particular notification and relevant Notifications with such novel foods.

Clause 6. Labeling of novel food shall be followed Notification of Ministry of Public Health regarding labeling of prepackaged foods, except for displaying date, month, and year of expiration for consumption, it shall be displayed both production and expiration for consumption by expressing date, month, year respectively, and shall incorporated with declarations of “Produce”, Expire”, or “Consume before”, as the case may be. In addition, the following information shall be expressed on its label;

(1) Name of active ingredients (if any);

(2) Instruction of use, or condition of use such as type or category of food and maximum permitted level of use.

Clause 7. This notification shall not apply to following cases:

(1) Novel food produced for export or;

(2) Novel food that producer or importer has been permitted for sale prior to the date of this notification come into force.

Clause 8. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Notified on 29th June B.E. 2559 (2016)

Signed Piyasakol Sakolsatayadorn

(Mr. Piyasakol Sakolsatayadorn)

Minister of Public Health

(Published in the Government Gazette Vol. 133, Special Part 159 Ngor, dated 15th July 2016.)

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

Attachment of Notification of the Ministry of Public Health (No 3) B.E 2559(2016)

Re: Novel food

---

1. Basic information for consideration on safety assessment

I .....on behalf of (company/firm/store) ..... which has head office located at address no. .....Trok/Soi.....

Thanon/Street.....Tambol/Khwang(subdistrict).....

Amphor/khet(District).....Province.....

Telephone no. .....Mobile no. .....

Fax no..... E-mail address.....

Intend to apply for safety assessment of Novel food as the following Notification of Ministry of Public Health regarding Novel food by submitting documents for consideration as summary as follows:

1. Name of food product or ingredient applied for safety assessment
   - Thai name.....
   - English name.....
   - Scientific name.....
   - Chemical name and molecular formulas.....
   - Recipe formula (100%) .....
   - Active ingredients (if any).....
2. Production process

   ☐ Detail of process method/innovation or production technology

   .....

   ☐ Type and concentration of solvent and extraction ratio between ingredient and active ingredient (in case of extracts)

   .....
3. Preparation method before consumption and daily recommended dose

   .....

   .....
4. Purpose for consumption / Expectation from consumption e.g. to be antioxidants

   .....

In this regard, I have submitted relevant evidence for consideration of safety assessment as attachments

Signed ..... Applicant

(.....)

Date/Month/Year .....

2. Relevant evidences for consideration of safety assessment for novel food

No.	List of document	Number (copies)
1	**General information of ingredient**	
1.1	Scientific name, chemical name or common name	
1.2	Part of use	
1.3	Geographic source / origin of ingredient	
2.	**General information of product**	
2.1	Recipe formula of product	
2.2	Purpose of use of such product	
2.3	Action/Health effect and expectation from consumption	
2.4	Country of producer (in case of import)	
3.	**Information on history of consumption as food**	
3.1	Duration of use for consumption as food (if it is used for another purpose, please indicate) and specify country where such food is generally consumed.	
3.2	Description of use includes purpose, form of use, duration of use in such form, targeted consumer group	
3.3	Consumption data	
4.	**Specification of ingredient**	
4.1	Characteristic	
4.2	Physical or chemical property	
4.3	Information on identity of ingredient	
4.4	Quantity of active ingredient/active substance/ marker	
4.5	Quantity of processing aid residues	
4.6	Requirement of impurities	
4.7	Microbiological criteria	
4.8	Specific requirements (i.e. relevant toxins)	
4.9	Stability (if any)	
4.10	Other information (i.e. sensitivity to light, heath stability) (in any)	
5.	**Specification of product**	
5.1	Characteristic	
5.2	Physical or chemical property	
5.3	Quantity of active ingredient/active substance/ marker	
5.4	Quantity of processing aid residues	
5.5	Requirement of impurities	
5.6	Microbiological criteria	
5.7	Specific requirements (i.e. relevant toxins)	
5.8	Stability (if any)	
5.9	Other information (i.e. sensitivity to light, heat stability) (if any)	

No.	List of document	Number (copies)
6	**Certificate of analysis**	
6.1	Certificate of analysis for ingredient	
6.2	Certificate of analysis for product	
7.	**Storage**	
7.1	Storage condition	
7.2	Shelf life	
8.	**Production process/Synthesis/ Extraction method**	
8.1	Preparation procedure / production method	
8.2	Type and concentration of solvent (in case of extract substance)	
8.3	Type of active substance or category of substance from extraction (in case of extract)	
8.4	Extraction ratio between ingredient and 1 gram of active ingredient (in case of extract)	
9.	**Basic information on chemical substances used in production**(*)	
9.1	Chemical name, i.e. CAS No., INS No.	
9.2	Specification of chemical substances and functional use of such substances	
10	**Characteristic/ Recommendation for consumption**	
10.1	1 Serving size (metric system)	
10.2	Frequency (times/day)	
10.3	Preparation method before consumption /Cooking method	
10.4	Targeted consumer	
10.5	Warning statement/ Recommendation for consumption (if any)	
11	**Information on safety**	
11.1	Biochemical Characteristics (if any)	
11.1.1	Absorption, distribution, and excretion	
11.1.2	Biotransformation	
11.1.3	Effect on enzyme and other parameters	
11.1.4	Reaction and fate of the food	
11.2	Toxicity studies in animals (Full version)	
11.2.1	Acute study	
11.2.2	Sub-chronic study	
11.2.3	Chronic study (in case no chronic study, at least clinical research study in healthy people shall be submitted)	
11.3	Study for use of pure culture (in case use of pure culture in production process)	
11.3.1	Specific properties of microorganism	
11.3.2	Qualification on antibiotic susceptibility pattern and resistance genes	
11.3.3	Evaluation of metabolic action	
11.3.4	Information on pathogenic trend	

No.	List of document	Number (copies)
11.4	Toxicity studies in specific area (in case of manifestation)	
11.5	Clinical research study or Epidemiological report (**)	
11.6	Other studies (if any)	
12	**Nutritional data(***)**	
13	**Result of safety assessment from international risk assessment agency or other recognized countries (if any)**	

Remark:

1. (*) In case chemical substance is made by microorganism, Identity and safety data of such microorganism used in production of the chemical substance shall be submitted.
2. (**) Only in case of novel food notifying expectation to health, clinical research study shall be submitted. If No expectation to health, Clinical research study may be submitted (if any).
3. (***) Only in case such novel food shall be complied with relevant Notifications of Ministry of Public Health.
4. Document and evidence supporting for safety assessment specified in this annex shall be reliable and based on principle or theory which is able to explain result of study or characteristic of novel food accurately, precisely, and clearly. To certify the truth and reliability of such document and evidence, following methods can be applied:
   4.1 Certifying by the applying applicant of safety assessment, for example;
   - Evidence document relating to general information of ingredient /product applying for safety assessment;
   - Specification of ingredient/product applying for safety assessment;
   - Instruction or recommendation for consumption;
   - Storage;
   - Detail of country or source of production, etc.

   4.2 Certifying by reliable agency, for example;
   - Laboratory accredited by the international standards, i.e. ISO/IEC 17025 in such test item related to novel food applying for safety assessment;
   - International recognized safety assessment agencies such as European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN) of U.S. Food and Drug Administration (USFDA), Food Standard Australia New Zealand (FSANZ), or Food Chemical Codex (FCC), etc.

   4.3 References from reliable data or technical document, for example:
   - Technical textbooks which are recognized by such area such as pharmacopeia, textbook regarding Thai herbal or foreign herbal, or other technical journals;
   - Official Monograph such as World Health Organization (WHO), Pharmacopoeia, Codex Advisory Specification for the identity and Purity of Food Additives;
   - Reliable databases such as Peer review journals i.e. Elsevier (Science direct, Embase, Scopus), TOXLINE, Pubmed, technical database, i.e. BIOSIS, TOXNET, NAPRALERT, or Food Safety Authority of foreign countries, etc.
   - Relevant reports from expert committee such as scientific committee of Codex, European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN), or Food Standard Australia New Zealand (FSANZ), etc.

3. Sources of reliable technical evidence to present history of use as food

Such as published articles in relevant and reliable technical journal or published herbal textbook (which identify use as food), a certificate letter from competent authorities or agencies or bodies assigned by competent authorities (from both domestic and international levels) with references of reliable sources or technical documents such following examples:

- Technical textbooks which are accepted by such area such as pharmacopeia, textbook regarding Thai herbal or foreign herbal, or other technical journals;
- Official Monograph such as World Health Organization (WHO), Pharmacopoeia, Codex Advisory Specification for the identity and Purity of Food Additives;
- Reliable databases such as Peer review journals i.e. Elsevier (Science direct, Embase, Scopus), TOXLINE, Pubmed, technical database, i.e. BIOSIS, TOXNET, NAPRALERT, or Food Safety Authority of foreign countries, etc.
- Relevant reports from expert committee such as scientific committee of Codex, European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN), or Food Standard Australia New Zealand (FSANZ), etc.

4. Report of safety assessment result by a safety assessment agency recognized by Food and Drug Administration

The report consists of 2 parts as follows:

Part 1 – Name of the safety assessment agency, list of experts considering such safety assessment and providing the result, confidential and non-conflict of interest statement signed by such experts.

Part 2 – Result of safety assessment consisting of the following detail:

1. Executive summary which entirely summarize information from no. 2 to no.7
2. Summary of general information of novel food as follows:
   - Scientific name, part of use, source of origin, history of use as food or other purpose of use including consumption data in Thailand
   - Formula recipe and specification
   - Production process, list of substances used in production, contaminant substances, chemical substance residues, and active ingredients
   - Shelf life, storage condition, purpose of consumption, target consumers
   - Information of producer/importer, countries which have distributed and sold such novel food including duration of sale till present
   - Certificate of analysis or analysis result for novel food
3. Summary of safety information of novel food as follows:
   - Result of toxicity studies in animals
   - Result of clinical research studies or epidemiological report (if any)
   - Result of biological studies (if any)
   - Result of other studies (if any)
4. Summary of nutritional data (if any)
5. Summary of efficacy studies regarding expectation to health (if any)
6. Summary of safety assessment of applying novel food by international or foreign countries recognized safety assessment agencies
7. Summary of recommendation or options for consideration of safety and suitability of consumption for Thai people
8. List of reference used in the report of safety assessment.