

Department of Agriculture, Food and the Marine
Trader Notice: MH 10/2023

**To All Food Business Operators (FBOs) at Approved Meat Establishments using
NITRITES/NITRATES in meat preparations/meat products**

Subject: Commission Regulation (EU) 2023/2108 of 6 October 2023 amending Annex II to Regulation (EC) No. 1333/2008 and the Annex to Commission Regulation (EU) No 231/2012 as regards the food additives nitrites (E 249-250) and nitrates (E 251-252). This Regulation was published in the Official Journal of the European Union on **09 October 2023** and entered 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.

Background: The recently published Commission [Regulation \(EU\) 2023/2108](#) establishes significantly reduced limits for these food additives which protect against pathogenic bacteria (e.g., *Listeria*, *Salmonella* and *Clostridium Botulinum*). The reductions in the maximum levels for these additives is intended to reduce the exposure of consumers to nitrosamines, some of which are carcinogenic.

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, 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 while maintaining their protective effects against the multiplication of bacteria, in particular of *C. botulinum*, responsible for botulism.

Why were the limits reduced for these food additives?

Article 32(1) of Regulation (EC) No 1333/2008 on food additives 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 (European Food Safety Authority).

The Authority delivered its scientific opinions re-evaluating the safety of nitrites and nitrates as food additives on 15 June 2017. The scientific opinion was published in 2017 in EFSA Journal (*EFSA Journal* 2017;15(6):4786) and can be consulted by accessing this link: [Re-evaluation of potassium nitrite \(E 249\) and sodium ... - EFSA](#)

What has been amended to the Regulation?

There were several amendments which are summarised below under the bullet points and most of the new/revised maximum limits (MLs) and new footnotes are presented within the tables no 1 and no 2.

- The title of the food categories 08.3.4 and 08.3.4.3 has been amended to allow them to accommodate certain traditional products for which the newly revised maximum levels (of nitrites) in the categories 08.3.1 and 08.3.2 are no longer sufficient.

- ‘General provisions’ for the use of nitrites in traditionally cured products at a (low) maximum residual level of 30 mg/kg have been introduced into categories 08.3.4.1, 08.3.4.2 and 08.3.4.3. *This is to accommodate those traditionally cured meat products not covered by the existing specific provisions under category 08.3.4, which are currently on the EU market based on the existing provisions in categories 08.3.1 and 08.3.2 and for which the newly revised provisions in FC 08.3.1 and 08.3.2 would not be sufficient.* The introduction of the general provisions in 08.3.4.1, 08.3.4.2 and 08.3.4.3 allowed the Commission to also delete some provisions for nitrites in those food categories (for cured tongue, rohschinken, nassgepökelt, trockengepökelt and similar products, jellied veal and brisket) and thus to a certain extent simplify the provisions in the category 08.3.4. Those products which have been deleted will now be covered by these general residual levels of 30 mg/kg.
- New provisions have been added for the following meat products (Svensk julsinka, Svensk leverpastej and similar products; Mettwurst, Teewurst and similar products;) to category 08.3.4.3.

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

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

To note the current maximum limits (MLs) are expressed as sodium nitrite (NaNO_2) or sodium nitrate (NaNO_3) whereas the newly revised MLs are expressed **on the nitrite and nitrate ion basis** (so there are included the equivalents). Also, to note that residual MLs will also apply.

Within the tables below is outlined the current provisions and comparing them to several of the newly revised maximum limits (MLs) for nitrites (Table 1) and for nitrates (Table 2) in the most frequently used meat categories used by Irish FBOs as well as the single entry (last entry in Table 2) for processed fish (food category 9.2).

Table 1 – Nitrites

Food category	Current legislation (Expressed as NaNO_2)	Revised MLs (Expressed as NO_2 ion)	Date of application for revised MLs	New footnotes (in green and bold)
Nitrites – NO_2 (E 249-E 250)				
08.2 Meat preparations as defined by Regulation (EC) No 853/2004	150 mg/kg ingoing (restricted to specific meat preparations)	80 mg/kg ingoing (Equivalent to 120 mg/kg when expressed as NaNO_2)	From 09 October 2025	XC and XD XC: The maximum amount that may be added during the manufacturing expressed as <u>NO_2 ion.</u> XD: The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed <u>45 mg/kg expressed as NO_2 ion.</u>
08.3.1 Non-heat-treated meat products	150 mg/kg ingoing	80 mg/kg ingoing (Equivalent to 120 mg/kg when expressed as NaNO_2)	From 09 October 2025	XC and XD XC: The maximum amount that may be added during the manufacturing expressed as <u>NO_2 ion.</u> XD: The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product shall not exceed <u>45 mg/kg expressed as NO_2 ion.</u>

08.3.2 Heat-treated meat products	<p>100 mg/kg ingoing, only sterilised meat products</p> <p>150 mg/kg ingoing, except sterilised products (Fo > 3,00)</p>	<p>55 mg/kg ingoing (equivalent to 82.5 mg/kg when expressed as NaNO₂)</p> <p>80 mg/kg ingoing (Equivalent to 120 mg/kg when expressed as NaNO₂)</p>	<p><i>From 09 October 2025</i></p> <p><i>From 09 October 2025</i></p>	<p>(58) (59) (XC) (XG)</p> <p>‘(XC): The maximum amount that may be added during the manufacturing expressed as NO₂ 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 NO₂ ion.</p> <p>(59) (XC) (XD)</p> <p>(58): Fo-value 3 is equivalent to 3 minutes heating at 121 °C (reduction of the bacterial load of one billion spores in each 1 000 cans to one spore in a thousand cans)</p> <p>(59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment.</p> <p>‘(XC): The maximum amount that may be added during the manufacturing expressed as NO₂ 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 NO₂ ion.</p> <p>(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 NO₂ ion.’;</p>
08.3.4.1 Traditional Immersion cured products				
only Wiltshire bacon and similar products: Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures	175 mg/kg residual amount	105 mg/kg residual NO ₂ ion (Equivalent to 157.5 mg/kg when expressed as NaNO ₂)	<i>From 09 October 2025</i>	<p>(XH)</p> <p>(XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO₂ ion.</p>
only Wiltshire ham and similar products: Meat is injected with curing solution followed by immersion curing for 3 to 10 days.	100 mg/kg residual amount	65 mg/kg residual amount (Equivalent to 97.5 mg/kg when expressed as NaNO ₂).	<i>From 09 October 2025</i>	<p>(XH)</p> <p>(XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO₂ ion.</p>

The immersion brine solution also includes microbiological starter culture.				
only bacon, filet de bacon and similar products: 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.	150 mg/kg ingoing amount expressed as NaNO ₂ .	100 mg/kg ingoing amount (equivalent to 150 mg/kg when expressed as NaNO ₂).	From 09 October 2025	(XC) (XJ) (XC): The maximum amount that may be added during the manufacturing expressed as NO ₂ ion. (XJ): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product <u>shall not exceed 50 mg/kg expressed as NO₂ ion.</u>
08.3.4.2 Traditional dry cured products				
only dry cured bacon and similar products: Dry curing followed by maturation for at least 4 days.	175 mg/kg residual amount	105 mg/kg residual amount (equivalent to 157.5 mg/kg when expressed as NaNO ₂).	From 09 October 2025	XH (XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO ₂ ion.
only dry cured ham and similar products: Dry curing followed by maturation for at least 4 days.	100 mg/kg residual amount	65 mg/kg residual amount (equivalent to 97.5 mg/kg when expressed as NaNO ₂).	From 09 October 2025	(XH) (XH): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO ₂ ion.

Table 2 - Nitrates

Food category	Current legislation (Expressed as NaNO ₂)	Revised MLs (Expressed as NO ₃ ion)	Date of application for revised MLs	New footnotes (in green and bold)
Nitrates – NO₃ (E 251-E 252)				
08.3.1 Non-heat-treated meat products	150 mg/kg ingoing	<p>90 mg/kg ingoing (equivalent to 126 mg/kg ingoing when expressed as NaNO₃)</p> <p>110 mg/kg ingoing only large bacon primals and dry sausages without nitrites added. (Equivalent to ~154 mg/kg ingoing expressed as NaNO₃)</p>	<p><i>From 09 October 2025</i></p> <p><i>From 09 October 2025</i></p>	<p>(XA), (XE) (XA): The maximum amount that may be added during the manufacturing expressed as NO₃ 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 NO₃ ion, food business operators shall investigate the reason of this excess.</p> <p>XA, XF (XA): The maximum amount that may be added during the manufacturing expressed as NO₃ ion. (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 NO₃ ion, food business operators shall investigate the reason of this excess.</p>
08.3.2 Heat treated meat products	No nitrates permitted in heat treated meat products	No nitrates permitted in heat treated meat products	-	-
08.3.4.1 Traditional immersion cured products				
only Wiltshire bacon and similar products: Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.	250 mg/kg maximum residual amount	150 mg/kg residual amount (Equivalent to 210 mg/kg residual when expressed as NaNO ₃)	<i>From 09 October 2025</i>	<p>(59) (XI) (59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment (XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO₃ ion.</p>
only Wiltshire ham and similar products: Meat is	250 mg/kg residual amount	150 mg/kg residual amount	<i>From 09 October 2025</i>	(59) (XI)

injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter culture.		(Equivalent to 210 mg/kg residual when expressed as NaNO ₃)		(59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment. (XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO ₃ ion.
only cured tongue: Immersion cured for at least 4 days and pre-cooked.	10 mg/kg residual amount	7 mg/kg residual amount (Equivalent to 9.8 mg/kg residual when expressed as NaNO ₃)	From 09 October 2025	(59) (XI) as outlined above.
only bacon, filet de bacon and similar products: 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	250 mg/kg ingoing amount	180 mg/kg ingoing amount (Equivalent to 252 mg/kg ingoing when expressed as NaNO ₃)	From 09 October 2025	(40) (59) (XA) (XK) (40): Without added nitrites. (59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low acid environment. (XA): The maximum amount that may be added during the manufacturing expressed as NO ₃ 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 ₃ ion, food business operators shall investigate the reason of this excess.’.
		08.3.4.2 Traditional dry cured products		
only dry cured bacon and similar products: Dry curing followed by maturation for at least 4 days.	250 mg/kg residual amount	150 mg/kg residual amount (Equivalent to 210 mg/kg residual when expressed as NaNO ₃)	From 09 October 2025	(59) (XI) (59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment (XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO ₃ ion.
only dry cured ham and similar products: Dry	250 mg/kg residual amount	150 mg/kg residual amount (Equivalent	From 09 October 2025	(59) (XI) (59): Nitrates may be present in some heat-treated meat products resulting from natural conversion of nitrites to nitrates in a low-acid environment

curing followed by maturation for at least 4 days.		to 210 mg/kg residual when expressed as NaNO ₃)		(XI): The maximum residual amount from all sources for the product ready for marketing throughout the shelf-life of the product expressed as NO ₃ ion.
09.2 Processed fish and fishery products including molluscs and crustaceans	500 mg/kg ingoing only pickled herring and sprat	270 mg/kg ingoing (Equivalent to 378 mg/kg ingoing when expressed as NaNO ₃)	From 09 October 2025	(XA) (XD) (XA): The maximum amount that may be added during the manufacturing expressed as NO ₃ 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 ₂ ion.’.

The conversion factors to be used as follow:

Sodium nitrite (NaNO₂) to Nitrite ion (NO₂) x by 0.67

Nitrite ion (NO₂) to Sodium nitrite (NaNO₂) x by 1.5.

A similar process is in place for nitrates.

Sodium nitrate (NaNO₃) to Nitrate ion (NO₃) x by 0.73 and

Nitrate ion (NO₃) to Sodium nitrate (NaNO₃) x by 1.4

Transitional periods to adapt to these new MLs.

Food business operators using nitrites/nitrates in their meat preparations/meat products will have **24 months** to adapt to these new maximum limits (MLs) after publication of the Regulation within the Official Journal of the European Union.

It means that the revised MLs established for meat preparations and meat products according to this Regulation 2023/2108 will apply **from 09 October 2025**.

The regulation also provides for the transitional period of **6 months** for food additives nitrites and nitrates and foods containing those food additives as regards **the revised limits for toxic elements (arsenic, lead and mercury)**. This is captured in the recitals 21 and 22 and in Article 3.

The following transitional periods also apply according to article 3:

- 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.
- 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*.

- 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'.

Obligations of the Food Business Operator (FBO).

- FBOs have the obligation to take any measures necessary to comply with the new limits for nitrites/nitrates used in their meat products in accordance with the transitional periods.
- As nitrites/nitrates protect against pathogenic bacteria (e.g., *Listeria*, *Salmonella* and *Clostridium Botulinum*), FBOs must take into consideration the shelf-life of the meat products when adapting the new limits for nitrites/nitrates.