**Application form for health claim assessment**

Company/Partnership/Shop.....

Address.....

.....

Tel.....Fax.....

E-mail.....

Date.....Month.....B.E.....

Re: Request for health claim assessment

To: Secretary General of Food and Drug Administration

Attachment: Numbers of evidenced documents for consideration .....items

Since I am..... on behalf of(Company/Partnership/Shop)..... . intend to request for health claim assessment for food or its compositions as follows:

1. Name of food product or composition of food requested for health claim assessment
   - in Thai.....
   - in English.....
   - Food Serial Number .....

2. Statement of Health claim

.....

.....

3. Use of statement of health claim such as label or advertising media

.....

.....

.....

4. Additional details for consideration
   - Purpose of consumption.....
   - Method of consumption and Consumption dosage .....
   - Warning statement of consumption (if any).....
   - Targeted group.....

So that I have submitted evidenced documents supporting for consideration on health claim assessment which having details as in the following attached documents.

Sign..... applicant

(.....)

**Preliminary Checklist supplementing for consideration on health claim assessment**

**Part 1** General information

Name of Product (in Thai).....
Name of Product (in English).....
Name –last name of the applicant/authorized person.....
Tel.....E-mail .....
Name of producing/import premise.....
License No. of production /import/producing premise.....

**Part 2 Preliminary Checklist supplementing for consideration for health claim assessment**

| Evidenced documents | Number (issue) | Applicant | | Official check | | Incompleteness record |
|---|---|---|---|---|---|---|
| | | yes | none | Yes | none | |
| 1. Application form for health claim assessment that presenting clear statement of health claim | | | | | | |
| 2. Letter of power of attorney from business operator which specify power for submission and receiving for additional correction, notification and following of consideration results together with a copy of ID card of granter and attorney that been certified (in case of assigning authority). | | | | | | |
| 3. One copy of identification card of the applicant | | | | | | |
| 4. Checklist with signature to verify the completeness of the documents | | | | | | |
| 5. Summary study of scientific evidenced documents enclosed for consideration | | | | | | |
| 6. Documents presenting product details | | | | | | |
| 6.1 Documents of Food Serial Number permission | | | | | | |
| 6.2 Product formula express as percentage by weight | | | | | | |
| 6.3 Production process | | | | | | |
| 6.4 Specification of product | | | | | | |
| 6.5 Packaging and packing size | | | | | | |
| 6.6 Consumption purpose | | | | | | |
| 6.7 Method of consumption | | | | | | |
| 6.8 Consumption dosage | | | | | | |
| 6.9 Recommendation for consumption and warning statement (if any) | | | | | | |
| 6.10 Targeted group | | | | | | |
| 6.11 Product label | | | | | | |
| 6.12 Certification of sale of the health claim product and its label used in foreign countries (if any) | | | | | | |
| 7. Supporting evidenced documents for consideration on | | | | | | |

| Evidenced documents | Number (issue) | Applicant | | Official check | | Incompleteness record |
|---|---|---|---|---|---|---|
| | | yes | none | Yes | none | |
| health claim assessment as the following case maybe:<br>7.1 **Nutrient function claims** other than those have been prescribed by the Food and Drug Administration<br>7.1.1 Systematic review and Meta-analysis published in reliable journals; or<br>71.2 Recognized and reliable scientific recommendation of internationally recognized scientific agency, organization or expert committees; or<br>7.1.3 Full report of well-designed human intervention study or other appropriately designed human intervention study that having the sufficient number of samples and preliminary study for consideration published in reliable journal. | | | | | | |
| **7.2 Other function claim and disease risk reduction claim**<br>7.2.1 Full report of well-designed human intervention study published in reliable journal together with either one of the following documents:<br>7.2.2 Systematic review and Meta-analysis published in reliable journal; or<br>7.2.3 Recognized and reliable scientific recommendation of internationally recognized scientific agency, organization or expert committees. | | | | | | |
| 8. Additional supporting documents (if any) such as<br>- Relevant Peer-reviewed published articles;<br>- *In vivo* study;<br>- *Ex vivo* or In vitro study;<br>- Observational evidence in epidemiological study that results are consistent to well-designed intervention study<br>- Technical texts, Evidence-based reference texts or other recognized and reliable texts | | | | | | |
| 9. CD-ROM contained supporting documents and evidences for consideration | | | | | | |

I do hereby certify that supporting evidence documents for consideration on health claim assessment 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 only | For official only |
|---|---|
| 1st time (1st submission)<br>***Part 1 Submission for checking an application and evidenced documents***<br>☐ Sign to accept checking result of the completeness of supporting documents for health claim<br>Sign .....an applicant/authorized person<br>(.....)<br>Date.....time.....<br>☐ Request to return supporting documents for health claim assessment in case of incomplete documents<br>Sign .....an applicant/authorized person<br>(.....)<br>Date.....time.....<br>☐ Agree with defects and will further finish for correction within 15 working days from the day after the date of checking the completeness of evidenced documents of the application. (from date.....to date.....) If it is overdue, cancellation and return of the application and evidenced documents can be undertaken.<br>Sign .....an applicant/authorized person<br>(.....)<br>Date.....time..... | 1st time (1st submission)<br>***Part 1 Checking for the completeness of evidenced documents***<br>☐ Completed documents to issue a receipt for technical evaluation fees as in list 2 item 2.2(4)<br>☐ Incomplete documents and the applicant request to return the documents<br>☐ 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 10 working days from the day after the date of receiving the application (from date.....to date .....). If it is overdue, the application will be terminated and further returned (the applicant shall be informed by signing and receive a copy)<br>notify to proceed.....<br>.....<br>.....<br>Sign by an official.....<br>(.....)<br>Date.....Time..... |
| ***Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical evaluation.<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 2 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |
| ***Part 3 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents and sufficient quality)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 3 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |

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

| For an applicant only | For official only |
|---|---|
| 2nd time submission to correct the defects<br>***Part 1 Submission the application and evidenced documents***<br>☐ I have submitted correcting or additional documents in the number of.....items as specified in the incompleteness recorded form.<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time.....<br>☐ Sign to accept checking result of the completeness of supporting documents for health claim assessment.<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time.....<br>☐ Request to return supporting documents for health claim assessment in case of incomplete documents<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time..... | 2nd time submission to correct the defects<br>***Part 1 Checking for the completeness of evidenced documents***<br>☐ correct or submit complete document and issue a receipt of technical assessment fee in list 2 item 2.2(4)<br>☐ Incorrect or submit incomplete documents and the applicant request to return supporting documents for health claim assessment.<br>☐ 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 10 working days from the day after the date of receiving the application (from date.....to date .....). If it is overdue, the application will be terminated and further returned (the applicant shall be informed by signing and receive a copy)<br>notify to proceed.....<br>.....<br>.....<br>Signed by checking official.....<br>(.....)<br>Date .....time..... |
| ***Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 2 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and consider to accept the application.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |
| ***Part 3 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents and sufficient quality)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 3 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |

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

| For an applicant only | For official only |
|---|---|
| 3rd time submission to correct the defects<br>***Part 1 Submission for checking the application and evidenced documents***<br>☐ I have submitted correcting or additional documents in the number of.....items as specified in the incompleteness recorded form.<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time.....<br>☐ Sign to accept checking result of the completeness of supporting documents for health claim assessment.<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time.....<br>☐ Request to return supporting documents for health claim assessment in case of incomplete documents<br>Sign ..... applicant/authorized person<br>(.....)<br>Date .....time..... | 3rd time submission to correct the defects<br>***Part 1 Checking for the completeness of evidenced documents***<br>☐ correct or submit complete document and issue a receipt of technical assessment fee in list 2 item 2.2(4)<br>☐ Incorrect or submit incomplete documents and the applicant request to return supporting documents for health claim assessment.<br>☐ Return the application together with supporting documents for health claim assessment since the correction is not undertaken or additional documents are not submitted on due date.<br>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<br>Signed by checking official.....<br>(.....)<br>Date .....time..... |
| ***Part 2 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 2 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |
| ***Part 3 Submission the application and evidenced documents for evaluation of technical documents (case of completed documents and sufficient quality)***<br>☐ I have submitted the application and evidenced documents that are checked for its completeness in the number of.....set together with receipt of payment for technical document evaluation<br>Sign .....applicant/authorized person<br>(.....)<br>Date .....time..... | ***Part 3 Acceptance of the application for technical document evaluation***<br>☐ Document is complete, receipt of payment for technical evaluation is presented and to accept the application is considered.<br>Signed by checking officer.....<br>(.....)<br>Date .....time..... |

**Part 4 Additional explanation relevant to information supporting health claim assessment**

1. Well-designed human intervention study

is randomized control trial clinical study (RCT) which study effect of treatment or either effect of any process in specific representative sample and be able to well control environment of intervention under optimum condition that are divided into 2 groups: study group and control group by randomization and having systematically study plan according to Good Clinical Practice (GCP). When design for human intervention study, the following details shall be considered:

(a) Study group shall be representative of targeted population;

(b) Control group shall be appropriate;

(c) Adequate exposure period and surveillance for expected result;

(d) Presenting of basic food consumption in study group and life style relevant to other areas;

(e) Composition and quantity of food being studied and other consumed food that effect to function of a particular health claim;

(f) Monitoring of implementing requirements relevant to consumption of food or its composition under testing of volunteer;

(g) Statistical data analysis should be made with appropriate method that recognized in scientific society for a particular study and appropriate statistical significance interpretation

(h) Result of the study, at least variation or defined factors shall be specified include variety and category of product, dosage of consumption and duration to have expected effect;

(i) If the study cannot directly measure the result because of adverse effect to health or long term to gain the effect or ethical issue and limited resource such as high analysis cost, suitable biomarker may be used instead such as concentration of Cholesterol plasma for CVD risk, however biomarker shall relate to final effect and variation in targeted population and analysis method of such biomarker shall be precise and accurate.

2. Systematic review and meta-analysis

is collation of reliable scientific evidences by use of distinctly systematic procedure in searching, selection and quality assessment of study report which having the same study pattern and making quantitative analysis of data by meta-analysis or synthesize to have summary of interested study result that able to reduce bias or random error of each relevant study and systematic review are most accurately done.

3. Recognized and reliable technical recommendation from internationally recognized and reliable scientific agency, organization or expert committee such as Scientific committee under Codex, European Food Safety Authority (EFSA), Center for Food Safety and Applied Nutrition (CFSAN) or Food Standard Australia New Zealand (FSANZ), etc.

4. Relevant peer-reviewed published articles that are able to search from reliable data base such as Elsevier (Science direct, Embase, Scopus), The Cochrane Library, Pubmed, BIOSIS, TOXNET, NAPRALERT, Thai-journal citation index centre or Food Safety Authority of foreign countries.

5. *In vivo study* is testing in body of animal or Eukaryote such as mouse or rabbit.

6. *Ex vivo study* is testing in organ, cell or tissues brought outside of living body.

7. *In vitro study* is testing without use of animal or living organisms or their component except for bacteria, microorganism cultures.

8. Observational evidence in epidemiological study

is one type in human study by collecting data from epidemiological study that factors and behavior observed without defining of factors or treatment during study are divided into

- Descriptive studies are systematic collection and analysis of data by observation of factors and behavior relate to interesting effect or area without defining of any comparison group or experiment.

- Case Report or Case Series

- Cross-sectional study is a study during specified period to present situation of problem at that time which factors and output will be measured in the same period.

- Analytical studies are studies of relation between one factor and occurring effect by having control or comparison group and study group that the study should come from more than one research centre or one research group consisted of

- Epidemiological study in form of cohort study which is forward surveillance of effect between treated and control group.

- Epidemiological study in form of case-control study is afterward surveillance by starting from effect and find out its cause from the past

9. Evidence-based reference texts or other recognized and reliable text in a particular field.

**Note:** Such scientific evidence-based documents shall be published in internationally recognized journal.

## Reference


1. Codex Alimentarius. Codex guidelines for use of nutrition and health claims (CAC/GL 23-1997, Rev. 1-2004). Codex Alimentarius 1997.
2. Aggett PJ, Antoine JM, Asp N-G, Bellisle F, Contor L, Cummings JH, et al. PASSCLAIM - Process for the assessment of scientific support for claims on foods. International Life Sciences Institute 2005.