



NOTIFICATION

<p>1. <b>Notifying Member:</b> <u>THAILAND</u> <b>If applicable, name of local government involved:</b></p>
<p>2. <b>Agency responsible:</b> Food and Drug Administration (Thai FDA)</p>
<p>3. <b>Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable):</b> Novel food (ICS Codes: 67.020, 67.040)</p>
<p>4. <b>Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> <b>All trading partners</b> <input type="checkbox"/> <b>Specific regions or countries:</b></p>
<p>5. <b>Title of the notified document:</b> Draft Ministry of Public Health Notification, No. .... B.E. .... (....) entitled "Novel food" <b>Language(s):</b> Thai <b>Number of pages:</b> 5 <a href="http://members.wto.org/crnattachments/2016/SPS/THA/16_0397_00_x.pdf">http://members.wto.org/crnattachments/2016/SPS/THA/16_0397_00_x.pdf</a></p>
<p>6. <b>Description of content:</b> 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:</p> <p>Clause 1 - Novel food in this notification means:</p> <ol style="list-style-type: none"><li>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; or</li><li>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; or</li><li>3) Any food product contains either 1) or 2) as an ingredient.</li></ol> <p>However, food additives and food obtained through certain techniques of Genetic Modification/Genetic Engineering are not included in this notification.</p> <p>Clause 2 - Novel food shall be evaluated on safety assessment prior to submit its label to Food and Drug Administration for approval before use.</p> <p>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.</p> <p>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 absorption, distribution, metabolism, and elimination (ADME) and toxicological studies in animal and/or human, and nutrition information.</p>

<p>Clause 4 - Novel food shall have specification and condition of use as approved by Food and Drug Administration.</p> <p>Clause 5 - Producers or Importers of novel food shall follow this notification, a particular notification and relevant regulations with such novel foods.</p> <p>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:</p> <ol style="list-style-type: none"> <li>1) Name of active ingredient (if any); and</li> <li>2) Instruction of use, or condition of use such as type or category of food and maximum permitted level of use.</li> </ol> <p>Clause 7 - This notification does not apply to novel food for exportation.</p> <p>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.</p> <p>Clause 9 - This notification shall come into force as from the day following date of its publication in the Government Gazette.</p>
<p><b>7. Objective and rationale:</b> <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests.</p>
<p><b>8. Is there a relevant international standard? If so, identify the standard:</b></p> <p><input type="checkbox"/> Codex Alimentarius Commission (<i>e.g. title or serial number of Codex standard or related text</i>)</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (<i>e.g. Terrestrial or Aquatic Animal Health Code, chapter number</i>)</p> <p><input type="checkbox"/> International Plant Protection Convention (<i>e.g. ISPM number</i>)</p> <p><input checked="" type="checkbox"/> None</p> <p><b>Does this proposed regulation conform to the relevant international standard?</b></p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p><b>If no, describe, whenever possible, how and why it deviates from the international standard:</b></p>
<p><b>9. Other relevant documents and language(s) in which these are available:</b> Notification of the Ministry of Public Health No. 367 B.E. 2557 (2014) entitled: Labeling of Prepackaged Foods (available in Thai and English)</p>
<p><b>10. Proposed date of adoption (dd/mm/yy):</b> To be determined. <b>Proposed date of publication (dd/mm/yy):</b> To be determined.</p>
<p><b>11. Proposed date of entry into force:</b> <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): On the date after being notified in the Official Gazette. <input type="checkbox"/> Trade facilitating measure</p>

**12. Final date for comments:  Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 4 April 2016**

**Agency or authority designated to handle comments:  National Notification Authority,  National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

E-mail: spsthailand@gmail.com

**13. Text(s) available from:  National Notification Authority,  National Enquiry Point. Address, fax number and e-mail address (if available) of other body:**

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