

(Unofficial)

Notification of the Ministry of Public Health

(No. 281) B.E. 2547 (2004)

Re: Food Additives

It deems appropriate to revise the Notification of the Ministry of Public Health regarding food colors, food enhancers, and food additives to suit the current situation and to increase the efficiency of consumer protection.

By the virtue of provisions of Section 5 and 6(1) (2) (4) (5) (6) (7) (9) 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 35, Section 39, Section 48, and Section 50 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. The following Notifications of the Ministry of Public Health shall be repealed:

(1) The Notification of the Ministry of Public Health No. 21 (B.E. 2522) Re: Prescribing Food Colors as Specified Controlled Food and Prescribed to have Qualities or Standards, Use, Admixture and Label dated 13th September B.E. 2522;

(2) The Notification of the Ministry of Public Health No. 38 (B.E. 2522) Re: Prescribing Food Enhancers as Specific Controlled Food and Prescribed to have Qualities or Standards dated 13th September B.E. 2522;

(3) The Notification of the Ministry of Public Health No. 55 (B.E. 2524) Re: Amendment of the Notification of the Ministry of Public Health No. 21 (B.E. 2522) dated 2nd January B.E. 2524;

(4) The Notification of the Ministry of Public Health No. 66 (B.E. 2525) Re: Amendment of the Notification of the Ministry of Public Health No. 55 (B.E. 2524) dated 11th January B.E. 2525;

(5) The Notification of the Ministry of Public Health No. 84 (B.E. 2527) Re: Food Additives dated 25th December B.E. 2527;

(6) The Notification of the Ministry of Public Health No. 119 (B.E. 2532) Re: Food Additives (No.2) dated 8th February B.E. 2532;

Clause 2. Food additives shall be specific controlled food.

Clause 3. Food additives mean substances that are not usually used as food or as essential ingredients of foods whether the substances will or will not provide food value, but are added to foods for the benefits of processing technology, food coloring, food enhancing, packaging, storage or transport that will affect the qualities or standards or characteristics of foods. Food additives shall also include substances not added to foods but are in the packaging containers together with the foods for the aforementioned purposes such as moisture absorbers, oxygen absorbers, etc.

The statement in the Paragraph 1 shall not include nutrients added to fortify or adjust the nutritive values of foods such as protein, fat, carbohydrate, vitamins, and minerals.

Clause 4. Food additives shall have the qualities or standards according to one of the following conditions:

(1) Prescribed in the Codex Advisory Specification for the Identity and Purity of Food Additives;

(2) The Announcement of the Food and Drug Administration according to an approval of the Food Committee;

(3) As approved by the Sub-Committee on Problem Analysis and Technical Consideration Concerning Foods. The Manufactures or importers shall provide the results of the safety assessment of such food additives along with other information together with the application as follows:

(3.1) Chemical composition and characteristics of food additives applied for safety assessment including

(3.1.1) Identity and purity of the food additives used in the toxicity test for safety assessment;

(3.1.2) Reactions and fate of the food additives in food

(3.1.3) Specifications of the food additives

(3.2) Procedures for testing and safety assessment including

(3.2.1) Specifying the indicator(s) used in the experiment and toxicological data study as follows:

(a) Functional manifestations

(b) Morphological manifestations

(c) Neoplasms

(d) Reproduction and development toxicity

(e) *In Vitro* studies

(3.2.2) Use of Metabolic and Pharmacokinetic Studies of the food additives in safety assessment regarding the following aspects:

- (a) Identifying relevant animal species
- (b) Determining the mechanisms of toxicity
- (c) Metabolism into normal body constituents
- (d) Effects of the gut microflora on the chemical and effects of the chemical on the gut microflora

(3.2.3) Influence of age, nutritional status, and health status in the design and interpretation of studies

(3.2.4) Use of human studies in the safety assessment as follows:

- (a) Epidemiological studies
- (b) Food intolerance

(3.2.5) Determination of the Acceptable Daily Intake (ADI) regarding the information used in the determination as follows:

- (a) No-observed-effect level (NOEL)
- (b) Safety factor used in the calculation
- (c) Toxicological versus physiological responses
- (d) Comparison of the determined ADI and the trend of actual exposure

Clause 5. The analytical procedure for the food additives shall be in accordance with the Codex Advisory Specification for the Identity and Purity of Food Additives. In the case that the analytical procedure is different from the aforementioned specifications, it shall be the procedure specified in the Announcement of the Food and Drug Administration according to an approval of the Food Committee.

Clause 6. The use of food additives shall follow the type of food additive, type of food and maximum usage level according to one of the following conditions:

6.1 The most current Codex General Standard for Food Additives

6.2 The Announcement of the Food and Drug Administration according to an approval of the Food Committee

6.3 The use of food additives other than those stipulated in 6.1 and 6.2 must be approved by the Food and Drug Administration.

Clause 7. The use of food additives that differs from the statement stipulated in Clause 6 and has been approved by the Food and Drug Administration prior to the day this Notification comes into force, the person granted approval shall amend the use of food additive in accordance with this Notification within one year from the day this Notification comes into force.

Clause 8. The manufacturers or importers of food additives for sale shall follow Notification of the Ministry of Public Health Re: Production Processes, Production Equipments and Food Storage.

Clause 9. Use of containers for food additives shall follow Notification of the Ministry of Public Health Re: Containers.

Clause 10. Use of labels for food additives shall follow Notification of the Ministry of Public Health Re: Labels.

Clause 11. This notification shall not enforce to flavoring agents according to the Notification of the Ministry of Public Health Re: Flavoring Agents.

Clause 12. Food registration, food label, or Food Serial Numbers granted and do not conflict with this Notification may still be used. In the case that they conflict with this Notification, they may be used for not more than one year from the day this Notification comes into force.

Clause 13. This notification shall come into force as from the day following date of its publication in the Government Gazette.

Notified on 18th August B.E. 2547 (2004)

(Signed) Sudarat Keyuraphan
(Mrs. Sudarat Keyuraphan)

Minister of Public Health

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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.