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43

GUIDANCE NOTE

Official Control Sampling of Meat Products for Nitrate/Nitrite (Revision 1)

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1. Introduction

Sodium and potassium nitrite and nitrate are commonly used food additives in curing meat and other perishable produce. They are added to meat for preservation purposes and to help suppress the growth of harmful microorganisms, in particular *Clostridium botulinum*, the bacterium responsible for the life-threatening illness called botulism.

Sodium and potassium nitrite and nitrate are also added to meat to maintain its red appearance and to provide flavour, while nitrates are used to prevent certain cheeses from bloating during fermentation. Nitrate is found naturally in vegetables, with the highest concentrations occurring in leafy vegetables like spinach and lettuce. It can also enter the food chain as an environmental contaminant in water due to its use in intensive farming methods and livestock production and its presence in sewage discharge.

The use of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) in meat and meat products must comply with the provisions laid down in Regulation (EC) No 1333/2008 (as amended) on food additives.

In 2017, the European Food Safety Authority (EFSA) published Scientific Opinions on its re-evaluation of the safety of nitrites and nitrates used as food additives. In these Scientific Opinions, EFSA concluded that nitrites and nitrates intentionally added at permitted levels to meat and other foods were safe (EFSA, 2017a; EFSA 2017b).

In 2023, a further EFSA Scientific Opinion was published on the risks to public health related to the presence of nitrosamines (EFSA, 2023). Following this, the European Commission (EC) concluded that it was necessary to reduce and amend the current conditions for the use of nitrites and nitrates as food additives by amending Regulation (EC) No 1333/2008 with Commission Regulation (EU) 2023/2108. Further details on the health implications associated with the use of nitrites and nitrates in food are provided in Appendix 1.

Food businesses should be aware that sodium and potassium nitrite and nitrate serve as important preservatives to inhibit microbial growth in meat products throughout their shelf life, particularly against pathogens such as *Clostridium botulinum, Listeria monocytogenes* and *Salmonella*.

Commission Regulation (EU) 2023/2108 has established significantly reduced limits for these additives to enhance consumer safety by decreasing exposure to nitrosamines. To comply with these new limits, modifications or reformulations of the production process for specific products may be necessary. As such, food businesses may need to revalidate the

shelf life of any products that have undergone substantial changes to meet the new regulatory limits for nitrites and nitrates. This will ensure that the safety and quality of the products are maintained throughout their shelf life under reasonably foreseeable conditions of distribution, storage and use. For guidance on establishing and validating product shelf life, refer to Food Safety Authority of Ireland (FSAI) Guidance Note No. 18, *Validation of product shelf-life* (FSAI, 2022).

This Guidance Note replaces the FSAI's *Guidance Document for Nitrate/Nitrite Sampling of Meat Products*, which was published in 2016 as part of the FSAI's Chemical Factsheet Series. This Guidance Note reflects the changes implemented by Regulation (EU) 2023/2108.

2. Scope

This Guidance Note is applicable for use by authorised officers for the purpose of taking official control samples of brine solutions and meat products, for their analysis and determination of compliance with the maximum levels for the use of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) as laid down in Regulation (EC) No 1333/2008 and as amended by Commission Regulation (EU) 2023/2108.

3. Overview of new requirements of Commission Regulation (EU) 2023/2108

Commission Regulation (EU) 2023/2108 made several important amendments to Part E of Annex II to Regulation (EC) No 1333/2008 in relation to meat products, which come into force on **9 October 2025,** and which are summarised in Sections 3.1–3.7.

3.1 Food categories

Some changes have been made to the title and applicability of various categories of meat under food category 08 in Regulation (EC) No 1333/2008:

- The titles of food categories 08.3.4 and 08.3.4.3 have been changed to allow these categories to accommodate certain traditional products for which the new maximum levels (of nitrites) in food categories 08.3.1 and 08.3.2 are no longer sufficient.
- General provisions for the use of nitrites in traditionally cured products at low residual levels (i.e. 30 milligrams per kilogram (mg/kg)) have been introduced under food categories 08.3.4.1, 08.3.4.2 and 08.3.4.3.
- New provisions for the meat products Svensk julskinka, Svensk leverpastej and similar products, and for Mettwurst, Teewurst and similar products, have been added to food category 08.3.4.3.

Note 1: The title of the food categories 08.3.4 and 08.3.4.3 have been changed to accommodate traditionally cured meat products not covered by previous specific provisions under food category 08.3.4 and that are currently on the European Union (EU) market, based on the previous provisions in food categories 08.3.1 and 08.3.2 and for which the newly revised provisions in food categories 08.3.1 and 08.3.2 would not be sufficient.

Note 2: The introduction of general provisions in food categories 08.3.4.1, 08.3.4.2 and 08.3.4.3 allowed the EC to delete provisions for nitrites in those food categories (i.e. cured tongue; rohschinken, nassgepökelt, trockengepökelt and similar products; jellied veal; and brisket) and simplify the provisions in food category 08.3.4. Those products that have been deleted are now covered at a low residual level (i.e. 30 mg/kg).

Section 5.1 of this Guidance Note provides details on how to determine the appropriate food category for meat preparations and meat products.

3.2 Maximum limits

The maximum limits for sodium and potassium nitrite and nitrate have been significantly reduced by Commission Regulation (EU) 2023/2108 across all categories of meat products. Please see Appendix 2 for further details (Appendix 2 is an extract taken from Annex II to Regulation (EC) No 1333/2008 on food additives).

3.3 Expression of maximum limits

Given that it is the nitrite (NO_2) or nitrate (NO_3) ions that are the subject of the most recent EFSA Scientific Opinions, and that should be subject to maximum levels in foods, it is appropriate that the controls for these additives should also be expressed on the basis of the ions themselves rather than their sodium or potassium salts (i.e. maximum levels of sodium

and potassium nitrite and nitrate will be expressed on the basis of the nitrite (NO_2) and nitrate (NO_3) ions). As such, Commission Regulation (EU) 2023/2108 provides maximum limits for sodium and potassium nitrite and nitrate, expressed as NO_2 and NO_3 ions, respectively.

3.4 Calculating the concentration of nitrite and nitrate ions

The new maximum limits (Appendix 2) of nitrites and nitrates in Commission Regulation (EU) 2023/2108 are expressed as NO_2 and NO_3 ions, respectively, in line with the acceptable daily intakes (ADIs) established by EFSA (Appendix 1).

In order to calculate the concentration of NO_2 or NO_3 ions from the quantity of sodium nitrite or sodium nitrate added to a food product, a simple conversion step is required before compliance with maximum limits can be determined with the new legislative limits.

The two conversion factors provided in Commission Regulation (EU) 2023/2108 are:

- Sodium nitrite ($NaNO_2$) to nitrite ion (NO_2) multiply **by 0.67**
- Sodium nitrate ($NaNO_3$) to nitrate ion (NO_3) multiply **by 0.73**.

Note 3: Prior to Commission Regulation (EU) 2023/2108, the maximum limits were based on the sodium salts of nitrite and nitrate (i.e. sodium nitrite ($NaNO_2$) or sodium nitrate ($NaNO_3$)) and therefore, if the potassium salt was used, then a conversion of the maximum permitted amount was needed in order to reflect the differences in molecular weight between the sodium and potassium ions.

For information purposes, the following are some other useful conversion factors that are not provided in Commission Regulation (EU) 2023/2108 (approximate rounded values):

- Potassium nitrite (KNO_2) to nitrite ion (NO_2) multiply **by 0.54**
- Potassium nitrate (KNO_3) to nitrate ion (NO_3) multiply **by 0.61**
- Sodium nitrite ($NaNO_2$) to potassium nitrite (KNO_2) multiply **by 1.23**
- Sodium nitrate ($NaNO_3$) to potassium nitrate (KNO_3) multiply **by 1.19**
- Nitrite ion (NO_2) to sodium nitrite ($NaNO_2$) multiply **by 1.50**
- Nitrite ion (NO_2) to potassium nitrite (KNO_2) multiply **by 1.85**
- Nitrate ion (NO_3) to sodium nitrate ($NaNO_3$) multiply **by 1.37**
- Nitrate ion (NO_3) to potassium nitrate (KNO_3) multiply **by 1.63.**

3.5 Definition of 'ready for marketing'

Article 11(3) of Regulation (EC) No 1333/2008 states that the maximum levels of food additives set out in Annex II shall apply to the food as marketed, unless otherwise stated. This principle considers the presence of food additives in foods close to the time of consumption.

The term 'ready for marketing' is not explicitly defined in European food law; however, it does appear in various other contexts across other regulations (e.g. Regulation (EC) No 178/2002, Regulation (EU) No 1169/2011, or Regulation (EU) No 1308/2013). Its meaning can depend on the specific regulation or product category.

In general terms, for the purposes of this Guidance Note, 'ready for marketing' refers to a meat product that has completed all of the manufacturer's processing steps (including any ripening and/or fermentation steps) and complies with all legal requirements to be placed on the market (i.e. it has been produced and packaged (if applicable); it complies with relevant EU food safety and labelling requirements; and it is fit for human consumption and is ready to be offered for sale or distributed). The term 'ready for marketing' should also apply to business-to-business trade (e.g. wholesale) or use as an ingredient in another product (e.g. ham used as a pizza topping) without further processing.

Note 4: Article 3(8) of Regulation (EC) No 178/2002 defines 'placing on the market' as meaning "the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves".

3.6 Controls on maximum limits

Controls on maximum limits of nitrite and nitrate in some meat and meat products are now based on both the ingoing amount of the additives and the residual levels of the additives (i.e. the maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product).

The new rules on the maximum levels being expressed as residual amounts (i.e. ready for marketing):

- Allow for information to be collected on the intake of nitrates/nitrites from foods
- Allow compliance checking of imported products (e.g. from third countries)

- Bring the EU approach to nitrate and nitrite additives into line with the approach followed by the Codex Committee on Food Additives (CCFA, 2019).

Note 5: Commission Regulation (EU) 2023/2108 indicates that in light of a lower concern related to the contribution of nitrates used as food additives to overall exposure and an ongoing discussion on the need to establish a single residual level for both nitrites and nitrates in all food categories, application of residual provisions differ when the residual provision had not existed before the changes introduced by that Regulation.

Therefore those meat products for which a residual provision is new for 2025, which is the subset of those under Category Number 08.3 Meat Products, in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives, where any of the three footnotes (XE), (XF) and (XK) apply, may continue to be placed on the market and remain on the market even if their respective maximum residual levels for nitrates are exceeded.

However, the relevant food business operator should investigate the reason for the exceedance in residual levels of nitrates in conjunction with the official agency and ensure their processes move towards compliance for all other products. Where the residual provision is not new, specifically where footnotes (XE), (XF) or (XK) do not apply, any exceedance of the residual provision requires the food business operator to cease placing implicated product on the market in accordance with Article 5 of Regulation (EC) No 1333/2008 and potentially withdrawal or recall of implicated product already on the market.

3.7 Purity criteria

Commission Regulation (EU) 2023/2108 also amends the Annex to Commission Regulation (EU) No 231/2012 regarding the food additives sodium and potassium nitrite and nitrate (i.e. E 249 to E 252) and introduced new limits for the toxic metals lead, mercury and arsenic in food additives. These food additives have been required to meet the new purity standards (i.e. maximum limits) for lead, mercury and arsenic since 19 October 2023.

4. Submission of official control samples

All official control samples must be accompanied by a completed National Sample Submission Form (NSSF), which is available from either the relevant Public Analyst's Laboratory (PAL) in Dublin, Cork or Galway or from the FSAI SafetyNet portal. A separate form must be completed for each sample submitted. Please ensure that the most recent

version of the NSSF is used when submitting samples. Guidance on the completion of the NSSF is also available to authorised officers via the FSAI SafetyNet portal.

The National Environmental Health Service (NEHS) and the PALs agree a programme of sampling and testing of meat products and brine samples annually as part of the National Chemical Food Sampling Programme for nitrite/nitrate testing.

Veterinary inspectors within the Department of Agriculture, Food and the Marine (DAFM) will be notified by the DAFM in advance of the number of samples to send and the dates these should be submitted to the PALs. Please note that the PALs will only be able to process samples during agreed, designated weeks. The PALs do not have the facilities to store samples that are sent early or to analyse samples that are sent late. However, all of the PALs can accept follow-up samples for testing at any time.

In completing the NSSF, it should be noted by the official agencies that the responsibility for producing safe food lies with the food business operator. As such it is the responsibility of the food business operator to ensure that the meat products they produce are correctly categorised and to provide this information to the official agencies when taking samples for the purpose of completing the NSSF.

Note 6: Samples should not be stored for bulk/future submission to the PALs. This is to avoid analysis of samples whose shelf life may have expired at the time of receipt by the PALs, and to ensure that samples are taken and submitted to the PALs during agreed, designated weeks.

Note 7: As the controls on nitrite and nitrate in some meat and meat products are now based on both the ingoing amounts and residual levels of the additives, the process outlined in Section 5 should be followed to determine whether a particular product is compliant with the requirements of Regulation (EC) No 1333/2008, as amended.

5. Determining compliance

The previous regulatory approach under Regulation (EC) No 1333/2008 on controls for nitrites/nitrates in meat products was divided into those products that were:

- Non-derogated products, i.e. those products for which nitrite/nitrate controls were based on determining the ingoing amount of the additives in the brine solutions

Or

- Derogated products, i.e. those products manufactured using traditional curing processes where control of ingoing amounts was not possible, and therefore controls were based on the residual concentration of nitrites/nitrates in the final product.

The amendment of Regulation (EC) No 1333/2008 by Commission Regulation (EU) 2023/2108, while importantly reducing the maximum limits for potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) in meat products, has also introduced residual levels as well as ingoing levels for many products within food categories 08.2, 08.3.1 and 08.3.2. As such, the clear distinction between 'non-derogated products' and 'derogated products' previously provided for under Regulation (EC) No 1333/2008 may not be as apparent given the introduction of residual levels for both groups of products.

The process outlined in Sections 5.1–5.3 should be followed to determine whether a particular product is compliant with the requirements of Regulation (EC) No 1333/2008, as amended. These sections should be read in conjunction with Regulation (EC) No 1333/2008, as amended, and with the EC *Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives* (European Commission, 2024).

5.1 Determine the appropriate food category

5.1.1 Non-derogated meat products

Non-derogated meat products include:

- Products cured by an injection process, possibly followed by a short period of immersion curing (for less than 3 days)
- Products that are dry cured for less than 4 days
- Sterilised meat products (Fo value >3.00) (the Fo value is the time in minutes at the reference temperature of 121 °C required to provide the equivalent lethal heat dose necessary for the appropriate *Clostridium botulinum* spore destruction to obtain minimum health protection or commercial sterility of the product)
- Cure-in-the-bag products, which are injected with curing solution and not immersed; therefore, this type of product is considered a non-derogated product and falls under the general meat products food category 08.3.1 or 08.3.2
- Cured tongue that is not precooked.

Depending on the food category, controls (i.e. maximum limits) for non-derogated products are now based on both the ingoing and residual levels of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) or potassium nitrate (E 252) that are added during processing/manufacture.

Maximum ingoing levels for nitrates and nitrites in non-derogated products are predominantly listed under the following food categories, expressed as either nitrite (i.e. No_2) or nitrate (i.e. No_3) ions:

- **08.2:** Meat preparations as defined by Regulation (EC) No 853/2004
- **08.3.1:** Non-heat-treated meat products
- **08.3.2:** Heat-treated meat products
- **08.3.4.1:** Traditional immersion cured products (i.e. bacon, filet de bacon and similar products, which also have maximum residual levels specified)
- **09.2:** Processed fish and fishery products including molluscs and crustaceans (i.e. only nitrates in pickled herring and sprat).

Non-derogated products must meet the definitions and requirements as outlined in the Restrictions/exceptions column of the table in Part E of Annex II to Regulation (EC) No 1333/2008, as well as the footnotes outlined under the above food categories of Regulation (EC) No 1333/2008, some of which also include requirements for residual levels in some products. Please see Appendix 2 for further details.

Note 8: Appendix 2 provides the current and newly revised maximum limits, restrictions and exemptions for nitrites (Table 1) and for nitrates (Table 2) in the most frequently seen non-derogated meat categories manufactured by Irish food business operators, as well as a single entry for processed fish (i.e. food category 09.2). Appendix 2 is not an exhaustive list, and reference should be made to Regulation (EC) No 1333/2008, as amended, for the full list of applicable products and food categories.

Note 9: Regulation (EC) No 1333/2008 permits the use of nitrate under food category 08.3.1 Non-heat-treated meat products, but not in food category 08.3.2 Heat-treated meat products.

Note 10: The use of nitrate is not considered necessary in products that have been heat treated to the extent that any bacteria have been destroyed. As such, the use of either sodium or potassium nitrate is not permitted in food category 08.3.2 Heat-treated meat products. However, nitrates may be present in some heat-treated meat products because of the natural conversion of nitrites to nitrates in a low-acid environment. Also see **Note 24**.

Note 11: The relevance of any heat treatment and the use of nitrates needs to consider the stage at which the heat treatment is applied and the effectiveness of any heat treatment in eliminating microorganisms that could convert the nitrates to nitrites, the form that is microbiologically effective (e.g. against *Clostridium botulinum*). In Ireland, some bacon/ham products may be heat treated/cooked before consumption or before being placed on the market (and possibly before purchase); however, this level of heat treatment is not considered sufficient in most cases to negate the need for nitrates at the earlier stages of production.

Note 12: For the purposes of this Guidance Note, some of these products should be classified under food category 08.3.1 Non-heat-treated meat products. Permitted levels of nitrates will depend on whether the product in question falls into the general (non-heat-treated) meat product category or into another category.

5.1.2 Derogated meat products

Derogated meat products are meat products that are produced by traditional curing processes and for which derogations were initially provided in Directive 2006/52/EC and then transferred into Regulation (EC) No 1333/2008 when the Directive was repealed. These products are now listed under food category 08.3.4 Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates, and its subcategories.

Specific derogations are provided for certain traditional meat products under food category 08.3.4 where it is not possible to control ingoing amounts of nitrate or nitrite because of the nature of the traditional manufacturing process used in their preparation. In such products, the maximum limits for both nitrates and nitrites relate to the maximum residual levels permitted in the finished product at the end of the production process (i.e. when the product is ready for marketing).

Typically, the product is cured by injection with a curing solution followed by immersion in brine, or by immersion only, for 3 days or more. Starter cultures may also be used (e.g. those produced following natural regeneration of the brine, or by use of commercial cultures). An example of a traditional Irish product listed in Regulation (EC) No 1333/2008 under food category 08.3.4 is Wiltshire bacon. This traditional immersion-cured product is regulated under food category 08.3.4.1 of Regulation (EC) No 1333/2008.

There are also certain traditional dry-cured products that are dry cured for more than 4 days. The dry curing process involves the dry application of a curing mixture containing nitrites

and/or nitrates, salt and other components to the surface of the meat, followed by a period of stabilisation/maturation. Derogation provisions are also included for dry-cured products under food category 08.3.4.2 of Regulation (EC) No 1333/2008.

Maximum residual levels of nitrates and nitrites in derogated products are predominantly listed under the following food categories, expressed as either nitrite (i.e. No_2) or nitrate (i.e. No_3) ions:

- **08.3.4:** Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates
- **08.3.4.1:** Traditional immersion cured products
- **08.3.4.2:** Traditional dry-cured products
- **08.3.4.3:** Other traditional and traditionally cured products
- **09.2:** Processed fish and fishery products including molluscs and crustaceans (i.e. only nitrites in pickled herring and sprat).

Derogated products must meet the definitions and requirements as outlined in the Restrictions/exceptions column of the table in Part E of Annex II to Regulation (EC) No 1333/2008, as well as the footnotes outlined in the tables under the above food categories of Regulation (EC) No 1333/2008, some of which include requirements for ingoing levels in some of these products (e.g. bacon, filet de bacon and similar products also have maximum ingoing levels specified).

Likewise, some products under food categories 08.2, 08.3.1, 08.3.2 and 09.2 also have residual levels specified in addition to ingoing levels. Please see Note 8 and Appendix 2 for further details.

Note 13: Products failing to comply with the requirements set out in Part E of Annex II to Regulation (EC) No 1333/2008 (summarised in Appendix 2 of this Guidance Note) are considered non-derogated products. The legislative limits for non-derogated products are set out under food categories 08.2 Meat preparations as defined by Regulation (EC) No 853/2004; 08.3.1 Non-heat-treated meat products; and 08.3.2 Heat-treated meat products (see Section 5.1.1).

Note 14: The notes in the Restrictions/exceptions column of the table in Part E of Annex II to Regulation (EC) No 1333/2008 specify in detail the production method used for the preparation of the derogated products. When interpreting the legislation, the information contained in Part E of Annex II to Regulation (EC) No 1333/2008 for each specific product should be read in conjunction with the general description for the type of product in question.

Attention should also be given to the various footnotes accompanying the maximum levels laid down for the specific products in question.

Note 15: Appendices 3 and 4 provide process flow diagrams for the derogated products Wiltshire ham and dry-cured ham.

The following is an example of how to determine the appropriate food category for a derogated meat product.

Example: Derogated meat product

From 9 October 2025, in order to meet the specifications for Wiltshire bacon, the product needs to comply with the following two requirements:

Firstly, it must comply with the description in the general heading of food category 8.3.4.1 (i.e. “Meat products cured by immersion in a curing solution containing nitrites and/or nitrates, salt and other components”).

and

Secondly, it must comply with the manufacturing process for Wiltshire bacon as laid down in the Restrictions/exceptions column of the table in Part E of Annex II to Regulation (EC) No 1333/2008 for food category 08.3.4.1 (i.e. “Meat is injected with curing solution followed by immersion curing for 3 to 10 days. The immersion brine solution also includes microbiological starter cultures.”)

In addition, the footnotes accompanying the maximum levels laid down for nitrites (XH) and nitrates (59 and XI) in Wiltshire bacon need to be adhered to:

- **(59):** Nitrates may be present in some heat-treated meat products as a result of the natural conversion of nitrites to nitrates in a low-acid environment.
- **(XH):** The maximum residual amount from all sources for the product when it is ready for marketing and throughout the shelf life of the product, expressed as NO_2 ion.
- **(XI):** The maximum residual amount from all sources for the product when it is ready for marketing and throughout the shelf life of the product, expressed as NO_3 ion.

This product may also undergo further treatment (e.g. smoking, cooking at the end of the curing process).

5.1.3 Similar products

Regulation (EC) No 1333/2008 contains the words “and similar products” beside many, but not all, of the food categories specified under food categories 08.3.4.1, 08.3.4.2 and 08.3.4.3. The term ‘similar products’ in the Regulation is meant to cover products that are not specifically named in the Regulation, but that are traditionally produced in the same manner as named traditional and traditionally cured meat products and that comply with the manufacturing/processing criteria listed in the footnotes.

There is no legal definition for what is meant by the term ‘similar products’, but they are described in recital 5 of the repealed Directive 2006/52/EC as “products which are not specifically named in the Directive, but which are traditionally produced in a similar manner”, and they can, if necessary, be categorised in accordance with Articles 19 and 28 of Regulation (EC) No 1333/2008.

In the case of similar products, the production methods described in the Restrictions/exceptions column of the table in Part E of Annex II to Regulation (EC) No 1333/2008 (as amended) for food categories 08.3.4.1, 08.3.4.2 and 08.3.4.3 should be used to decide whether a product is similar or not. For example, if there is another traditional Irish product that is produced in a similar way to one of the products named in the Regulation when the production methods are compared, then this product could be considered a similar product and would therefore be subject to the same maximum limits as the named product.

5.2 Sampling

5.2.1 Procedure for sampling ingoing amounts from brine

To establish the ingoing amounts of either nitrite or nitrate ion used in a meat product, the brine prepared and used by the food business operator in the production of the product should be sampled. The variables considered most important in ensuring compliance with the legislation are:

- The nitrite/nitrate concentration of the brine solution used by the food business operator
- The volume of brine injected into the cuts of meat being cured
- The size of the individual cuts, with the largest injection volume/smallest cut of meat being deemed to be most at risk of non-compliance.

Therefore, these variables should also be assessed when undertaking sampling in order to establish the ingoing amounts of nitrite or nitrate used in meat products. The following is the recommended procedure to take samples of brine and establish the ingoing amounts of nitrite or nitrate used in meat products by the food business operator:

- Gently mix the brine solution to ensure the brine is homogenous.
- Take a minimum of 250 millilitres (mL) of freshly made-up brine before the injection and/or tumbling and/or other processing using the brine commences.
- Submit brine samples in screw-cap jars or bottles like those used for sampling in microbiological analysis.
- Store all samples under refrigerated conditions, protected from light, and forward to the laboratory in a sealed, insulated container as soon as possible after sampling.
- Determine the target injection rate in conjunction with the food business operator for particular cuts of meat, taking account of the smallest cuts available at the time of sampling, as these are most at risk of being non-compliant.
- Select at least three of the smallest individual pieces of meat, tag them and weigh them individually prior to injection and/or tumbling and/or other processing with brine.
- Immediately weigh the same portions again following injection and/or tumbling and/or other processing with brine by the food business operator.

Note 16: Nitrate levels are known to deplete in the presence of light, as nitrate gets converted into amino acids and proteins. As a result, samples should be protected from light.

Note 17: Brine samples should never be frozen prior to analysis, as this can impact on the outcome of any laboratory analysis.

Note 18: The average of the determined concentrations of the nitrite or nitrate ion in the (at least) three pieces of meat should be used when determining whether the manufacturer's process results in the production of compliant products in relation to ingoing amounts.

Note 19: With Commission Regulation (EU) 2023/2108, many of the products covered under food category 08 Meat should also comply with maximum residual limits for the product when it is ready for marketing and throughout the shelf life of the product (Section 3.5), subject to the various footnotes and Restrictions/Exceptions outlined in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives.

Note 20: For injected products, the ingoing amount (in mg/kg) must be based on the finished post-injection meat weight. This requires the food business operator to measure the meat weight to include retained brine (i.e. post-injection), allowing for immediate drip loss if

appropriate. If tumbling/massaging takes place, then the final weight of the tumbled meat and brine should be used for calculating the ingoing amount.

Note 21: Cure-in-the-bag products are typically injected with curing solution and are not immersed. Therefore, it is possible to accurately regulate the ingoing amount of curing solution used for these types of products. As a result, these products fall under the general meat product food categories 08.3.1 or 08.3.2.

5.2.2 Calculations related to ingoing amounts

From 9 October 2025, the maximum limits provided in Regulation (EC) No 1333/2008 are expressed as either the nitrite or nitrate ion, respectively, in line with the ADIs established by EFSA.

Examples 1–3 show how the concentration of the nitrite or nitrate ion in brine samples submitted to the official laboratories can be used to calculate the ingoing levels in meat products at the time of manufacture.

The conversion factors provided in the legislation and some other useful conversion factors are listed in Section 3.4.

Example 1: Product falling under food category 08.3.1 Non-heat-treated meat products, as per Commission Regulation (EU) 2023/2108

Maximum permitted ingoing amount of nitrite (NO_2) = 80 mg/kg

This is the maximum amount that may be added during manufacturing, expressed as NO_2 ion.

Weight of meat before injection = 1 kg

Weight of meat after injection = 1.5 kg

Weight of added brine = 0.5 kg

Analysed concentration of NO_2 in brine sample = 200 mg/kg

Therefore, the ingoing amount of NO_2 is calculated as follows:

Laboratory results for concentration of NO_2 in brine sample (mg/kg) × weight of added brine (kg) ÷ weight of meat after injection (kg)

Therefore, the ingoing amount of NO_2 = 200 × 0.5 ÷ 1.5 = 66.8 mg/kg

As the maximum amount added during the manufacturing process (expressed as NO_2 ion) is <80 mg/kg, this sample is deemed to be compliant for ingoing amounts.

Example 2: Product falling under food category 08.3.1 Non-heat-treated meat products, as per Commission Regulation (EU) 2023/2108

Maximum permitted ingoing amount of nitrate (NO_3) = 90 mg/kg

This is the maximum amount that may be added during manufacturing, expressed as NO_3 ion.

Weight of meat before injection = 1 kg

Weight of meat after injection = 1.5 kg

Weight of added brine = 0.5 kg

Analysed concentration of NO_3 in brine sample = 225 mg/kg

Therefore, the ingoing amount of NO_3 is calculated as follows:

Laboratory results for concentration of NO_3 in brine sample (mg/kg) × weight of added brine (kg) ÷ weight of meat after injection (kg)

Therefore, the ingoing amount of NO_3 = 225 × 0.5 ÷ 1.5 = 75 mg/kg

As the maximum amount added during the manufacturing process (expressed as NO_3 ion) is <90 mg/kg, this sample is deemed to be compliant for ingoing amounts.

Example 3: Product falling under food category 08.3.2 Heat-treated meat products, as per Commission Regulation (EU) 2023/2108

Maximum permitted ingoing amount of nitrite (NO_2) (except sterilised meat products (Fo >3.00)) = 80 mg/kg

This is the maximum amount that may be added during manufacturing, expressed as NO_2 ion.

Weight of meat before injection = 0.5 kg

Weight of meat after injection = 0.8 kg

Weight of added brine = 0.3 kg

Analysed concentration of NO_2 in brine sample = 175 mg/kg

Therefore, the ingoing amount of NO_2 is calculated as follows:

Laboratory results for concentration of NO_2 in brine sample (mg/kg) × weight of added brine (kg) ÷ weight of meat after injection (kg)

Therefore, the ingoing amount of NO_2 = 175 × 0.3 ÷ 0.8 = 65.6 mg/kg

As the maximum amount added during the manufacturing process (expressed as NO_2 ion) is <80 mg/kg, this sample is deemed to be compliant for ingoing amounts.

5.3 Procedure for sampling for residual amounts

For certain meat products (e.g. those under food category 08.3.4) that are produced using traditional curing techniques, such as Wiltshire-style immersion curing or dry curing (e.g. Wiltshire ham or bacon), derogations were set out under previous legislative controls that allowed the evaluation of compliance for these products to be undertaken based on residual amounts of nitrate/nitrite in the product rather than ingoing amounts. This remains the case following the amendment to Regulation (EC) No 1333/2008 by Commission Regulation (EU) 2023/2108. However, the categorisation and maximum levels have been amended to reduce the amount allowed in many products. Also, some products that previously had only ingoing

maximum limits (e.g. those under food categories 08.2, 08.3.1 and 08.3.2) now also have residual maximum limits set down in the Regulation (Appendix 2).

The procedure for sampling meat products for analysis of residual amounts is as follows:

- The sample must be taken at a point when the product is ready for marketing. This may include some products that are cooked as part of processing.
- The minimum weight of the sample for analysis should be at least 400 grams (g).
- If products in their ready-for-marketing form are very large, a cross-section from the middle of the product to be tested can be removed. Samples must not be chopped, minced, etc.
- These samples should be placed in a sealed container (vacuum packed if possible, or placed in sealed plastic bags).
- All samples must be stored under refrigerated conditions, protected from light and forwarded to the laboratory in a sealed, insulated container as soon as possible after sampling.
- Samples of meat products in their ready-for-market form can also be frozen for transport to the laboratory.

Note 22: For dry-cured products, the dry cure mix should be applied by the food business operator in a consistent manner following the manufacturer's/supplier's instructions for use.

Note 23: Commission Regulation (EU) 2023/2108 makes no distinction between sampling and testing of residual levels in meat products that are ready for marketing and are either raw or cooked. However, nitrite is easily oxidised in high-temperature aerobic environments, such as those used in cooking. As such, concentrations of nitrites may decrease, and concentrations of nitrates may increase in some meat products following cooking. The impact of these changes depends on the cooking temperature, the type of product, and the cooking method used.

Note 24: Non-derogated products that previously only had ingoing maximum limits now have residual limits applied to products that are ready for marketing (Appendix 2).

Note 25: Sampling of products for residual amounts of nitrate and nitrite should only take place once the product is ready for marketing. However, it is important to note that the residual amount of nitrite in a product will decrease with time (i.e. during the product's shelf life). In some products, the decrease can be up to 50% during the first 24 hours, and by the end of the product's shelf life, residual levels of nitrites can be as low as 20% of the ingoing amount.

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Appendix 1 Health implications associated with the use of nitrites and nitrates in food

In humans, nitrite and nitrate from food are rapidly absorbed by the body and, for the most part, are excreted as nitrate. Some of the nitrate absorbed by the body is recirculated through the salivary glands, and part of it is converted into nitrite by bacteria in the mouth. Absorbed nitrite can oxidise haemoglobin to methaemoglobin, an excess of which reduces the ability of red blood cells to bind and transport oxygen through the body. Nitrite in food (and nitrate converted into nitrite in the body) may also contribute to the formation of a group of compounds known as nitrosamines, some of which are carcinogenic.

In 2017, the European Food Safety Authority (EFSA) re-evaluated the safety of potassium nitrite (E 249), sodium nitrite (E 250), sodium nitrate (E 251) and potassium nitrate (E 252) in two published Scientific Opinions (EFSA 2017a; EFSA 2017b). EFSA based its assessment on the previous evaluations of these food additives, new scientific literature that had become available since those previous evaluations were published, and information it received following public calls for data. For nitrate, EFSA was able to derive an acceptable daily intake (ADI), as it did not consider nitrate to be genotoxic or carcinogenic.

EFSA considered the most relevant adverse effect for setting a safe level of daily intake was elevated blood concentrations of methaemoglobin, caused by nitrate being converted into nitrite in the saliva. Based on this effect, EFSA concluded that the ADI set by the Scientific Committee on Food (SCF) of 3.7 milligrams per kilogram (mg/kg) of body weight per day (bw/day) was sufficiently protective of public health (SCF, 1997). For nitrite, EFSA calculated an ADI of 0.07 mg/kg bw/day, which corresponds to the safe level that was previously established by the Joint Food and Agriculture Organization of the United Nations/World Health Organization Expert Committee on Food Additives and is close to the slightly more conservative current ADI of 0.06 mg/kg bw/day derived by the SCF. In the same way as for nitrate, this ADI is based on increased methaemoglobin levels in the blood following the consumption of nitrite as a food additive.

Based on the available evidence, EFSA concluded that existing safe levels for nitrites and nitrates added to meat and other foods are sufficiently protective for consumers. Using more realistic data (i.e. actual concentration levels in food), EFSA estimated that consumer exposure to nitrate solely from its use as a food additive was less than 5% of the overall exposure to nitrate in food and did not exceed the ADI.

For nitrites used as food additives, EFSA estimated that exposure is within safe levels for all population groups, except for a slight exceedance in children whose diet is high in foods containing these additives. If all sources of dietary nitrite are considered (i.e. food additives, natural presence in food, and environmental contaminants), the ADI may be exceeded for individuals of all age groups with medium to high exposure. Nitrite exposure from all dietary sources may exceed the ADI for infants, toddlers, and children with average exposure, and for highly exposed individuals of all age groups.

The French Agency for Food, Environmental and Occupational Health & Safety (Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail) (ANSES) also evaluated these additives in 2022 and concluded that there is an association between the risk of colorectal cancer and exposure to nitrites and/or nitrates, whether they are ingested via the consumption of processed meat or drinking water. The higher the exposure to these compounds, the greater the risk of colorectal cancer in the population. The risk of other types of cancer is also suspected, but based on the data currently available, no conclusion can be drawn as to a causal relationship.

Nitrosamines in food

In January 2023, EFSA's Panel on Contaminants in the Food Chain published a Scientific Opinion on the risks for human health related to the presence of nitrosamines in food. This document presents an evaluation of the toxicity of *N*-nitrosamines, the estimated dietary exposure of European citizens to the carcinogenic nitrosamines present in food and, based on these, the risk assessment of the health risks to the European Union (EU) population. This EFSA Scientific Opinion concluded that the margin of exposure for nitrosamines (i.e. 10 carcinogenic nitrosamines occurring in food) at the P95 exposure level is highly likely (98–100% certain) to be less than 10,000 for all age groups, which raises a health concern.

The International Agency for Research on Cancer (IARC) re-evaluated data available on nitrite and nitrate in 2010 but did not comment on the ADIs that had been set previously by other organisations. The IARC evaluation includes a review of the effects of ingested nitrate in experimental animals and in humans arising from epidemiological studies. In 2015, the IARC classified processed meat as a carcinogenic hazard to humans (Group 1), with the formation of carcinogenic nitrosamines as one contributing factor. While the IARC assesses the carcinogenic properties of substances (i.e. the potential hazard they pose), EFSA also evaluates the likelihood and level of exposure for different population groups in its risk assessments.

Given that EFSA's Scientific Opinions indicated that the ADIs established could be exceeded if all dietary sources of nitrates and nitrites are taken into account (i.e. food additives, natural presence in food, and environmental contamination), and in addition to concerns around the formation of nitrosamines, the European Commission decided to take appropriate risk management measures in order to reduce exposure to these additives as well as to nitrosamines. It was seen as more difficult to control the presence of these substances from natural sources and via environmental contamination.

In reviewing the permitted levels of both nitrate and nitrite, the European Commission and EU Member States took account of the lower maximum permitted levels that were laid down in Commission Regulation (EC) No 889/2008 for organic products and of the lower maximum permitted levels that Denmark has adopted in national legislation, both of which indicated that the revision of the conditions for the use of nitrates and nitrites should be feasible.

Appendix 2 Maximum limits, restrictions and exemptions for nitrites and nitrates in meat preparations and meat products

Table 1 Nitrites (NO_2) (E 249 and E 250)

Food category	**Up to 8 October 2025 Legislative limit** (expressed as sodium nitrite ($NaNO_2$))	**From 9 October 2025 Legislative limit** (expressed as NO_2 ion) **Ingoing**	**From 9 October 2025 Legislative limit** (expressed as NO_2 ion) **Residual**	**Restrictions/exceptions** (see Regulation (EC) No 1333/2008 on food additives for full details)
08.2 Meat preparations as defined by Regulation (EC) No 853/2004	**150 mg/kg** (7) **Ingoing**	**80 mg/kg** (XC)	**45 mg/kg** (XD)	Restricted to specific meat preparations
08.3.1 Non-heat-treated meat products	**150 mg/kg** (7) **Ingoing**	**80 mg/kg** (XC)	**45 mg/kg** (XD)	Not applicable
08.3.2	**100 mg/kg** (7) (58) (59) **Ingoing**	**55 mg/kg** (58) (59) (XC)	**25 mg/kg** (XG)	Only sterilised meat products

Heat-treated meat products	**150 mg/kg** (7) (59) **Ingoing**	**80 mg/kg** (59) (XC)	**45 mg/kg** (XD)	Except sterilised meat products (Fo >3.00)
08.3.4 Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates **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)	Not applicable	Not applicable	**30 mg/kg** (XH)	Only traditionally cured products
	175 mg/kg (39) **Residual**	Not applicable	**105 mg/kg** (XH)	**Only Wiltshire bacon and similar products:** Meat is injected with curing solution followed by immersion curing for 3–10 days. The immersion brine solution also includes microbiological starter cultures.
	100 mg/kg (39) **Residual**	Not applicable	**65 mg/kg** (XH)	**Only Wiltshire ham and similar products:** Meat is injected with curing solution followed by immersion curing for 3–10 days. The immersion brine solution also includes microbiological starter cultures.
	150 mg/kg (7) **Ingoing**	**100 mg/kg** (XC)	**50 mg/kg** (XJ)	**Only bacon, filet de bacon, and similar products:** Immersion cured for 4–5 days at 5–7 °C, matured for

				typically 24–40 hours at 22 °C, possibly smoked for 24 hours at 20–25 °C, and stored for 3–6 weeks at 12–14 °C.
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)	Not applicable	Not applicable	**30 mg/kg** (XH)	Only traditionally cured products
	175 mg/kg (39) **Residual**	Not applicable	**105 mg/kg** (XH)	**Only dry-cured bacon and similar products:** Dry curing followed by maturation for at least 4 days.
	100 mg/kg (39) **Residual**	Not applicable	**65 mg/kg** (XH)	**Only dry-cured ham and similar products:** Dry curing followed by maturation for at least 4 days.
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	Not applicable	Not applicable	**30 mg/kg** (XH)	Only traditionally cured products

into the product prior to cooking)				
09.2 Processed fish and fishery products including molluscs and crustaceans	Please note ingoing value for nitrates in Table 2	Please note ingoing value for nitrates in Table 2	**45 mg/kg** (XD)	Only pickled herring and sprat

Note: From 9 October 2025, the use of nitrites in cured tongue will not be allowed.

Note: For the full list of categories, products, maximum levels and restrictions, please see Regulation (EC) No 1333/2008.

Note: *Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives* for further information on various products under each category.

Table 2 Nitrates (NO_3) (E 251 and E 252)

Food category	Up to 8 October 2025 **Legislative limit** (expressed as sodium nitrate ($NaNO_3$))	From 9 October 2025 **Legislative limit** (expressed as NO_3 ion) **Ingoing**	From 9 October 2025 **Legislative limit** (expressed as NO_3 ion) **Residual**	**Restrictions/exceptions** (see Regulation (EC) No 1333/2008 on food additives for full details)
08.3.1 Non-heat-treated meat products	**150 mg/kg** (7) **Ingoing**	**90 mg/kg** (XA)	**90 mg/kg** * (XE)	Not applicable
	Not applicable	**110 mg/kg** (XA)	**110 mg/kg** * (XF)	Only large bacon primals and dry sausages without nitrites added
08.3.4 Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates	**250 mg/kg** (39) (59) **Residual**	Not applicable	**150 mg/kg** (59) (XI)	**Only Wiltshire bacon and similar products:** Meat is injected with curing solution followed by immersion curing for 3–10 days. The immersion brine solution also includes microbiological starter cultures.
08.3.4.1 Traditional immersion cured products (Meat products cured by immersion in a curing solution containing	**250 mg/kg** (39) (59) **Residual**	Not applicable	**150 mg/kg** (59) (XI)	**Only Wiltshire ham and similar products:** Meat is injected with curing solution followed by immersion curing for 3–10 days. The immersion brine solution also includes microbiological starter cultures.

nitrites and/or nitrates, salt and other components)	**10 mg/kg** (39) (59) **Residual**	Not applicable	**7 mg/kg** (59) (XI)	**Only cured tongue:** Immersion cured for at least 4 days and precooked.
	250 mg/kg (7) (40) (59) **Ingoing**	**180 mg/kg** (40) (59) (XA)	**95 mg/kg** * (XK)	**Only bacon, filet de bacon, and similar products:** Immersion cured for 4–5 days at 5–7 °C, matured for typically 24–40 hours at 22 °C, possibly smoked for 24 hours at 20–25 °C, and stored for 3–6 weeks at 12–14 °C.
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)	**250 mg/kg** (39) (59) **Residual**	Not applicable	**150 mg/kg** (59) (XI)	**Only dry-cured bacon and similar products:** Dry curing followed by maturation for at least 4 days.
	250 mg/kg (39) (59) **Residual**	Not applicable	**150 mg/kg** (59) (XI)	**Only dry-cured ham and similar products:** Dry curing followed by maturation for at least 4 days.
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	**10 mg/kg** (39) (59) **Residual**	Not applicable	**7 mg/kg** (59) (XI)	**Only jellied veal and brisket:** Injection of curing solution is followed, after a minimum of 2 days, by cooking in boiling water for up to 3 hours.

compound product or where the curing solution is injected into the product prior to cooking)				
09.2 Processed fish and fishery products including molluscs and crustaceans	**500 mg/kg** **Ingoing**	**270 mg/kg** (XA)	Please note residual value for nitrites in Table 1	Only pickled herring and sprat

* Not a legislative limit, in the case of those meat products under Category Number 08.3 Meat Products, in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives with footnotes (XE), (XF) and (XK). If the residual amount from all sources in the product when it is ready for marketing and throughout the shelf life exceeds the stated value under the respective footnote (XE), (XF) and (XK), expressed as NO_3 ion, the meat product may continue to be placed on the market. However, the food business operator shall investigate the reason for this excess in conjunction with the official agency. Please also see Note 5.

Note: The use of nitrates in heat-treated meat products is not permitted.

Note: For the full list of categories, products, maximum levels and restrictions, please see Regulation (EC) No 1333/2008.

Note: *Guidance document describing the food categories in Part E of Annex II to Regulation (EC) No 1333/2008 on Food Additives* for further information on various products under each category.

Footnotes

Up to 8 October 2025

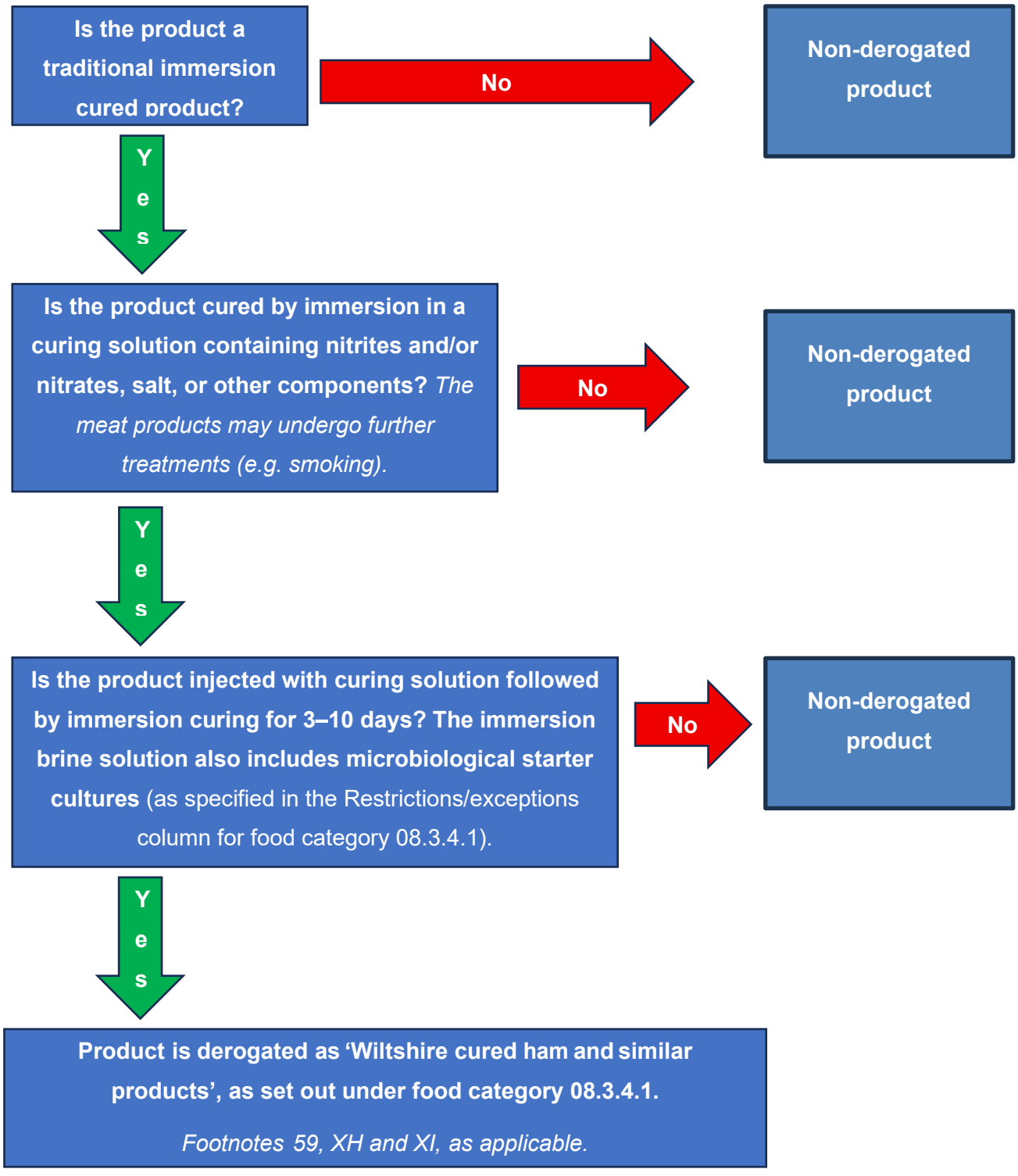
(7): Maximum amount that may be added during the manufacturing process, expressed as sodium nitrite ($NaNO_2$) or sodium nitrate ($NaNO_3$).
(39): Maximum residual amount, residue level at the end of the production process, expressed as $NaNO_2$ or $NaNO_3$.
(40): Without added nitrites.
(58): Fo value of 3 is equivalent to 3 minutes of heating at 121 °C (reduction of the bacterial load from 1 billion spores in every 1,000 cans to 1 spore in every 1,000 cans).
(59): Nitrates may be present in some heat-treated meat products as a result of the natural conversion of nitrites to nitrates in a low-acid environment.

From 9 October 2025

(XA): The maximum amount that may be added during the manufacturing process, expressed as NO_3 ion.
(XC): The maximum amount that may be added during the manufacturing process, expressed as NO_2 ion.
(XD): The maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product shall not exceed 45 mg/kg, expressed as NO_2 ion.
(XE): In the event that the residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product exceeds 90 mg/kg, expressed as NO_3 ion, food business operators shall investigate the reason for this excess.
(XF): In the event that the residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product exceeds 110 mg/kg, expressed as NO_3 ion, food business operators shall investigate the reason for this excess.
(XG): The maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product shall not exceed 25 mg/kg, expressed as NO_2 ion.
(XH): The maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product, expressed as NO_2 ion.
(XI): The maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product, expressed as NO_3 ion.
(XJ): The maximum residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product shall not exceed 50 mg/kg, expressed as NO_2 ion.
(XK): In the event that the residual amount from all sources in the product when it is ready for marketing and throughout the shelf life of the product exceeds 95 mg/kg, expressed as NO_3 ion, food business operators shall investigate the reason for this excess.
(40): Without added nitrites.
(58): An Fo value of 3 is equivalent to 3 minutes of heating at 121 °C (reduction of the bacterial load from 1 billion spores in every 1,000 cans to 1 spore in every 1,000 cans).
(59): Nitrates may be present in some heat-treated meat products as a result of the natural conversion of nitrites to nitrates in a low-acid environment.

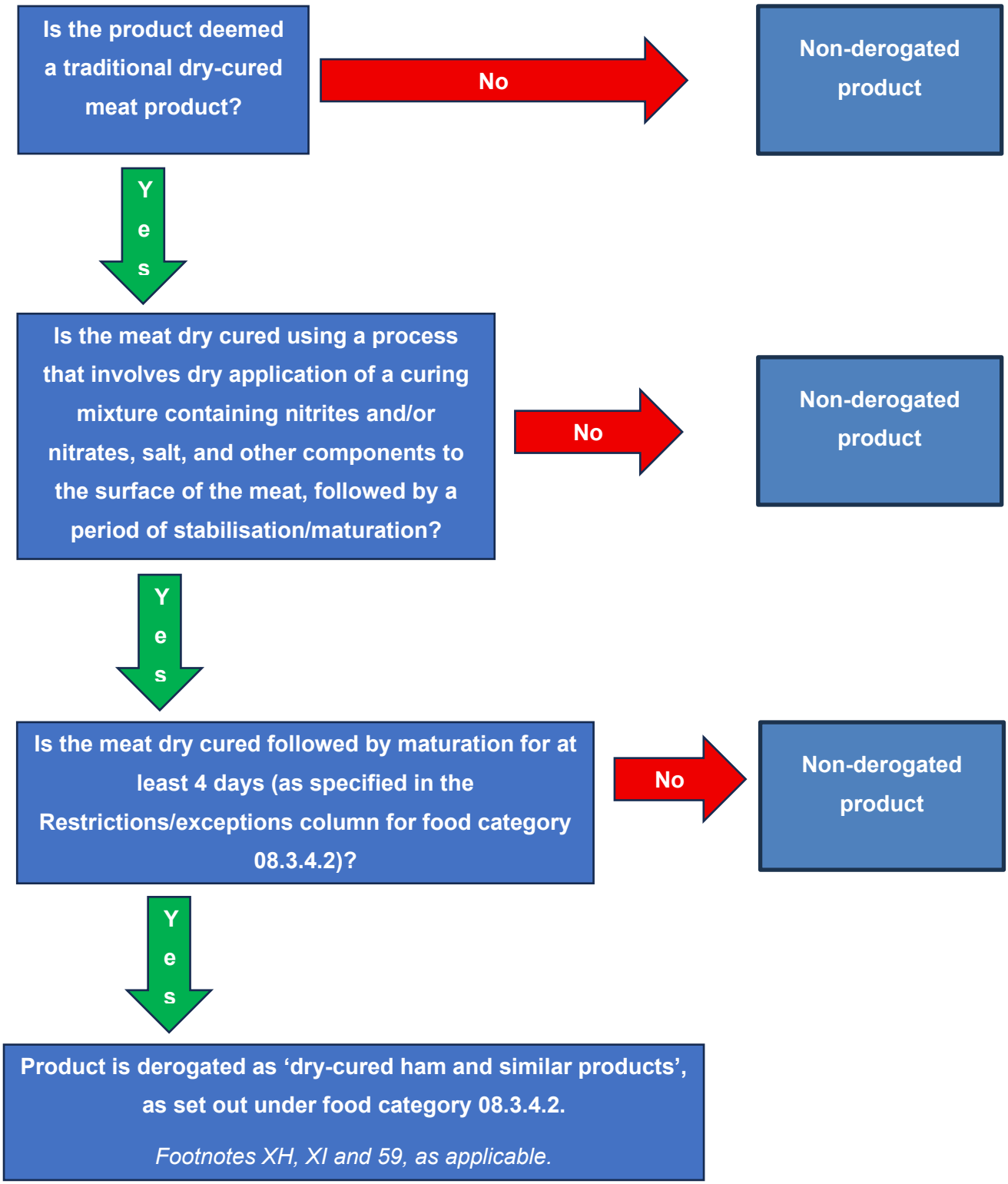
Appendix 3 Process flow diagram for Wiltshire ham and similar products

Process flow diagram for Wiltshire ham and similar products in accordance with Regulation (EC) No 1333/2008, as amended, under food category 08.3.4.1 (from 9 October 2025)



Appendix 4 Process flow diagram for dry-cured ham and similar products

Process flow diagram for dry-cured ham and similar products in accordance with Regulation (EC) No 1333/2008, as amended, under food category 08.3.4.2 (from 9 October 2025)



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