



5 June 2019

(19-3855)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION OF EMERGENCY MEASURES

1. Notifying Member: <u>EUROPEAN UNION</u> If applicable, name of local government involved:
2. Agency responsible: European Commission, Health and Food Safety Directorate-General
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): Flavourings, 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: Commission Regulation (EU) 2019/799 amending Annex I to Regulation (EC) No 1334/2008 of the European Parliament and of the Council as regards removal from the Union list of the flavouring substance furan- 2(5H)-one (FL-no 10.066) (Text with EEA relevance). Language(s): English, French and Spanish. Number of pages: 3 https://members.wto.org/crnattachments/2019/SPS/EEC/19_3290_00_e.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_3290_00_f.pdf https://members.wto.org/crnattachments/2019/SPS/EEC/19_3290_00_s.pdf
6. Description of content: The Union list of flavourings and source materials is laid down in Annex I to Regulation (EC) No 1334/2008. It was established by Commission Implementing Regulation (EU) No 872/2012 of 1 October 2012 adopting the list of flavouring substances notified in G/SPS/N/EU/13/Add.1 (12 October 2012) which is now amended by this Regulation. This addendum concerns the removal of the flavouring substance furan-2(5H)-one (FL-no 10.066) from the European Union list of flavourings following the European Food Safety Authority opinion published at the end of January 2019 which concluded that this substance is genotoxic in vivo and therefore its use as a flavouring substance raises a safety concern. The measure has been taken in urgency in view of this EFSA assessment indicating a serious risk (genotoxicity) of this flavouring substance FL 10.066 on the basis of new scientific data. Therefore, its addition to foods should be stopped swiftly. It has not been possible to notify the draft measure in view of the nature of the risk involved. According to the European Association of producers of flavourings (EFFA) as reported in the opinion by EFSA, the poundage for this substance in Europe is very low (zero in 2017). This substance furan-2(5H)-one (FL No 10.066) can also be identified with CAS No. 497-23-4, JECFA No 2000 and JECFA name "4-hydroxy-2-butenic acid gamma lactone". The EFSA opinion is available as EFSA Scientific Opinion on Flavouring Group Evaluation 217 Revision 2 (FGE.217Rev2), consideration of genotoxicity potential for alpha, beta

	unsaturated ketones and precursors from chemical subgroup 4.1 of FGE.19: lactones; EFSA Journal 2019;17(1):5568.
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.	Nature of the urgent problem(s) and reason for urgent action: The flavouring substance FL 10.066 is genotoxic and therefore this substance should not be added to foods. This substance could be used as a flavouring substance in food before the adoption of the new measure and consumers should not be exposed to genotoxic substances added to food.
9.	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): <input type="checkbox"/> International Plant Protection Convention (e.g. ISPM number): <input checked="" type="checkbox"/> None Does this proposed regulation conform to the relevant international standard? <input type="checkbox"/> Yes <input type="checkbox"/> No If no, describe, whenever possible, how and why it deviates from the international standard:
10.	Other relevant documents and language(s) in which these are available:
11.	Date of entry into force (dd/mm/yy)/period of application (as applicable): 21 May 2019 <input type="checkbox"/> Trade facilitating measure
12.	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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu
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: European Commission DG Health and Food Safety, Unit D2-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 Fax: +(32 2) 29 98090 E-mail: sps@ec.europa.eu