



NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	Notifying Member: <u>THAILAND</u> If applicable, name of local government involved (Article 3.2 and 7.2):
2.	Agency responsible: Food and Drug Administration (Thai FDA) Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:
3.	Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [], 5.7.1 [], other:
4.	Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable): Novel food (ICS: 67.020, 67.040)
5.	Title, number of pages and language(s) of the notified document: Draft Ministry of Public Health Notification, No. ... B.E. ... (...) entitled "Novel food" (5 pages, in Thai)
6.	Description of content: The Ministry of Public Health (MOPH) considered that novel ingredients which have never been used for consumption as food or used as food ingredients as well as novel process that never been used earlier for production of food. Therefore, the notification of MOPH entitled "Novel food" has been issued for providing risk assessment measure in order to protect consumer as follows: <ul style="list-style-type: none">• Clause 1 – Novel food in this notification means:<ol style="list-style-type: none">1) (1) Any object used as food or food ingredients which have been significantly used for human consumption less than fifteen years based on scientific or reliable evidence, or2) (2) Any object used as food or food ingredients to which has been applied a production process not currently used, where that process gives rise to significant changes in the composition or structure of such food which affect their nutritional value, metabolism or level of undesirable substances, or3) (3) Any food product contains either (1) or (2) as an ingredient. However, food additives and food obtained through certain techniques of Genetic Modification/Genetic Engineering are not included in this notification. <ul style="list-style-type: none">• Clause 2 – Novel food shall be evaluated on safety assessment prior to submit its label to Food and Drug Administration for approval before use.• Clause 3 – To evaluate safety assessment of such novel food, results of safety assessment by risk assessment centres recognized by Food and Drug Administration together with other relevant information described in the annex of this notification shall be submitted to Food and Drug Administration. Information and scientific data about novel food required in Annex covers general information, specification, history of use, production process, analytical method, recommended dose or instruction for use, toxicological information consisting of

<p>absorption, distribution, metabolism, and elimination (ADME) and toxicological studies in animal and/or human, and nutrition information.</p> <ul style="list-style-type: none"> • Clause 4 – Novel food shall have specification and condition of use as approved by Food and Drug Administration. • Clause 5 – Producers or Importers of novel food shall follow this notification, a particular notification and relevant regulations with such novel foods. • Clause 6 – Labeling of novel food shall comply with the notification of MOPH (No.367) B.E. 2557 (2014) Re: Labeling of Prepackaged Foods, except clause 4(9) shall display date, month, and year of production and date, month, and year of expiration for consumption by expressing date, month, year respectively, and shall incorporated with declarations of "Produce", "Expire", or "Consume before", as the case may be. In addition, the following information shall be expressed on its label; <ol style="list-style-type: none"> 1) Name of active ingredient (if any), and 2) Instruction of use, or condition of use such as type or category of food and maximum permitted level of use. • Clause 7 – This notification does not apply to novel food for exportation • Clause 8 – This notification does not apply to producers or importers of novel foods which are permitted and produced or imported prior to the date of this notification come into force. • Clause 9 – This notification shall come into force as from the day following date of its publication in the Government Gazette.
<p>7. Objective and rationale, including the nature of urgent problems where applicable: Consumer protection</p>
<p>8. Relevant documents: Notification of the Ministry of Public Health No. 367 B.E. 2557 (2014) entitled: Labelling of Prepackaged Foods.</p>
<p>9. Proposed date of adoption: To be determined Proposed date of entry into force: On the date after being notified in the Official Gazette</p>
<p>10. Final date for comments: 60 days from notification</p>
<p>11. Texts available from: National enquiry point [X] or address, telephone and fax numbers and email and website addresses, if available, of other body: https://members.wto.org/crnattachments/2016/TBT/THA/16_0396_00_x.pdf</p>