

(Unofficial)

Notification of the Ministry of Public Health

Re: Use of Probiotic Microorganisms in Foods

In deems appropriate to establish criteria, procedure and conditions for appropriate use of Probiotic Microorganisms and safe for consumption.

By the virtue of provisions of Section 5 and 6(3) (4) (5) and (10) of the Food Act B.E.2522 (1979), in which contain provisions in relation to the restriction of Rights and Liberties of the Persons, in respect of which Section 29 and in conjunction with Section 33, Section 41, Section 43 and Section 45 of the constitution of the Kingdom of Thailand so permit by virtue of provisions of law; the Minister of Public Health hereby issues the notification as follows:

Clause 1. In this Notification

“Probiotic Microorganisms” mean viable microorganisms that are beneficial to body if intake in sufficient amount but excluding:

- (1) Biotherapeutic agents;
- (2) Beneficial microorganisms not used in food;
- (3) Genetically Modified Microorganisms, GMM;

(4) Microorganisms, bacteria or yeast as specified in the following Notifications of the Ministry of Public Health:

(4.1) Notification of the Ministry of Public Health (No. 144) B.E. 2535 (1992), Re: Food in Sealed Container, dated 2nd July B.E. 2535 (1992), which addition has been made by Notification of the Ministry of Public Health (No. 301) B.E. 2549 (2006), Re: Food in Sealed Container (4th Edition), dated 28th September B.E. 2549 (2006);

(4.2) Notification of the Ministry of Public Health (No. 156) B.E. 2537 (1994), Re: Modified Milk for Infant and Modified Milk of Follow up Formula for Infant and Children dated 14th October B.E. 2537 (1994);

(4.3) Notification of the Ministry of Public Health (No. 157) B.E. 2537 (1994), Re: Infant Foods and Follow-up Formula Food for Infant and Young Children, dated 14th October B.E. 2537 (1994);

(4.4) Notification of the Ministry of Public Health (No. 157) B.E. 2537 (1994), Re: Supplementary Foods for Infant and Young Children, dated 14th October B.E. 2537 (1994);

(4.5) Notification of the Ministry of Public Health (No. 266) B.E. 2545 (2002), Re: Flavored Milk, dated 19th December B.E. 2545 (2002);

(4.6) Notification of the Ministry of Public Health (No. 267) B.E. 2545 (2002), Re: Other Milk Products, dated 19th December B.E. 2545 (2002);

(5) Microorganisms as specified in an Annex of this Notification that use for other purposes regarding to necessity in food processing and have followed a particular Notification,

“Health Claim” means any representation of pictures, photograph, invented designs, mark, trade mark or any texts on labels that states a relationship existed between a food or constituents of that food or nutrients and health both direct and indirect, divide into 3 characteristics as follows:

(1) Nutrient function claim means any representation of properties or benefits related to effect of nutrients to body physiology such as growth, development or normal function of body which have been technical proved and accepted, Example: Calcium cause to have strong bone and teeth.

(2) Other function claim means any representation of properties or benefits relate to effect of nutrients other than (1) to specific beneficial effects or improvement of function, example: Functional claim on constituent of food that effect is to stimulate calcium absorption.

(3) Reduction of disease risk claim means any representation of properties or benefits of food or constituent of that food which effect to risk reduction of developing a disease or health-related condition by changing major risk factor of particular disease significantly. Example: Claim of high calcium food will effect on reduction of Osteoporosis.

Clause 2. Food contained Probiotic microorganisms shall be approved by Food and Drug Administration (Thai FDA) and shall use microorganisms specified in an Annex of this Notification, viable Probiotic microorganisms in such food shall be not less than 10^6 cfu/1g food at the end of its shelf life.

Use of Probiotic microorganisms other than specified in an Annex of this Notification, manufacturers or importers shall deliver safety assessment results and characteristics of such Probiotic microorganisms regarding to Guidelines for the Evaluation of Probiotics in Food, Joint FAO/WHO Working Group Report on Drafting Guidelines for the Evaluation of Probiotics in Food, year 2002 with detailed information for permission application as follows:

(1) Testing of Identity of genus, species, strain using the most current, valid methodology using the most current, valid methodology and nomenclature of microorganisms Nomenclature of the bacteria must conform to the current, scientifically recognized names.

(2) The following test for Probiotic Characteristics:

(2.1) Resistance to gastric acidity;

(2.2) bile salt resistance;

(2.3) adherence to mucus and/or human epithelial cell and cell line;

(2.4) bile salt hydrolase activity; and

(2.5) other characteristics (if any) as the case maybe.

(3) Safety assessment of Probiotics to human with testing in vitro or in vivo and human studies for safety assurance and body reaction to such Probiotics as follows:

(3.1) Antimicrobial resistance.

(3.2) Metabolic effect assessment such as D-lactate or bile salt deconjugation;

(3.3) Side effect in human intervention study.

(3.4) Epidemiological surveillance of adverse incidents after marketing.

(3.5) Test for toxin production, if the strain under evaluation belongs to a species that is a known toxin producer.

(3.6) Test for hemolytic activity if the strain under evaluation belongs to a species with known hemolytic potential.

Clause 3. Health claim for use of Probiotic in food shall be the following criteria, procedures, and conditions:

(1) Manufacturers or Importers shall inform sufficient and adequate details of food and its component relate to such claim and shall deliver human studies of at least two institutes for consideration of effective of such Probiotics to health as follows:

(1.1) Well design human intervention study; or

(1.2) Other appropriate designs human intervention study that have sufficient sample and result of preliminary study of strains or food

Design of human intervention study according to (1.1) and (1.2) shall take into account the following details:

(a) Study groups that are representative of the target group;

(b) Control shall be appropriate control;

(c) An adequate duration of exposure and follow up to demonstrate the intended effect;

(d) Characterization of the study groups' background diet and other aspects of relevant of lifestyle;

(e) An amount of the food or food component consistent with its intended pattern of consumption;

(f) The influence of the food matrix and dietary context on the functional effect of the component;

(g) Monitoring of subjects' compliance concerning intake of food or food component under test;

(h) The statistical power to test the hypothesis.

Result of the studies according to Clause(1.1) and Clause(1.2), shall at least specify related variables or parameters including kinds and types of food, serving size, quantity of Probiotics and length of time to have an intended effect of use; in case of such result of the study cannot be directly measured the endpoint because of health effect or taking a long time to have major benefit, probability, ethical issues and limitation of resources such as costly expense for analysis that may use appropriate markers instead, however this markers shall have biological accuracy that relate to final result and internal variables of target population and shall have accurate identity test method of such parameters.

(2) Health claim shall be scientific proof, totality and completeness of data and evidence shall be considered in the following issues :

(2.1) Results are consistent with results that obtained from other evidences or other methods.

(2.2) Appropriateness is regarding to food technology procedure.

(2.3) Sample(s) are taken by random sampling.

(2.4) Response Relation between amount of food or component of food and effect to health.

(2.5) Biological possibility.

(3) To make Health Claim on label shall be the following conditions:

Health Claim shall not mislead that intake of food or component of such food or such nutrients can cure, heal, treat or prevent diseases and shall display texts in Thai language with similar size of letters, easily seen and legible; may also have other languages with the same meaning and display the following particulars:

(3.1) Text of “This product is not for treat, heal, cure or prevent of disease”.

(3.2) Genus, Species, and Strain of Probiotics which is a component of food.

(3.3) Quantity and time recommended to intake for Health Claim effect.

(3.4) Text of Health Claim such as “Probiotic microorganisms” “Probiotics” or other claims.

(3.5) Instruction of use and appropriate condition for storage

(3.6) Channel to provide information to consumer such as address, telephone number or website.

Clause 4. Labeling of food contained Probiotics shall be followed:

(1) Notification of the Ministry of Public Health; Re: Label;

(2) Notification of the Ministry of Public Health; Re: Nutritional label;

(3) Notification of the Ministry of Public Health regarding particular food.

Clause 5. Manufacturers or Importers according to Clause 2 prior to this Notification come into force shall be complied with this Notification within 1 year and the remaining labels are allowed to be used but not exceeding to 1 year after this notification come into force.

Clause 6. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Notified on 27th June B.E. 2554 (2011)

(Signed) Jurin Laksanawisit

(Mr. Jurin Laksanawisit)

Minister of Public Health

(Published in the Government Gazette Vol. 128, Special Part 86 Ngor, dated 3rd August 2011.)

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

List of Probiotic Microorganisms in Foods

Attachment of Notification of the Ministry of Public Health

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1. *Bacillus coagulans*
 2. *Bifidobacterium adolescentis*
 3. *Bifidobacterium animalis*
 4. *Bifidobacterium bifidum*
 5. *Bifidobacterium breve*
 6. *Bifidobacterium infantis*
 7. *Bifidobacterium lactis*
 8. *Bifidobacterium longum*
 9. *Bifidobacterium pseudolongum*
 10. *Enterococcus durans*
 11. *Enterococcus faecium*
 12. *Lactobacillus acidophilus*
 13. *Lactobacillus crispatus*
 14. *Lactobacillus gasseri*
 15. *Lactobacillus johnsonii*
 16. *Lactobacillus paracasei*
 17. *Lactobacillus reuteri*
 18. *Lactobacillus rhamnosus*
 19. *Lactobacillus salivarius*
 20. *Lactobacillus zeae*
 21. *Propionibacterium arabinosum*
 22. *Staphylococcus sciuri*
 23. *Saccharomyces cerevisiae* subsp. *Boulardii*

Reference: Bulletin of the International Dairy Federation No.377/2002