



19 September 2025

(25-5894)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English/French

NOTIFICATION

1.	Notifying Member: CANADA If applicable, name of local government involved:
2.	Agency responsible: Health Canada
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): Pullulanase from <i>Klebsiella pneumoniae</i> AE-PUL (ICS codes: 67.220.20)
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: Modification to the List of Permitted Food Enzymes to authorize the use of pullulanase from a new source. Language(s): English and French. Number of pages:
6.	Description of content: Health Canada's Food and Nutrition Directorate completed a premarket safety assessment of a food additive submission seeking authorization for the use of pullulanase from <i>Klebsiella pneumoniae</i> AE-PUL to be used as a food enzyme in brewers' mash and beer. The requested maximum level of use for this food enzyme is "Good Manufacturing Practice". The results of the premarket assessment support the safety of pullulanase from <i>K. pneumoniae</i> AE-PUL for its requested uses. Consequently, Health Canada will authorize the use of pullulanase from this source as described in the notice by modifying the <i>List of Permitted Food Enzymes</i> (https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted/5-enzymes.html) on 20 October 2025 . This modification will come into force on the day it is published in the list. The purpose of the notice of modification (notified document) is to publicly announce the Department's decision in this regard and to provide the appropriate contact information for those wishing to submit an inquiry or new scientific information relevant to the safety of this food additive.
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.
8.	Is there a relevant international standard? If so, identify the standard: <input type="checkbox"/> Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text): <input type="checkbox"/> World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):

<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: Health Canada's food and nutrition website: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/notices-proposal-notices-modification.html, "Notices of proposal and notices of modification", posted on 15 September 2025 (available in English and French)</p>
<p>10. Proposed date of adoption (dd/mm/yy): The modification described in the notice will be legally enabled once published in Health Canada's Lists of Permitted Food Additives: https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html.</p> <p>Proposed date of publication (dd/mm/yy): 20 October 2025</p>
<p>11. Proposed date of entry into force: <input type="checkbox"/> Six months from date of publication, and/or (dd/mm/yy): The modification described in the notice comes into force the day it is made to the Lists of Permitted Food Additives: https://www.canada.ca/en/health-canada/services/food-nutrition/food-safety/food-additives/lists-permitted.html.</p> <p><input type="checkbox"/> Trade facilitating measure</p>
<p>12. Final date for comments: <input type="checkbox"/> Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 29 November 2025 (75 days from the date of publication of the notice of modification)</p> <p>Agency or authority designated to handle comments: <input 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>13. Text(s) available from: <input 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>The notice "Modification to the List of Permitted Food Enzymes to authorize the use of pullulanase from a new source" is available through the following weblinks: https://www.canada.ca/en/health-canada/services/food-nutrition/legislation-guidelines/acts-regulations/notices-proposal-notices-modification/permitted-food-enzymes-authorize-pullulanase-from-new-source.html (English) https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/legislation-lignes-directrices/lois-reglements/avis-proposition-avis-modification/enzymes-alimentaires-autorisees-pullulanase-nouvelle-source.html (French)</p> <p>Or requested from: Canada's Notification Authority and Enquiry Point Technical Barriers and Regulations Division Global Affairs Canada 111 Sussex Drive Ottawa, Ontario, K1A 0G2 Canada Tel: +(343) 203 4273 Fax: +(613) 943 0346 E-mail: enquiry@international.gc.ca</p>