



21 July 2023

(23-4994)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

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| 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): Food products |
| 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 Commission Regulation amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additives nitrites (E 249-250) and nitrates (E 251-252) (Text with EEA relevance). Language(s): English. Number of pages: 49 https://members.wto.org/crnattachments/2023/SPS/EEC/23_11184_00_e.pdf https://members.wto.org/crnattachments/2023/SPS/EEC/23_11184_01_e.pdf |
| 6. Description of content: The text revises the conditions of use and the EU specifications of the authorised food additives potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252). Nitrites and nitrates are food additives authorised in the European Union used as a preservative to secure, in conjunction with other factors, the microbiological safety of foods. At the same time, the presence of nitrites and nitrates in foods can give rise to the formation of nitrosamines some of which are carcinogenic. The European Food Safety Authority (EFSA) in its 2017 scientific opinions re-evaluating the safety of nitrites and nitrates as food additives concluded that their respective Acceptable Daily Intake values (ADIs) were not exceeded from food additive uses; however the ADIs would be exceeded if all sources of dietary exposure were to be considered together. In addition, EFSA considered that there was some concern for the overall exposure to nitrosamines present in food, which was also confirmed by the recent scientific opinion on the risks to public health related to the presence of nitrosamines in food (2023). Following the EFSA re-evaluation of nitrites and nitrates as food additives, it is appropriate to reduce the maximum amounts of nitrites and nitrates that may be added to foods to keep the level of nitrosamines potentially formed due to that use as low as possible, while ensuring microbiological safety. It is also appropriate to amend the specifications and lower the existing maximum permitted limits for lead, mercury and arsenic in nitrites and nitrates additives. In order to allow for a smooth transition, the text lays down transitional periods for food business operators to adapt to the new more stringent conditions of use and specifications. |

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): Codex General Standard for Food Additives – Codex Stan 192-1995

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: The food additive specifications of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) developed by JECFA do not contain maximum limits for arsenic and mercury. The maximum limit for lead in the specifications developed by JECFA is higher (2 mg/kg) than in the revised EU specifications.

In the Codex General Standard for Food Additives (GSFA, CODEX STAN 192-1995), there are provisions for nitrites (INS 249, 250) and nitrates (INS 251, 252) however limited to certain standardised products only resulting from the alignment between the GSFA and Codex Commodity standards. The Codex work on the food additive provisions for nitrites and nitrates has not been completed and has been postponed until consensus is reached on a reporting basis for the nitrate residual provisions pending the advice of CCMAS (Codex Committee on Methods of Analysis and Sampling), see REP21/FA, paras 139-141.

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

– EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Alicja Mortensen, Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Oliver Lindtner, Peter Moldeus, Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Piet van den Brandt, Cristina Fortes, Leonardo Merino, Fidel Toldrà, Davide Arcella, Anna Christodoulidou, José Cortinas Abrahantes, Federica Barrucci, Ana Garcia, Fabiola Pizzo, Dario Battacchi, Maged Younes, 2017. Scientific Opinion on the re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives. EFSA Journal 2017;15(6):4786, 157 pp.

<https://www.efsa.europa.eu/en/efsajournal/pub/4786>

– EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS), Alicja Mortensen, Fernando Aguilar, Riccardo Crebelli, Alessandro Di Domenico, Birgit Dusemund, Maria Jose Frutos, Pierre Galtier, David Gott, Ursula Gundert-Remy, Claude Lambré, Jean-Charles Leblanc, Oliver Lindtner, Peter Moldeus, Pasquale Mosesso, Agneta Oskarsson, Dominique Parent-Massin, Ivan Stankovic, Ine Waalkens-Berendsen, Rudolf Antonius Woutersen, Matthew Wright, Piet van den Brandt, Cristina Fortes, Leonardo Merino, Fidel Toldrà, Davide Arcella, Anna Christodoulidou, Federica Barrucci, Ana Garcia, Fabiola Pizzo, Dario Battacchi, Maged Younes, 2017. Scientific Opinion on the re-evaluation of sodium nitrate (E 251) and potassium nitrate (E 252) as food additives. EFSA Journal 2017;15(6):4787, 123 pp.

<https://www.efsa.europa.eu/en/efsajournal/pub/4787>

– EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel), Dieter Schrenk, Margherita Bignami, Laurent Bodin, James Kevin Chipman, Jesús del Mazo, Christer Hogstrand, Laurentius (Ron) Hoogenboom, Jean-Charles Leblanc, Carlo Stefano Nebbia, Elsa Nielsen, Evangelia Ntzani, Annette Petersen, Salomon Sand, Tanja

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| <p>Schwerdtle, Christiane Vleminckx, Heather Wallace, Benigni Romualdo, Cristina Fortes, Stephen Hecht, Marco Iammarino, Olaf Mosbach-Schulz, Francesca Riolo, Anna Christodoulidou, Bettina Grasl-Kraupp, 2023. Scientific Opinion on the risk assessment of N-nitrosamines in food. EFSA Journal 2023;21(3):7884, 278 pp. https://www.efsa.europa.eu/en/efsajournal/pub/7884 (available in English)</p> |
| <p>10. Proposed date of adoption (dd/mm/yy): Foreseen for Q3 2023. Proposed date of publication (dd/mm/yy): Foreseen for Q3 2023.</p> |
| <p>11. Proposed date of entry into force: [] Six months from date of publication, and/or (dd/mm/yy): 20 days after publication in the Official Journal of the European Union (with transitional provisions for 6, 24, 36 and 48 months). [] Trade facilitating measure</p> |
| <p>12. Final date for comments: [X] Sixty days from the date of circulation of the notification and/or (dd/mm/yy): 19 September 2023 Agency or authority designated to handle comments: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p> |
| <p>13. Text(s) available from: [X] National Notification Authority, [X] National Enquiry Point. Address, fax number and e-mail address (if available) of other body: European Commission DG Health and Food Safety, Unit A4-Multilateral International Relations Rue Froissart 101 B-1049 Brussels Tel: +(32 2) 29 54263 E-mail: sps@ec.europa.eu</p> |