



20 September 2022

(22-7074)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1. Notifying Member: <u>THE SEPARATE CUSTOMS TERRITORY OF TAIWAN, PENGHU, KINMEN AND MATSU</u> If applicable, name of local government involved:
2. Agency responsible: Ministry of Health and Welfare
3. 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): Food ingredients to be used in food
4. Regions or countries likely to be affected, to the extent relevant or practicable: <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
5. Title of the notified document: Draft Amendment for "The Use Restrictions and Labeling Requirements of 2'-fucosyllactose Produced by Genetically Modified <i>Escherichia coli</i> strain BL21 (DE3) #1540 as a Food Ingredient" and "The Use Restrictions and Labeling Requirements of 2'-fucosyllactose Produced by Genetically Modified <i>Escherichia coli</i> strain K-12 DH1 MDO MAP1001d as a Food Ingredient". Language(s): English. Number of pages: 6 https://members.wto.org/crnattachments/2022/SPS/TPKM/22_6408_00_e.pdf https://members.wto.org/crnattachments/2022/SPS/TPKM/22_6408_01_e.pdf
6. Description of content: "The Use Restrictions and Labeling Requirement of 2'-fucosyllactose Produced by Genetically Modified <i>Escherichia coli</i> strain BL21 (DE3) #1540 as a Food Ingredient" and "The Use Restriction and Labeling Requirement of 2'-fucosyllactose Produced by Genetically Modified <i>Escherichia coli</i> strain K-12 DH1 MDO MAP1001d as a Food Ingredient" were promulgated and came into effect on 16 December 2020 and 16 June 2021, respectively. 2'-fucosyllactose referred to above regulations can be used for infant formula, follow-up infant formula and milk powder or similar products for children under seven years old. In accordance with the provisions of subparagraph 2 of Article 3 of the Act Governing Food Safety and Sanitation and Article 2 of the Enforcement Rules of the Act Governing Food Safety and Sanitation, the term "infant and follow-up formula" prescribed in the Act shall include infant formula, follow-up infant formula and infant formula for special medical purposes. Therefore, this draft amendment specifies to extend "infant formula for special medical purposes" to the usage scope, other use restrictions and labeling requirements have not changed.
7. Objective and rationale: <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>8. Is there a relevant international standard? If so, identify the standard:</p> <p><input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</p> <p><input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</p> <p><input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number):</p> <p><input checked="" type="checkbox"/> None</p> <p>Does this proposed regulation conform to the relevant international standard?</p> <p><input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>If no, describe, whenever possible, how and why it deviates from the international standard:</p>
<p>9. Other relevant documents and language(s) in which these are available:</p>
<p>10. Proposed date of adoption (dd/mm/yy): To be determined.</p> <p>Proposed date of publication (dd/mm/yy): To be determined.</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): To be determined.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input checked="" type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 19 November 2022</p> <p>Agency or authority designated to handle comments: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Food and Drug Administration Ministry of Health and Welfare No.161-2, Kunyang St, Nangang District, Taipei City 115-61, Taiwan Tel: +(886 2) 2787 8000 ext. 7318 Fax: +(886 2) 2653 1062 E-mail: yoannaluo@fda.gov.tw</p>
<p>13. Text(s) available from: <input checked="" type="checkbox"/> National Notification Authority, <input checked="" type="checkbox"/> National Enquiry Point. Address, fax number and e-mail address (if available) of other body:</p> <p>Food and Drug Administration Ministry of Health and Welfare No.161-2, Kunyang St, Nangang District, Taipei City 115-61, Taiwan Tel: +(886 2) 2787 8000 ext. 7318 Fax: +(886 2) 2653 1062 E-mail: yoannaluo@fda.gov.tw</p>