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Delegations will find attached document D089496/03.

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COMMISSION REGULATION (EU) .../...

of **XXX**

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)

COMMISSION REGULATION (EU) .../...

of **XXX**

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)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives¹, and in particular Article 10(3) and Article 14 thereof,

Having regard to Regulation (EC) No 1331/2008 of the European Parliament and of the Council of 16 December 2008 establishing a common authorisation procedure for food additives, food enzymes and food flavourings², and in particular Article 7(5) thereof,

Whereas:

- (1) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use.
- (2) Commission Regulation (EU) No 231/2012³ lays down specifications for food additives that are listed in Annex II to Regulation (EC) No 1333/2008.
- (3) Pursuant to Article 3(1) of Regulation (EC) No 1331/2008, the Union list of food additives may be updated either on the initiative of the Commission or following an application.
- (4) Potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) are substances authorised in accordance with Annex II to Regulation (EC) No 1333/2008. They have been used for many decades as a preservative to secure, in conjunction with other factors, the preservation and microbiological safety of foods, in particular meat, fish and cheese products, and to contribute to their characteristic organoleptic properties. However, at the same time, it is recognised that the presence of nitrites and nitrates in foods can give rise to the formation of nitrosamines some of which are carcinogenic. Therefore, there is a need to minimise the risk of formation of nitrosamines through the presence of nitrites and nitrates in foods, on the one hand, and maintain their protective effects against the multiplication of bacteria, in particular of *C. botulinum*, responsible for botulism, on the other hand.

¹ OJ L 354, 31.12.2008, p. 16.

² OJ L 354, 31.12.2008, p. 1.

³ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

- (5) The maximum levels of nitrites (E 249 and E 250) and nitrates (E 251 and E 252) in foods currently laid down in Regulation (EC) No 1333/2008 are based on the opinions from the Scientific Committee for Food of 1990⁴ and 1995⁵ as well as on the opinion of the European Food Safety Authority ('the Authority') of 26 November 2003⁶. They are expressed as 'added amount', where possible, as according to the Authority the added amount of nitrites, rather than the residual amount, contributes to the inhibitory activity against *C. botulinum*.
- (6) By way of exception, maximum residual levels of nitrites and nitrates are laid down for certain traditionally cured meat products. For such products, cured by immersion in a curing solution, using dry application of curing mixture to the surface of the meat or a combination of both, or where nitrites and/or nitrates are included in a compound product or where the curing solution is injected into the product prior to cooking, it is not practicable to determine the added amount of curing salts absorbed by the meat due to the nature of the manufacturing process associated with those traditional products.
- (7) In 2014, the Commission finalised a desk study to monitor the implementation by the Member States of the Union rules on nitrites. That study revealed that with some exceptions the typical amount of nitrites added to non-sterilised meat products is lower than the established Union maximum level. In the report, the Commission concluded that considering that in most Member States nitrites were usually added to meat products at levels lower than the maximum permitted levels, the possibility of reviewing the current maximum levels of nitrites to further reduce the exposure to those food additives had to be explored. The Commission therefore launched an ad hoc study regarding the use of nitrites by the industry in different categories of meat products. The study, completed in 2016, also concluded that there was a possibility to lower the current maximum levels of nitrites authorised in the Union legislation.
- (8) Article 32(1) of Regulation (EC) No 1333/2008 provides that all food additives that were already permitted in the Union before 20 January 2009 are subject to a new risk assessment by the Authority. The Authority delivered its scientific opinions re-evaluating the safety of nitrites and nitrates as food additives on 15 June 2017⁷.
- (9) For nitrites, the Authority derived an Acceptable Daily Intake (ADI) of 0,07 mg nitrite ion/kg bw per day. The estimated exposure resulting from its use as a food additive did not exceed this ADI for the general population, except for a slight exceedance in children at the highest percentile and it represented approximately 17% of the overall dietary exposure. If all sources of dietary exposure were considered together (food additives, natural presence and contamination), the ADI would be exceeded in infants, toddlers and children at the mean exposure and for all age groups at the highest exposure. As regards the exposure to exogenous nitrosamines, the Authority concluded that it is not possible to clearly discern the nitrosamines formed from the nitrite added as a food additive from those formed from the nitrite present in the food

⁴ Opinion on nitrates and nitrites expressed on 19 October 1990, European Commission — Reports of the Scientific Committee for Food (twenty-sixth series), p. 21.

⁵ Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission — Reports of the Scientific Committee for Food (thirty eighth series), p. 1.

⁶ Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products, <https://www.efsa.europa.eu/en/efsajournal/pub/14>

⁷ *EFSA Journal* 2017;15(6):4786 and *EFSA Journal* 2017;15(6):4786.

naturally or as result of contamination. The Authority considered that there was some concern for the overall exposure to exogenous nitrosamines at high levels for all age groups except for the elderly. Finally, the Authority confirmed evidence to link preformed N-nitrosodimethylamine and colorectal cancers and some evidence to link dietary nitrite with gastric cancers and to link the combination of nitrite plus nitrate from processed meat with colorectal cancers. This is in line with the conclusion reached by the International Agency for Research on Cancer in 2015⁸.

- (10) For nitrates, the Authority maintained an ADI of 3,7 mg nitrate ion/kg bw per day and estimated that the exposure resulting from its use as a food additive did not exceed this ADI. If all sources of dietary nitrate exposure were considered together, the ADI would be exceeded for all age groups at the mean and the highest exposure. The contribution of nitrates used as food additives represented approximately 2% of the overall exposure.
- (11) In both opinions, the Authority issued some recommendations suggesting further studies on nitroso compounds, nitrites and nitrates and lowering the current limits for toxic elements (lead, mercury and arsenic) in the Union specifications for nitrites (E 249 and E 250) and nitrates (E 251 and E 252).
- (12) On 7 December 2022, the Commission launched a public call for technical data on toxic elements, to address this latter recommendation of the Authority. The data were submitted in January 2023.
- (13) In its scientific opinion on the risks to public health related to the presence of nitrosamines in food published on 28 March 2023⁹, the Authority concluded that the Margin of Exposure for carcinogenic nitrosamines occurring in food is highly likely to be less than 10 000 at the high exposure for all age groups, which may indicate a health concern, and that ‘meat and meat products’ is the main food category contributing to the exposure.
- (14) Commission Implementing Regulation (EU) 2021/1165¹⁰ only authorises the use of sodium nitrite (E 250) and potassium nitrate (E 252) in organic meat products at lower maximum levels than the maximum levels set out in Regulation (EC) No 1333/2008 and only under the condition that it has been demonstrated to the satisfaction of the competent authority that there is no technological alternative.
- (15) By Commission Decision (EU) 2021/741¹¹, the Commission approved for a limited period of three years the request of the Kingdom of Denmark to maintain more stringent national provisions on the addition of nitrites to meat products. The Danish national provisions maintain lower maximum levels of nitrites for certain meat products, compared with the maximum levels set out in Regulation (EC) No 1333/2008 and do not allow the placing on the market of products for which only maximum residual levels can be established.
- (16) Given the re-evaluation of nitrites and nitrates as food additives and the assessment of carcinogenic nitrosamines in food by the Authority and taking into account the desk

⁸ *IARC Monographs Volume 114: Evaluation of consumption of red meat and processed meat.*

⁹ *EFSA Journal* 2023;21(3):7884.

¹⁰ Commission Implementing Regulation (EU) 2021/1165 of 15 July 2021 authorising certain products and substances for use in organic production and establishing their lists (OJ L 253, 16.7.2021, p. 13).

¹¹ Commission Decision (EU) 2021/741 of 5 May 2021 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products (OJ L 159, 6.5.2021, p. 13).

study with the Member States, the ad-hoc study as regards the use of nitrites by industry, the experience gained with the application of the maximum levels for nitrites and nitrates authorised in organic meat products, the experience of Denmark related to more stringent national provisions for the use of nitrites in meat products and the extensive consultation of organisations representing the relevant food business operators, consumers and experts from competent authorities of Member States, it is appropriate to amend the current conditions of use of nitrites and nitrates as food additives.

- (17) Given the re-evaluation of nitrites and nitrates as food additives by the Authority, it is also appropriate to lower the existing maximum limits for the presence of lead, mercury and arsenic in nitrites (E 249 and E 250) and nitrates (E 251 and E 252), laid down in the Union specifications.
- (18) In particular, the maximum amounts of nitrites and nitrates that may be added as food additives to foods should be reduced to keep the level of nitrosamines, potentially formed due to that use as low as possible while ensuring microbiological safety. Furthermore, for each provision for the use of nitrites and nitrates the maximum residual levels from all sources should be established for products ready for marketing throughout the shelf-life to monitor better the exposure vis-à-vis the respective ADIs. The use of both maximum levels for added and residual amounts is in line with the approach agreed by the Codex Committee on Food Additives¹². Nevertheless, in light of a lower concern related to the contribution of nitrates used as food additives to the overall exposure and the ongoing discussion on the need to establish a single residual level for both nitrites and nitrates in each food category, the products should still be allowed to be placed on the market if the new maximum residual levels for nitrates are exceeded, but the relevant food business operator should investigate the reason of this excess.
- (19) The food categories 08.3.1 ‘Non-heat-treated meat products’ and 08.3.2 ‘Heat-treated meat products’ in Part D of Annex II to Regulation (EC) No 1333/2008 cover a broad variety of processed meat products, including some traditional and traditionally cured products for which there are no specific provisions in the food category 08.3.4 ‘Traditionally cured meat products with specific provisions concerning nitrites and nitrates’. However, the new maximum levels for nitrites set out for the categories 08.3.1 and 08.3.2 may not be sufficient for the preservation of some of those traditional and traditionally cured meat products. Therefore, it is appropriate to lay down provisions in the food category 08.3.4 for the concerned products.
- (20) Finally, while the current maximum levels are expressed as sodium nitrite or sodium nitrate, the revised maximum levels should be expressed as nitrite and nitrate ion respectively, in line with the ADIs established by the Authority. The conversion factors between sodium nitrite and nitrite ion is 0,67 and between sodium nitrate and nitrate ion is 0,73.
- (21) The application of new maximum levels should be deferred and the transitional periods should be provided for products placed on the market before the date of application of the respective maximum levels to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent conditions of use laid down in this Regulation. For cheeses, the date of application should be set

¹² Report of the 51st Session of the Codex Committee on Food Additives, paragraph 107.

taking into account the time needed for ripening before their placing on the market, which for certain products may be up to 24 months or more.

- (22) Considering that the Authority did not identify an immediate health concern linked to the presence of toxic elements in the food additives potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252), it is appropriate to allow during a transitional period the use of these food additives lawfully placed on the market before the date of entry into force of this Regulation. For the same reasons, it is appropriate that foods containing the food additives potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) that have been lawfully placed on the market before the date of entry into force of this Regulation may continue to be placed on the market during a transitional period and to remain on the market until their date of minimum durability or ‘use-by-date’.
- (23) Regulations (EC) No 1333/2008 and (EU) No 231/2012 should therefore be amended accordingly.
- (24) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Annex II to Regulation (EC) No 1333/2008 is amended in accordance with Annex I to this Regulation.

Article 2

The Annex to Regulation (EU) No 231/2012 is amended in accordance with Annex II to this Regulation.

Article 3

1. Foods not complying with the provisions laid down in Annex I applicable from the respective date indicated therein that have been lawfully placed on the market before the respective date of application may continue to be marketed until their date of minimum durability or ‘use-by’ date.
2. The food additives potassium nitrite (E 249) and/or sodium nitrite (E 250) and/or sodium nitrate (E 251) and/or potassium nitrate (E 252) that have been lawfully placed on the market before ... [*date of the entry into force of this Regulation*] and that do not comply with the maximum limits for lead, mercury and arsenic laid down in Annex II applicable from ... [*date of the entry into force of this Regulation*] may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until ... [*6 months after the date of entry into force of this Regulation*].
3. Foods containing the food additives potassium nitrite (E 249) and/or sodium nitrite (E 250) and/or sodium nitrate (E 251) and/or potassium nitrate (E 252) that have been lawfully placed on the market before ... [*date of the entry into force of this Regulation*] and that do not comply with the maximum limits for lead, mercury and arsenic laid down in Annex II applicable from ... [*date of the entry into force of this Regulation*] may continue to be placed on the market until ... [*6 months after the date of entry into force of this Regulation*] and may continue to be marketed until their date of minimum durability or ‘use-by date’.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN