



2023/2108

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**COMMISSION REGULATION (EU) 2023/2108**

**of 6 October 2023**

**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 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 additives <sup>(1)</sup>, 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 flavourings <sup>(2)</sup>, 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 231/2012 <sup>(3)</sup> 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.
- (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 1990 <sup>(4)</sup> and 1995 <sup>(5)</sup> as well as on the opinion of the European Food Safety Authority ('the Authority') of 26 November 2003 <sup>(6)</sup>. 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*.

<sup>(1)</sup> OJ L 354, 31.12.2008, p. 16.

<sup>(2)</sup> OJ L 354, 31.12.2008, p. 1.

<sup>(3)</sup> 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).

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

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

<sup>(6)</sup> 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>

- (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 2017 <sup>(7)</sup>.
- (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 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 2015 <sup>(8)</sup>.
- (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.

<sup>(7)</sup> EFSA Journal 2017;15(6):4786 and EFSA Journal 2017;15(6):4786.

<sup>(8)</sup> IARC Monographs Volume 114: Evaluation of consumption of red meat and processed meat.

- (13) In its scientific opinion on the risks to public health related to the presence of nitrosamines in food published on 28 March 2023 <sup>(9)</sup>, 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) 2021/1165 <sup>(10)</sup> 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) 2021/741 <sup>(11)</sup>, the Commission approved for a limited period of 3 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 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 Additives <sup>(12)</sup>. 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.

<sup>(9)</sup> EFSA Journal 2023;21(3):7884.

<sup>(10)</sup> 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).

<sup>(11)</sup> 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).

<sup>(12)</sup> Report of the 51st Session of the Codex Committee on Food Additives, paragraph 107.

- (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 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 29 October 2023 and that do not comply with the maximum limits for lead, mercury and arsenic laid down in Annex II applicable from 29 October 2023 may be added to food in accordance with Annexes II and III to Regulation (EC) No 1333/2008 until 29 April 2024.

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 29 October 2023 and that do not comply with the maximum limits for lead, mercury and arsenic laid down in Annex II applicable from 29 October 2023 may continue to be placed on the market until 29 April 2024 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, 6 October 2023.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

Annex II to Regulation (EC) No 1333/2008 is amended as follows:

(1) Part D is amended as follows:

(a) the entry for food category 08.3.4 is replaced by the following:

'08.3.4	Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates';
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(b) the entry for food category 08.3.4.3 is replaced by the following:

'08.3.4.3	Other traditional and traditionally cured products (including immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)';
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(2) Part E is amended as follows:

(a) the entry for food category 08.3.4 is replaced by the following:

'08.3.4	Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates';
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(b) the entry for food category 08.3.4.3 is replaced by the following:

'08.3.4.3	Other traditional and traditionally cured products (including immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)';
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(c) Category 01.7.2 (Ripened cheese) is amended as follows:

(i) the entry for E 251–252 (Nitrates) is replaced by the following:

	E 251–252	Nitrates	150	(30)	only hard, semi-hard and semi-soft cheese Period of application: until 9 October 2026
	E 251–252	Nitrates	75	(30) (XA) (XB)	only hard, semi-hard and semi-soft cheese Period of application: from 9 October 2026

	E 251–252	Nitrates	110	(30) (XA) (XB)	only traditional Swedish granular-eyed cheese from Gäsene ripened for a minimum of 11 months Period of application: until 9 October 2027
	E 251–252	Nitrates	110	(30) (XA) (XB)	only traditional Swedish Cheddar cheese from Kvibille ripened for a minimum of 4 months Period of application: until 9 October 2027
	E 251–252	Nitrates	110	(30) (XA) (XB)	only traditional Swedish granular-eyed cheese from Falköping ripened for a minimum of 12 months Period of application: until 9 October 2027;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XB): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 35 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’;

(d) Category 01.7.4 (Whey cheese) is amended as follows:

(i) the entry for E 251–252 (Nitrates) is replaced by the following:

	E 251–252	Nitrates	150	(30)	only cheese milk of hard, semi-hard and semi-soft cheese Period of application: until 9 October 2026
	E 251–252	Nitrates	75	(30) (XA) (XB)	only cheese milk of hard, semi-hard and semi-soft cheese Period of application: 9 October 2026’;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XB): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 35 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’;

(e) Category 01.7.6 (Cheese products (excluding products falling in category 16)) is amended as follows:

(i) the entry for E 251–252 (Nitrates) is replaced by the following:

	E 251–252	Nitrates	150	(30)	only hard, semi-hard and semi-soft ripened products Period of application: until 9 October 2026
	E 251–252	Nitrates	75	(30) (XA) (XB)	only hard, semi-hard and semi-soft ripened products Period of application: from 9 October 2026’;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XB): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 35 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’;

(f) Category 01.8 (Dairy analogues, including beverage whiteners) is amended as follows:

(i) the entry for E 251–252 (Nitrates) is replaced by the following:

	E 251–252	Nitrates	150	(30)	only dairy-based cheese analogue Period of application: until 9 October 2025
	E 251–252	Nitrates	75	(30) (XA) (XB)	only dairy-based cheese analogue Period of application: from 9 October 2025’;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XB): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 35 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’;

(g) Category 08.2 (Meat preparations as defined by Regulation (EC) No 853/2004) is amended as follows:

(i) the entry for E 249–250 (Nitrites) is replaced by the following:

	E 249–250	Nitrites	150	(7)	only <i>lomo de cerdo adobado</i> , <i>pincho moruno</i> , <i>careta de cerdo adobada</i> , <i>costilla de cerdo adobada</i> , <i>Kasseler</i> , <i>Bräte</i> , <i>Surfleisch</i> , <i>toorvorst</i> , <i>šaslökk</i> , <i>ahjupraad</i> , <i>kielbasa surowa biała</i> , <i>kielbasa surowa metka</i> , <i>tatar wołowy (danie tatarskie)</i> and <i>golonka peklowana</i> Period of application: until 9 October 2025
	E 249–250	Nitrites	80	(XC) (XD)	only <i>lomo de cerdo adobado</i> , <i>pincho moruno</i> , <i>careta de cerdo adobada</i> , <i>costilla de cerdo adobada</i> , <i>Kasseler</i> , <i>Bräte</i> , <i>Surfleisch</i> , <i>toorvorst</i> , <i>šaslökk</i> , <i>ahjupraad</i> , <i>kielbasa surowa biała</i> , <i>kielbasa surowa metka</i> , <i>tatar wołowy (danie tatarskie)</i> and <i>golonka peklowana</i> Period of application: from 9 October 2025’;

(ii) the following footnotes are added:

‘(XC): The maximum amount that may be added during the manufacturing expressed as NO<sub>2</sub> ion.

(XD): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 45 mg/kg expressed as NO<sub>2</sub> ion.’;



(h) Category 08.3.1 (Non-heat-treated meat products) is amended as follows:

(i) the entries for E 249–250 (Nitrites) and E 251–252 (Nitrates) are replaced by the following:

	E 249–250	Nitrites	150	(7)	Period of application: until 9 October 2025
	E 249–250	Nitrites	80	(XC) (XD)	Period of application: from 9 October 2025
	E 251–252	Nitrates	150	(7)	Period of application: until 9 October 2025
	E 251–252	Nitrates	90	(XA) (XE)	Period of application: from 9 October 2025
	E 251–252	Nitrates	110	(XA) (XF)	only large bacon primals and dry sausages without nitrites added Period of application: from 9 October 2025;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XC): The maximum amount that may be added during the manufacturing expressed as NO<sub>2</sub> ion.

(XD): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 45 mg/kg expressed as NO<sub>2</sub> ion.

(XE): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 90 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.

(XF): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 110 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’

(i) Category 08.3.2 (Heat-treated meat products) is amended as follows:

(i) the entries for E 249–250 (Nitrites) are replaced by the following:

	E 249–250	Nitrites	100	(7) (58) (59)	only sterilised meat products (Fo > 3,00) Period of application: until 9 October 2025
	E 249–250	Nitrites	55	(58) (59) (XC) (XG)	only sterilised meat products (Fo > 3,00) Period of application: from 9 October 2025
	E 249–250	Nitrites	150	(7) (59)	except sterilised meat products (Fo > 3,00) Period of application: until 9 October 2025
	E 249–250	Nitrites	80	(59) (XC) (XD)	except sterilised meat products (Fo > 3,00) Period of application: from 9 October 2025’

(ii) the following footnotes are added:

(XC): The maximum amount that may be added during the manufacturing expressed as NO<sub>2</sub> ion.

(XD): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 45 mg/kg expressed as NO<sub>2</sub> ion.

(XG): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 25 mg/kg expressed as NO<sub>2</sub> ion.;

(j) Category 08.3.4.1 (Traditional immersion cured products (Meat products cured by immersion in a curing solution containing nitrites and/or nitrates, salt and other components)) is amended as follows:

(i) the entries for E 249–250 (Nitrites) and E 251–252 (Nitrates) are replaced by the following:

E 249–250	Nitrites	30	(XH)	only traditionally cured products Period of application: from 9 October 2025
E 249–250	Nitrites	175	(39)	<b>only Wiltshire bacon and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: until 9 October 2025
E 249–250	Nitrites	105	(XH)	<b>only Wiltshire bacon and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only Wiltshire bacon and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only Wiltshire bacon and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: from 9 October 2025

E 249–250	Nitrites	100	(39)	<b>only Wiltshire ham and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: until 9 October 2025
E 249–250	Nitrites	65	(XH)	<b>only Wiltshire ham and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only Wiltshire ham and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only Wiltshire ham and similar products:</b> Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures Period of application: from 9 October 2025
E 249–250	Nitrites	175	(39)	<b>only entremeada, entrecosto, chispe, orelheira e cabeça (salgados), toucinho fumado and similar products:</b> Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity Period of application: until 9 October 2025
E 249–250	Nitrites	105	(XH)	<b>only entremeada, entrecosto, chispe, orelheira e cabeça (salgados), toucinho fumado and similar products:</b> Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only entremeada, entrecosto, chispe, orelheira e cabeça (salgados), toucinho fumado and similar products:</b> Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity Period of application: until 9 October 2025

E 251–252	Nitrates	150	(59) (XI)	<b>only entremeada, entrecosto, chispe, orelheira e cabeça (salgados), toucinho fumado and similar products:</b> Immersion cured for 3 to 5 days. Product is not heat-treated and has a high water activity Period of application: from 9 October 2025
E 249–250	Nitrites	50	(39)	<b>only cured tongue:</b> Immersion cured for at least 4 days and pre-cooked Period of application: until 9 October 2025
E 251–252	Nitrates	10	(39) (59)	<b>only cured tongue:</b> Immersion cured for at least 4 days and pre-cooked Period of application: until 9 October 2025
E 251–252	Nitrates	7	(59) (XI)	<b>only cured tongue:</b> Immersion cured for at least 4 days and pre-cooked Period of application: from 9 October 2025
E 249–250	Nitrites	150	(7)	<b>only kylmäsavustettu poronliha/kallrökt renkött:</b> Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks Period of application: until 9 October 2025
E 249–250	Nitrites	100	(XC) (XI)	<b>only kylmäsavustettu poronliha/kallrökt renkött:</b> Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks Period of application: from 9 October 2025
E 251–252	Nitrates	300	(7)	<b>only kylmäsavustettu poronliha/kallrökt renkött:</b> Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks Period of application: until 9 October 2025
E 251–252	Nitrates	180	(XA) (XK)	<b>only kylmäsavustettu poronliha/kallrökt renkött:</b> Meat is injected with curing solution followed by immersion curing. Curing time is 14 to 21 days followed by maturation in cold-smoke for 4 to 5 weeks Period of application: from 9 October 2025

E 249–250	Nitrites	150	(7)	<b>only bacon, filet de bacon and similar products:</b> Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C Period of application: until 9 October 2025
E 249–250	Nitrites	100	(XC) (X)	<b>only bacon, filet de bacon and similar products:</b> Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C Period of application: from 9 October 2025
E 251–252	Nitrates	250	(7) (40) (59)	<b>only bacon, filet de bacon and similar products:</b> Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C Period of application: until 9 October 2025
E 251–252	Nitrates	180	(40) (59) (XA) (XK)	<b>only bacon, filet de bacon and similar products:</b> Immersion cured for 4 to 5 days at 5 to 7 °C, matured for typically 24 to 40 hours at 22 °C, possibly smoked for 24 hrs at 20 to 25 °C and stored for 3 to 6 weeks at 12 to 14 °C Period of application: from 9 October 2025
E 249–250	Nitrites	50	(39)	<b>only Rohschinken, nassgepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation Period of application: until 9 October 2025
E 251–252	Nitrates	250	(39)	<b>only Rohschinken, nassgepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation Period of application: until 9 October 2025
E 251–252	Nitrates	150	(XI)	<b>only Rohschinken, nassgepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 2 days/kg followed by stabilisation/maturation Period of application: from 9 October 2025;

(ii) the following footnotes are added:

(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XC): The maximum amount that may be added during the manufacturing expressed as NO<sub>2</sub> ion.

(XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>2</sub> ion.

(XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>3</sub> ion.

(XJ): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 50 mg/kg expressed as NO<sub>2</sub> ion.

(XK): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 95 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.;

(k) Category 08.3.4.2 (Traditional dry cured products. (Dry curing process involves dry application of curing mixture containing nitrites and/or nitrates, salt and other components to the surface of the meat followed by a period of stabilisation/maturation)) is amended as follows:

(i) the entries for E 249–250 (Nitrites) and E 251–252 (Nitrates) are replaced by the following:

	E 249–250	Nitrites	30	(XH)	only traditionally cured products Period of application: from 9 October 2025
	E 249–250	Nitrites	175	(39)	<b>only dry cured bacon and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: until 9 October 2025
	E 249–250	Nitrites	105	(XH)	<b>only dry cured bacon and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: from 9 October 2025
	E 251–252	Nitrates	250	(39) (59)	<b>only dry cured bacon and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: until 9 October 2025
	E 251–252	Nitrates	150	(59) (XI)	<b>only dry cured bacon and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: from 9 October 2025

E 249–250	Nitrites	100	(39)	<b>only dry cured ham and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: until 9 October 2025
E 249–250	Nitrites	65	(XH)	<b>only dry cured ham and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only dry cured ham and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only dry cured ham and similar products:</b> Dry curing followed by maturation for at least 4 days Period of application: from 9 October 2025
E 249–250	Nitrites	100	(39)	<b>only jamón curado, paleta curada, lomo embuchado y cecina and similar products:</b> Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days Period of application: until 9 October 2025
E 249–250	Nitrites	65	(XH)	<b>only jamón curado, paleta curada, lomo embuchado y cecina and similar products:</b> Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only jamón curado, paleta curada, lomo embuchado y cecina and similar products:</b> Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only jamón curado, paleta curada, lomo embuchado y cecina and similar products:</b> Dry curing with a stabilisation period of at least 10 days and a maturation period of more than 45 days Period of application: from 9 October 2025

E 249–250	Nitrites	100	(39)	<b>only presunto, presunto da pá e paio do lombo and similar products:</b> Dry cured for 10 to 15 days followed by a 30 to 45-day stabilisation period and a maturation period of at least 2 months Period of application: until 9 October 2025
E 249–250	Nitrites	65	(XH)	<b>only presunto, presunto da pá e paio do lombo and similar products:</b> Dry cured for 10 to 15 days followed by a 30 to 45-day stabilisation period and a maturation period of at least 2 months Period of application: from 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only presunto, presunto da pá e paio do lombo and similar products:</b> Dry cured for 10 to 15 days followed by a 30 to 45-day stabilisation period and a maturation period of at least 2 months Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only presunto, presunto da pá e paio do lombo and similar products:</b> Dry cured for 10 to 15 days followed by a 30 to 45-day stabilisation period and a maturation period of at least 2 months Period of application: from 9 October 2025
E 249–250	Nitrites	50	(39)	<b>only Rohschinken, trockengepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation Period of application: until 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only Rohschinken, trockengepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation Period of application: until 9 October 2025
E 251–252	Nitrates	150	(59) (XI)	<b>only Rohschinken, trockengepökelt and similar products:</b> Curing time depending on the shape and weight of meat pieces for approximately 10 to 14 days followed by stabilisation/maturation Period of application: from 9 October 2025



E 251–252	Nitrates	250	(39) (40) (59)	<b>only jambon sec, jambon sel and other similar dried cured products:</b> Dry cured for 3 days + 1 day/kg followed by a 1-week post-salting period and an ageing/ripening period of 45 days to 18 months Period of application: until 9 October 2025
E 251–252	Nitrates	150	(40) (59) (XI)	<b>only jambon sec, jambon sel and other similar dried cured products:</b> Dry cured for 3 days + 1 day/kg followed by a 1-week post-salting period and an ageing/ripening period of 45 days to 18 months Period of application: from 9 October 2025;

(ii) the following footnotes are added:

‘(XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>2</sub> ion.

(XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>3</sub> ion.’;

(l) Category 08.3.4.3 (Other traditional and traditionally cured products (including immersion and dry cured processes used in combination or where nitrite and/or nitrate is included in a compound product or where the curing solution is injected into the product prior to cooking)) is amended as follows:

(i) the entries for E 249–250 (Nitrites) and E 251–252 (Nitrates) are replaced by the following:

E 249–250	Nitrites	30	(XH)	only traditionally cured products Period of application: from 9 October 2025
E 249–250	Nitrites	50	(39)	<b>only Rohschinken, trocken-/nassgepökelt and similar products:</b> Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/ maturation Period of application: until 9 October 2025
E 251–252	Nitrates	250	(39) (59)	<b>only Rohschinken, trocken-/nassgepökelt and similar products:</b> Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/ maturation Period of application: until 9 October 2025

E 251–252	Nitrates	150	(59) (XI)	<b>only Rohschinken, trocken-/nassgepökelt and similar products:</b> Dry curing and immersion curing used in combination (without injection of curing solution). Curing time depending on the shape and weight of meat pieces for approximately 14 to 35 days followed by stabilisation/ maturation Period of application: from 9 October 2025
E 249–250	Nitrites	50	(39)	<b>only jellied veal and brisket:</b> Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours Period of application: until 9 October 2025
E 251–252	Nitrates	10	(39) (59)	<b>only jellied veal and brisket:</b> Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours Period of application: until 9 October 2025
E 251–252	Nitrates	7	(59) (XI)	<b>only jellied veal and brisket:</b> Injection of curing solution followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours Period of application: from 9 October 2025
E 251–252	Nitrates	300	(40) (7)	<b>only Rohwürste (Salami and Kantwurst):</b> Product has a minimum 4-week maturation period and a water/protein ratio of less than 1,7 Period of application: until 9 October 2025
E 251–252	Nitrates	180	(40) (XA) (XK)	<b>only Rohwürste (Salami and Kantwurst):</b> Product has a minimum 4-week maturation period and a water/protein ratio of less than 1,7 Period of application: from 9 October 2025
E 251–252	Nitrates	250	(40) (7) (59)	<b>only salchichón y chorizo tradicionales de larga curación and similar products:</b> Maturation period of at least 30 days Period of application: until 9 October 2025
E 251–252	Nitrates	180	(40) (59) (XA) (XK)	<b>only salchichón y chorizo tradicionales de larga curación and similar products:</b> Maturation period of at least 30 days Period of application: from 9 October 2025

E 249–250	Nitrites	180	(7)	<b>only vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunajská klobása, paprikáš and similar products:</b> Dried product cooked to 70 °C followed by 8 to 12-day drying and smoking process. Fermented product subject to 14 to 30-day three-stage fermentation process followed by smoking Period of application: until 9 October 2025
E 249–250	Nitrites	105	(XC) (X)	<b>only vysočina, selský salám, turistický trvanlivý salám, poličan, herkules, lovecký salám, dunajská klobása, paprikáš and similar products:</b> Dried product cooked to 70 °C followed by 8 to 12-day drying and smoking process. Fermented product subject to 14 to 30-day three-stage fermentation process followed by smoking Period of application: from 9 October 2025
E 249–250	Nitrites	100	(XC) (X)	<b>only Svensk julsinka and Svensk leverpastej and similar products:</b> Cured/uncooked or cooked in its consumer package Period of application: from 9 October 2025
E 249–250	Nitrites	100	(XC) (X)	<b>only Mettwurst, Teewurst and similar products:</b> Spreadable, soft, short-ripened raw sausages Period of application: from 9 October 2025
E 251–252	Nitrates	250	(40) (7) (59)	<b>only saucisson sec and similar products:</b> raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22 °C or lower (10 to 12 °C) and then has a minimum ageing/ripening period of 3 weeks. Product has a water/protein ratio of less than 1,7 Period of application: until 9 October 2025
E 251–252	Nitrates	180	(40) (59) (XA) (XK)	<b>only saucisson sec and similar products:</b> raw fermented dried sausage without added nitrites. Product is fermented at temperatures in the range of 18 to 22 °C or lower (10 to 12 °C) and then has a minimum ageing/ripening period of 3 weeks. Product has a water/protein ratio of less than 1,7 Period of application: from 9 October 2025;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XC): The maximum amount that may be added during the manufacturing expressed as NO<sub>2</sub> ion.

(XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>2</sub> ion.

(XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO<sub>3</sub> ion.

(XJ): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 50 mg/kg expressed as NO<sub>2</sub> ion.

(XK): In case the residual amount from all sources for the product ready for marketing throughout the shelf-life of the product exceeds 95 mg/kg expressed as NO<sub>3</sub> ion, food business operators shall investigate the reason of this excess.’;

(m) Category 09.2 (Processed fish and fishery products including molluscs and crustaceans) is amended as follows:

(i) the entry for E 251–252 (Nitrates) is replaced by the following:

	E 251–252	Nitrates	500		only pickled herring and sprat Period of application: until 9 October 2025
	E 251–252	Nitrates	270	(XA) (XD)	only pickled herring and sprat Period of application: from 9 October 2025’;

(ii) the following footnotes are added:

‘(XA): The maximum amount that may be added during the manufacturing expressed as NO<sub>3</sub> ion.

(XD): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed 45 mg/kg expressed as NO<sub>2</sub> ion.’.

## ANNEX II

The Annex to Regulation (EU) No 231/2012 is amended as follows:

- (1) in the entry for 'E 249 potassium nitrite', the specification 'Purity' is replaced by the following:

<b>Purity</b>	
Loss on drying	Not more than 3 % (4 hours, over silica gel)
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg';

- (2) in the entry for 'E 250 sodium nitrite', the specification 'Purity' is replaced by the following:

<b>Purity</b>	
Loss on drying	Not more than 0,25 % (4 hours, over silica gel)
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg';

- (3) in the entry for 'E 251 sodium nitrate', part '(i) solid sodium nitrate', the specification 'Purity' is replaced by the following:

<b>Purity</b>	
Loss on drying	Not more than 2 % (105 °C, 4 hours)
Nitrites	Not more than 30 mg/kg expressed as NaNO <sub>2</sub>
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg';

- (4) in the entry for 'E 251 sodium nitrate', part '(ii) liquid sodium nitrate', the specification 'Purity' is replaced by the following:

<b>Purity</b>	
Free nitric acid	Not more than 0,01 %
Nitrites	Not more than 10 mg/kg expressed as NaNO <sub>2</sub>
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg';

(5) in the entry for 'E 252 potassium nitrate', the specification 'Purity' is replaced by the following:

<b>Purity</b>	
Loss on drying	Not more than 1 % (105 °C, 4 hours)
Nitrites	Not more than 20 mg/kg expressed as KNO <sub>2</sub>
Arsenic	Not more than 0,1 mg/kg
Lead	Not more than 0,1 mg/kg
Mercury	Not more than 0,1 mg/kg'.