

Application Form for verification of being novel food  
together with checklist supporting verification (Novel food)

**Part 1** General information

<p><b>Details of an applicant</b></p> <p>Name –last name of the applicant/authorized person.....tel.....</p> <p>E-mail .....name of producing/import premise.....</p> <p>Address..... Building .....</p> <p>Moo..... Trok/soi.....Street.....</p> <p>Tambol/subdistrict..... Ampoe/district.....</p> <p>Province..... Tel.....Fax.....</p> <hr/> <p><b>Details of Novel food</b></p> <p>1. Name of a requested food product or raw material to be assessed for safety</p> <p style="margin-left: 20px;">- in Thai.....</p> <p style="margin-left: 20px;">- in English.....</p> <p style="margin-left: 20px;">-Scientific name.....</p> <p style="margin-left: 20px;">- Chemical name and molecular formula.....</p> <p>2. Purpose for consumption / Expectation from consumption e.g. to be antioxidants</p> <p>.....</p> <p>.....</p> <p>3. Preparation method before consumption and daily recommended dose</p> <p>.....</p> <p>.....</p> <p>4. Production process (if it is extract, kinds and concentration of solvent, extract ratio shall be specified) / Name of innovation or technology of production.</p> <p>.....</p> <p>.....</p>	<p style="text-align: center;"><u>Please bring this document together with an application accepting form attached with correction of incompleteness for the next time (if any)</u></p>
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In this regard, I have provided evidence supporting for verification of novel food that have details in attachments.

Sign ..... applicant

(.....)

**Part 2 Preliminary Checklist supplementing for verification of being Novel food**

No.	Item of document	applicant		Checking official		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue))	none	
<b>1</b>	<b>General information of ingredient</b>					
1.1	Scientific, Chemical name, or common name					
1.2	Part of use					
1.3	Geographical origin/source of origin of composition					
<b>2.</b>	<b>General information of product</b>					
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)					
<b>3.</b>	<b>Information on history of consumption as food</b>					
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					
<b>4.</b>	<b>Specification of ingredient</b>					
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)					
<b>5.</b>	<b>Specification of product</b>					
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					

No.	Item of document	applicant		Checking official		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue))	none	
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)					
<b>6</b>	<b>Certificate of analysis</b>					
6.1	Certificate of analysis for ingredient					
6.2	Certificate of analysis for product					
<b>7.</b>	<b>Storage</b>					
7.1	Storage condition					
7.2	Shelf life					
<b>8.</b>	<b>Production process/Synthesis/ Extraction method</b>					
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)					
<b>9.</b>	<b>Basic information on chemical substances used in production<sup>(*)</sup></b>					
9.1	Chemical name, i.e. CAS No., INS No.					
9.2	Specification of chemical substances and functional use of such substances					
<b>10</b>	<b>Characteristic/ Recommendation for consumption</b>					
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)					
<b>11</b>	<b>Information on safety</b>					
11.1	Biochemical Characteristics (if any)					
11.1.1	Absorption, distribution, and excretion					
11.1.2	Biotransformation					

No.	Item of document	applicant		Checking official		Record of checking
		Yes/ number (issue)	none	Yes/ number (issue)	none	
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					
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)					
<b>12</b>	<b>Nutritional data</b> (***)					
<b>13</b>	<b>Result of safety assessment from international risk assessment agency or other recognized countries (if any)</b>					

**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.

I do hereby certify that supporting evidence documents for verification of being Novel food attached herewith are true and trustworthy and if an official have any query in these documents, I agree to give more additional data for official when requesting

Sign ..... an applicant/authorized person

(.....)

**Part 3 Checking result of completeness of supporting documents**

For an applicant of verification only	For official only
<p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u></p> <p><input type="checkbox"/> Sign to accept checking result of the completeness of supporting documents.</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for verification of being novel food in case of incomplete documents</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p> <p><input type="checkbox"/> Agree with defects and will further finish for correction within 15 working days from the day after the date of receiving the application (if any).</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p>	<p><u>1<sup>st</sup> time (1<sup>st</sup> submission)</u></p> <p><input type="checkbox"/> Complete documents and consider to notify result of verification</p> <p>By fall in/not fall in a scope of novel food under the Notification of the Ministry of Public Health (No.376) B.E.2559 Re: Novel food</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the supporting documents for verification of being novel food</p> <p><input type="checkbox"/> Incomplete documents and consider to accept the application with a condition due to incomplete or incorrect documents as specify in checklist (defects found as above specified). The applicant shall correct or submit additional documents for the first round within 15 working days from the day after the date of receiving the application (from date.....to date .....). If it is overdue, the application will be <u>terminated and further returned</u> (the applicant shall be informed by signing and receive a copy)</p> <p>notify to proceed..... ..... .....</p> <p>Sign by an official..... (.....)</p> <p>Date.....Time.....</p>

**Part 3 Checking result of completeness of supporting documents (continued)**

For an applicant of verification only	For official only
<p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u></p> <p><input type="checkbox"/> Sign to accept result in consideration of the completeness of supporting documents.</p> <p>Sign .....applicant/authorized person (.....)</p> <p>Date .....time.....</p> <p><input type="checkbox"/> Request to return supporting documents for verification of being novel food in case of incomplete documents</p> <p>Sign .....applicant/authorized person (.....)</p> <p>Date .....time.....</p> <p><input type="checkbox"/> Agree with incompleteness and will further finish for correction within 15 working days from the day after the date of receiving the application (if any).</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p>	<p><u>2<sup>nd</sup> time (1<sup>st</sup> round of submission to correct the defects)</u></p> <p><input type="checkbox"/> Correct or submit complete document and consider to notify result of verification</p> <p>By it fall in/does not fall in a scope of novel food under the Notification of the Ministry of Public Health (No.376) B.E.2559, Re: Novel food</p> <p><input type="checkbox"/> Incomplete documents and the applicant request to return the supporting documents for verification of being novel food</p> <p><input type="checkbox"/> Incomplete documents and consider to accept the application with a condition due to incomplete or incorrect documents as specify in checklist (defects found as above specified). The applicant shall correct or submit additional documents for the second round within 15 working days from the day after the date of receiving the application (from date.....to date .....). If it is overdue, the application will be <u>terminated and further returned</u> (the applicant shall be informed by signing and receive a copy)</p> <p>notify to proceed..... ..... .....</p> <p>Sign by an official..... (.....)</p> <p>Date.....Time.....</p>

**Part 3 Checking result of completeness of supporting documents (continued)**

For an applicant of verification only	For official only
<p><u>3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)</u></p> <p><input type="checkbox"/> I have submitted corrected documents or additional documents in a number of ..... item as specified in the incompleteness recorded form.</p> <p><input type="checkbox"/> I have received returned application together with supporting documents for verification of being novel food.</p> <p>Sign .....an applicant/authorized person (.....)</p> <p>Date.....time.....</p>	<p><u>3<sup>rd</sup> time (2<sup>nd</sup> round of submission to correct the defects)</u></p> <p><input type="checkbox"/> Correct or submit completed document and consider to notify result of verification</p> <p>By it fall in/does not fall in a scope of novel food under the Notification of the Ministry of Public Health (No.376) B.E.2559, Re: Novel food</p> <p><input type="checkbox"/> Return the application together with supporting documents for verification of being novel food since.....</p> <p>.....</p> <p><input type="checkbox"/> Correction and additional documents are not undertaken on due date.</p> <p><input type="checkbox"/> Correction or submission of documents are incomplete.</p> <p>You have right to renew the submission by providing with accurate and complete documents or may appeal for document return at this time by submit a letter of appeal to the Secretary General of the Food and Drug Administration within 15 working days from the day of receiving the returned application.</p> <p>Signed by checking official..... (.....)</p> <p>Date .....time.....</p>