National Food Institute

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Checklist for food safety assessment

No.	List of document	Number (copies)	Officer		Remark
			Yes	No	
1.	Assessment application (Novel Food)/Assessment application (Non-Novel Food)				
2.	Copy of ID card or passport of the applicant				
3.	Copy the application has to be signed by the entrepreneur or business operator or authorized director (according to the certificate of juristic person)				
4.	Copy of Power of Attorney from the business operator (in case of power granting)				
5.	Documents and supporting evidence correctly according to the checklist, sign with signed. And results of examination document or evidence by Thai FDA				
6.	Overview of product or ingredient to request a safety assessment with the following topics: • General information (No. 7.1 – 7.10) • Information on safety (No. 7.11)				
7.	Information of safety assessment as specified in checklists				
7.1	**General information of ingredient**				
7.1.1	Scientific name, chemical name or common name				
7.1.2	Part of use				
7.1.3	Geographic source / origin of ingredient/ raw material				
7.2	**General information of product**				
7.2.1	Recipe formula of product				
7.2.2	Purpose of use of such product				
7.2.3	Action/Health effect and expectation from consumption				
7.2.4	Country of producer (in case of import)				
7.3	**Information on history of consumption as food**				
7.3.1	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.				
7.3.2	Description of use includes purpose, form of use, duration of use in such form, targeted consumer group				
7.3.3	Consumption data				

No.	List of document	Number (copies)	Officer		Remark
			Yes	No	
7.4	**Specification of ingredient**				
7.4.1	Characteristic				
7.4.2	Physical or chemical property				
7.4.3	Information on identity of ingredient				
7.4.4	Quantity of active ingredient/active substance/ marker				
7.4.5	Quantity of processing aid residues				
7.4.6	Requirement of impurities				
7.4.7	Microbiological criteria				
7.4.8	Specific requirements (i.e. relevant toxins)				
7.4.9	Stability (if any)				
7.4.10	Other information (i.e. sensitivity to light, heath stability) (in any)				
7.5	**Specification of product**				
7.5.1	Characteristic				
7.5.2	Physical or chemical property				
7.5.3	Quantity of active ingredient/active substance/ marker				
7.5.4	Quantity of processing aid residues				
7.5.5	Requirement of impurities				
7.5.6	Microbiological criteria				
7.5.7	Specific requirements (i.e. relevant toxins)				
7.5.8	Stability (if any)				
7.5.9	Other information (i.e. sensitivity to light, heat stability) (if any)				
7.6	**Certificate of analysis**				
7.6.1	Certificate of analysis for ingredient				
7.6.2	Certificate of analysis for product				
7.7	**Storage**				
7.7.1	Storage condition				
7.7.2	Shelf life				
7.8	**Production process/Synthesis/ Extraction method**				
7.8.1	Preparation procedure / production method				
7.8.2	Type and concentration of solvent (in case of extract substance)				
7.8.3	Type of active substance or category of substance from extraction (in case of extract)				

No.	List of document	Number (copies)	Officer		Remark
			Yes	No	
7.8.4	Extraction ratio between ingredient and 1 gram of active ingredient (in case of extract)				
7.9	**Basic information on chemical substances used in production(*)**				
7.9.1	Chemical name, i.e. CAS No., INS No.				
7.9.2	Specification of chemical substances and functional use of such substances				
7.10	**Characteristic/ Recommendation for consumption**				
7.10.1	1 Serving size (metric system)				
7.10.2	Frequency (times/day)				
7.10.3	Preparation method before consumption /Cooking method				
7.10.4	Targeted consumer				
7.10.5	Warning statement/ Recommendation for consumption (if any)				
7.11	**Information on safety**				
7.11.1	Biochemical Characteristics (if any)				
	1) Absorption, distribution, and excretion				
	2) Biotransformation				
	3) Effect on enzyme and other parameters				
	4) Reaction and fate of the food				
7.11.2	Toxicity studies in animals (Full version)				
	1) Acute toxicity				
	2) Sub-chronic toxicity				
	3) Chronic study (in case no chronic study, at least clinical research study in healthy people shall be submitted)				
7.11.3	Study for use of pure culture (in case use of pure culture in production process)				
	1) Specific properties of microorganism				
	2) Qualification on antibiotic susceptibility pattern and resistance genes				
	3) Evaluation of metabolic action				
	4) Information on pathogenic trend				
7.11.4	Toxicity studies in specific area (in case of manifestation)				
7.11.5	Clinical research study or Epidemiological report (**) (if any)				
7.11.6	Other studies (if any)				

No.	List of document	Number (copies)	Officer		Remark
			Yes	No	
7.12	Nutritional data (***)				
7.13	Result of safety assessment from international risk assessment agency or other recognized countries (if any)				

Signed ..... Applicant

(.....)

Date/Month/Year .....

Signed ..... Officer

(.....)

Date/Month/Year .....

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
     - Production/synthesis/extraction process of food components/products submitted 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).

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.