

通报

1.	通报成员: 加拿大
2.	负责机构: 加拿大卫生部
3.	覆盖的产品: 来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶 (ICS 代码: 67.220.20; 67.060)
4.	可能受影响的地区或国家: [X] 所有贸易伙伴 [] 特定地区或国家
5.	通报标题: 关于修订许可食品酶清单, 将来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶的使用扩大到面包、面粉、全麦面粉和非标准化烘焙产品。

	<p>页数：4 使用语言：英语和法语 链接网址： https://members.wto.org/crnattachments/2022/SPS/CAN/22_2603_00_f.pdf https://members.wto.org/crnattachments/2022/SPS/CAN/22_2603_00_e.pdf</p>
<p>6.</p>	<p>内容简述：加拿大卫生部食品管理局对食品添加剂申请进行了上市前安全评估，旨在请求批准在面包、面粉、全麦面粉和非标准化烘焙产品中使用来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶（一孵化蛋白酶）。</p> <p>来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶已被允许在某些水解食物中使用，但之前其在允许的食物酶清单中为“来自嗜热脂肪土芽孢杆菌 TP7 的蛋白酶”。其他来源蛋白酶已被允许用于申请人要求的食品中。</p> <p>上市前评估结果证明了来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶用作相关用途时的安全性。因此，加拿大卫生部已允许使用来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶，并通过修订许可食品酶清单，将来源嗜热脂肪土芽孢杆菌 TP7 的名称改为热解蛋白无氧芽孢杆菌，以与信息文件中的当前分类相匹配，上述规定于 2022 年 3 月 24 日生效。</p> <p>本文件的目的是公告卫生部的这一决定，同时提供相关联系方式，方便相关人士提交查询或提交同该食品添加剂安全性相关的其他科学信息。</p>
<p>7.</p>	<p>目的和理由：</p> <p><input checked="" type="checkbox"/> 食品安全</p> <p><input type="checkbox"/> 动物健康</p> <p><input type="checkbox"/> 植物保护</p> <p><input type="checkbox"/> 保护国家免受有害生物的其他危害</p>

	<input type="checkbox"/> 保护人类免受动/植物有害生物的危害 保护国家免受有害生物的其他危害：
8.	是否有相关国际标准？如有，指出标准： <input type="checkbox"/> 食品法典委员会(例如：食品法典委员会标准或相关文件的名称或序号) <input type="checkbox"/> 世界动物卫生组织(OIE)(例如：陆生或水生动物卫生法典，章节号) <input type="checkbox"/> 国际植物保护公约(例如：ISPM N°) <input checked="" type="checkbox"/> 无 该法规草案是否符合相关国际标准： <input type="checkbox"/> 是 <input type="checkbox"/> 否
9.	可提供的相关文件及文件语种： 加拿大卫生部食品和营养-“公共参与及合作”网站，于 2022 年 3 月 24 日发布（英语和法语版本）： https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships.html https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats.html
10.	拟批准日期： 2022 年 3 月 24 日 拟公布日期：
11.	拟生效日期： <input type="checkbox"/> 公布日后 6 个月，及/或(年月日)： 2022 年 3 月 24 日 <input type="checkbox"/> 贸易促进措施

12.	<p>意见反馈截至日期:</p> <p><input type="checkbox"/> 通报发布之日起 60 天, 及/或(年/月/日): 2022 年 6 月 6 日</p>
13.	<p>负责处理反馈意见的机构:</p> <p><input type="checkbox"/> 国家通报机构</p> <p><input checked="" type="checkbox"/> 国家咨询点, 或其他机构的联系地址、传真及电子邮件地址(如能提供):</p>
14.	<p>文本可从以下机构得到:</p> <p><input type="checkbox"/> 国家通报机构</p> <p><input checked="" type="checkbox"/> 国家咨询点, 或其他机构的联系地址、传真及电子邮件地址(如能提供):</p> <p>“关于修订许可食品酶清单以将来自热解蛋白无氧芽孢杆菌 TP7 的嗜热菌蛋白酶的使用扩大到面包、面粉、全麦面粉和非标准化烘焙产品的通报”可通过以下网页链接获取: https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-modification-list-permitted-food-enzymes-thermolysin-anoxybacillus-caldiproteolyticus-tp7.html (英语)</p> <p>https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats/avis-modification-liste-enzymes-alimentaires-autorisees-thermolysine-anoxybacillus-caldiproteolyticus-tp7.html (法语)</p> <p>加拿大通报机构和咨询点</p> <p>技术性壁垒和法规处</p> <p>加拿大国际事务部</p>

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NOTIFICATION

1.	Notifying Member: <u>CANADA</u> 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): Thermolysin from <i>Anoxybacillus caldiproteolyticus</i> TP7 (ICS Codes: 67.220.20; 67.060)
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: Notice of Modification to the <i>List of Permitted Food Enzymes</i> to Extend the Use of Thermolysin from <i>Anoxybacillus caldiproteolyticus</i> TP7 to Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products. Language(s): English and French. Number of pages: 4 https://members.wto.org/crnattachments/2022/SPS/CAN/22_2603_00_f.pdf https://members.wto.org/crnattachments/2022/SPS/CAN/22_2603_00_e.pdf
6.	Description of content: Health Canada's Food Directorate completed a premarket safety assessment of a food additive submission seeking approval for the use of the thermolysin (a type of protease) from <i>Anoxybacillus caldiproteolyticus</i> TP7 in bread, flour, whole wheat flour and unstandardized bakery products. Thermolysin from <i>A. caldiproteolyticus</i> TP7 was already permitted for use in certain hydrolyzed foods, but it previously appeared in the <i>List of Permitted Food Enzymes</i> as "Protease from <i>Geobacillus stearothermophilus</i> TP7". Protease from other sources is already permitted for use in

the same foods as those requested by the petitioner.

The results of the premarket assessment support the safety of thermolysin from *A. caldiproteolyticus* TP7 for its requested uses. Consequently, Health Canada has enabled the uses of thermolysin from *A. caldiproteolyticus* TP7 and changed the name of the source *Geobacillus stearothermophilus* TP7 to *A. caldiproteolyticus* TP7 to match the current taxonomic classification as described in the information document by modifying the *List of Permitted Food Enzymes*, effective 24 March 2022.

The purpose of this communication is to publically 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:** food safety, animal health, plant protection, protect humans from animal/plant pest or disease, protect territory from other damage from pests.

8. **Is there a relevant international standard? If so, identify the standard:**

Codex Alimentarius Commission (*e.g. title or serial number of Codex standard or related text*):

World Organization for Animal Health (OIE) (*e.g. Terrestrial or Aquatic Animal Health Code, chapter number*):

International Plant Protection Convention (*e.g. ISPM number*):

None

Does this proposed regulation conform to the relevant international standard?

Yes No

If no, describe, whenever possible, how and why it deviates from the international standard:

9. **Other relevant documents and language(s) in which these are available:** Health Canada's Food and Nutrition – 'Public Involvement and Partnerships' Website, posted 24 March 2022 (available in English and French):

<https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships.html>

<https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats.html>

10. Proposed date of adoption *(dd/mm/yy)*: 24 March 2022

Proposed date of publication *(dd/mm/yy)*:

11. Proposed date of entry into force: Six months from date of publication, and/or *(dd/mm/yy)*: 24 March 2022

Trade facilitating measure

12. Final date for comments: Sixty days from the date of circulation of the notification and/or *(dd/mm/yy)*: 6 June 2022

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:

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

The "Notice of Modification to the *List of Permitted Food Enzymes* to Extend the Use of Thermolysin from *Anoxybacillus caldiproteolyticus* TP7 to Bread, Flour, Whole Wheat Flour and Unstandardized Bakery Products" is available through the following weblink:

<https://www.canada.ca/en/health-canada/services/food-nutrition/public-involvement-partnerships/notice-modification-list-permitted-food-enzymes-thermolysin-anoxybacillus-caldiproteolyticus-tp7.html> (English)

<https://www.canada.ca/fr/sante-canada/services/aliments-nutrition/participation-public-partenariats/avis-modification-liste-enzymes-aliments-autorisees-thermolysine-anoxybacillus-caldiproteolyticus-tp7.html> (French)

Canada's Notification Authority and Enquiry Point

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