



4 October 2017

(17-5332)

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Committee on Sanitary and Phytosanitary Measures

Original: English

**NOTIFICATION**

<b>1. Notifying Member:</b> <u>EUROPEAN UNION</u> <b>If applicable, name of local government involved:</b>
<b>2. Agency responsible:</b> European Commission, Health and Food Safety Directorate-General
<b>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):</b> Fine bakery products for special nutritional uses
<b>4. Regions or countries likely to be affected, to the extent relevant or practicable:</b> <input checked="" type="checkbox"/> All trading partners <input type="checkbox"/> Specific regions or countries:
<b>5. Title of the notified document:</b> Commission Regulation (EU) amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council as regards the use of sweeteners in fine bakery wares (Text with EEA relevance). <b>Language(s):</b> English. <b>Number of pages:</b> 4 and 2 <a href="https://members.wto.org/crnattachments/2017/SPS/EEC/17_4521_00_e.pdf">https://members.wto.org/crnattachments/2017/SPS/EEC/17_4521_00_e.pdf</a> <a href="https://members.wto.org/crnattachments/2017/SPS/EEC/17_4521_01_e.pdf">https://members.wto.org/crnattachments/2017/SPS/EEC/17_4521_01_e.pdf</a>
<b>6. Description of content:</b> The text takes away the authorisation of use of nine sweeteners (E 950 Acesulfame K, E 951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E 954 Saccharin and its Na, K and Ca salts, E 955 Sucralose, E 959 Neohesperidine DC, E 961 Neotame, E 962 Salt of aspartame-acesulfame and E 969 Advantame) in "fine bakery products for special nutritional uses" (food category 07.2 fine bakery wares of Annex II to Regulation (EC) No 1333/2008 on food additives).  In order to allow economic operators to adapt to the new rules, it is appropriate to provide for a transitional period during which fine bakery products for special nutritional uses containing any of those sweeteners may continue to be marketed.
<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.
<b>8. Is there a relevant international standard? If so, identify the standard:</b> <input checked="" type="checkbox"/> <b>Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):</b> General standard for food additives - CODEX STAN 192-1995 <input type="checkbox"/> <b>World Organization for Animal Health (OIE) (e.g. Terrestrial or Aquatic Animal Health Code, chapter number):</b> <input type="checkbox"/> <b>International Plant Protection Convention (e.g. ISPM number):</b> <input type="checkbox"/> <b>None</b>

**Does this proposed regulation conform to the relevant international standard?**

[ ] Yes [X] No

**If no, describe, whenever possible, how and why it deviates from the international standard:** The Codex Alimentarius Standard for food additives includes provisions for the use of INS 950 Acesulfame K, INS 951 Aspartame, INS 952 Cyclamates, INS 954 Saccharins, INS 955 Sucralose, INS 961 Neotame, and INS 962 aspartame-acesulfame salt as sweeteners in food category "07.2 fine bakery wares (sweet, salty, savoury) and mixes" for special nutritional uses only (footnote 77) or for use in products for special nutritional use only (footnote 165).

In the European Union the use of sweeteners (E 950 Acesulfame K, E 951 Aspartame, E952 Cyclamic acid and its Na and Ca salts, E 954 Saccharin and its Na, K and Ca salts, E 955 Sucralose, E 959 Neohesperidine DC, E 961 Neotame, E 962 Salt of aspartame-acesulfame and E 969 Advantame) in "fine bakery products for special nutritional uses" was authorised by the European Parliament and Council Directive 94/35/EC. The food "fine bakery products for special nutritional uses" covered "food for persons suffering from carbohydrate metabolism disorders (diabetes)" regulated by Council Directive 89/398/EEC. This Directive established a common definition for "foodstuffs for particular nutritional uses" and provided that specific provisions could be adopted as regards "food for persons suffering from carbohydrate metabolism disorders (diabetes)", a category of food falling within the definition of foodstuffs for particular nutritional uses.

However, as concluded in the Commission's report on foods for persons suffering from diabetes, the scientific basis for setting specific compositional requirements for those foods was lacking. Furthermore, Regulation (EU) No 609/2013 of the European Parliament and of the Council has abolished the concept of "foodstuffs for particular nutritional uses", including that of "food for persons suffering from carbohydrate metabolism disorders (diabetes)".

On 29 May 2017 the European Commission published the draft Commission Regulation in the Better Regulation Portal ([http://ec.europa.eu/info/law/better-regulation/initiatives/isc-2017-02792\\_en](http://ec.europa.eu/info/law/better-regulation/initiatives/isc-2017-02792_en)) for a feedback mechanism during 4-weeks; the period of feedback mechanism ended on 26 June 2017. The comments received addressed mainly the establishment of a transitional period whereby fine bakery products for special nutritional uses should continue to be marketed.

As a result of all the above, the authorisation of use of those nine sweeteners (E 950, E 951, E 952, E 954, E 955, E 959, E 961, E 962, E 969) in "fine bakery products for special nutritional uses" in accordance with Article 7(c) of Regulation (EC) No 1333/2008 is no longer justified and those products should not continue to be marketed.

However, the European Commission provides a transitional period during which fine bakery products for special nutritional uses containing any of those nine sweeteners (E 950, E 951, E 952, E 954, E 955, E 959, E 961, E 962, E 969) that have been lawfully placed on the market before the entry into force of the Regulation may continue to be marketed until the stocks are exhausted.

**9. Other relevant documents and language(s) in which these are available:**

- European Parliament and Council Directive 94/35/EC (OJ L 237, 10 September 1994, p. 3) and Council Directive 89/398/EEC (OJ L 186, 30 June 1989, p. 27)
- Regulation (EU) No 609/2013 of the European Parliament and of the Council (OJ L 181, 29 June 2013, p. 35).
- Report from the Commission to the European Parliament and the Council on foods for persons suffering from carbohydrate metabolism disorders (diabetes) of 1 July 2008 (COM(2008) 392 final)

(available in English)

**10. Proposed date of adoption (dd/mm/yy):** Beginning of 2018**Proposed date of publication (dd/mm/yy):** Beginning of 2018

**11. Proposed date of entry into force:**  Six months from date of publication, and/or (dd/mm/yy): Twenty days after publication in the Official Journal of the European Union.  
 Trade facilitating measure

**12. Final date for comments:**  Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 2 December 2017

**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:

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**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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