



2024/1225

2.5.2024

COMMISSION DECISION (EU) 2024/1225

of 30 April 2024

concerning national provisions notified by Denmark on the addition of nitrite to certain meat products

(notified under document C(2024) 2669)

(Only the Danish text is authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114(6) thereof,

Whereas:

I. FACTS AND PROCEDURE

- (1) Commission Decision (EU) 2021/741 ⁽¹⁾ approved Danish national provisions on the addition of potassium nitrite (E 249) and sodium nitrite (E 250) ('nitrites') to meat products contained in Order No 1247 of 30 October 2018 on additives in foodstuffs (*BEK nr 1247 af 30.10.2018, Udskriftsdato:3.9.2020, Miljø- og Fødevareministeriet*), which the Kingdom of Denmark notified to the Commission by letter of 6 November 2020, pursuant to Article 114(4) of the Treaty on the Functioning of the European Union (TFEU). These national provisions are approved until 5 May 2024.
- (2) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽²⁾ on food additives lays down the levels and other conditions of use of nitrites in meat products.
- (3) According to Decision (EU) 2021/741, Denmark is to monitor the situation and collect data on whether the application of the levels laid down in Regulation (EC) No 1333/2008 would achieve the required level of protection and, if not, whether it would lead to an unacceptable risk to human health in Denmark.
- (4) By letter of 3 November 2023, Denmark notified the Commission of its intention to maintain national provisions on the use of nitrites in meat products that differ from Regulation (EC) No 1333/2008. In support of its notification, Denmark submitted information that includes data on consumption and imports of meat products, exposure to nitrites, analysis of nitrites in meat products, prevalence of botulism and an updated risk assessment from the National Food Institute of Technical University of Denmark (DTU) of 18 August 2023.

1. UNION LEGISLATION

1.1. **Article 114(4) and (6) TFEU**

- (5) Article 114(4) TFEU provides that, 'if, after the adoption of a harmonisation measure by the European Parliament and the Council, by the Council or by the Commission, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 36, or relating to the protection of the environment or the working environment, it shall notify the Commission of these provisions as well as the grounds for maintaining them'.

⁽¹⁾ 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, ELI: <http://data.europa.eu/eli/dec/2021/741/oj>).

⁽²⁾ Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16, ELI: <http://data.europa.eu/eli/reg/2008/1333/oj>).

- (6) According to Article 114(6) TFEU, the Commission shall, within six months of the notification, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

1.2. Regulation (EC) No 1333/2008

- (7) In accordance with Regulation (EC) No 1333/2008, the approval of a food additive is contingent upon demonstrating a reasonable technological need, its safety, and that its use is safe and not misleading and provides advantages and benefits for the consumer.
- (8) 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. Only food additives included in the Union list may be placed on the market as such and used in foods under the conditions of use specified therein.
- (9) Nitrites have been used in meat products for many decades, inter alia, to secure, in conjunction with other factors, the preservation and microbiological safety of meat products, in particular cured meat products, inhibiting, amongst other things, the multiplication of *Clostridium botulinum*, the bacteria responsible for life-threatening botulism. At the same time, it is recognised that the presence of nitrites in meat products can give rise to the formation of nitrosamines, some of which have been found to be carcinogenic. Legislation in this field must, therefore, strike a balance between the risk of the formation of nitrosamines through the presence of nitrites in meat products, on the one hand, and the protective effects of nitrites against the multiplication of bacteria, in particular those responsible for botulism, on the other.

1.2.1. Maximum levels of nitrites applicable until 9 October 2025

- (10) In Annex II, Part E, food category 08.3 'Meat products', Regulation (EC) No 1333/2008 lays down maximum levels for nitrites that may be added during manufacture. Until 9 October 2025, the maximum added amount is 150 mg/kg for meat products in general, 100 mg/kg for sterilised meat products and, for a few specified cured meat products made traditionally in specific Member States, 180 mg/kg.
- (11) However, Regulation (EC) No 1333/2008, in Annex II, Part E, food category 08.3.4 'Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates', lays down maximum residual levels at the end of the production process for specific traditional cured meat products made using traditional manufacturing methods. There are maximum residual levels of 50 mg/kg, 100 mg/kg and 175 mg/kg applying to different groups of such products, such as 175 mg/kg for Wiltshire bacon, dry cured bacon and similar products, and 100 mg/kg for Wiltshire ham and similar products.
- (12) Setting out maximum levels of residual content of nitrites in food is an exception to the general rule which consist in setting out the maximum amounts of nitrites that may be added to food. Residual levels only apply to specific products which are traditionally manufactured in certain Member States and for which it is not possible to control the ingoing amount of curing salts absorbed by the meat due to the nature of the manufacturing process associated with these products. The production process of these specific products is described in Regulation (EC) No 1333/2008 to enable the identification of 'similar products' and to make clear which products are covered by the different maximum levels.

- (13) The maximum levels applicable until 9 October 2025 laid down in Regulation (EC) No 1333/2008, are based on the opinions of the Scientific Committee for Food ('SCF') of 1990 ⁽³⁾ and 1995 ⁽⁴⁾ as well as of the European Food Safety Authority ('EFSA') of 26 November 2003 ⁽⁵⁾. They reflect the ranges referred to in these scientific opinions.

1.2.2. Maximum levels of nitrites applicable from 9 October 2025

- (14) Given the re-evaluation of nitrites as food additives by EFSA ⁽⁶⁾ and taking into account other pertinent information and the extensive consultation of organisations representing the relevant food business operators, consumers and experts from competent authorities of Member States, Commission Regulation (EU) 2023/2108 ⁽⁷⁾ revised the maximum levels of nitrites. In particular, the maximum amounts that may be added to foods were 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 of a maximum added amount, a maximum residual level from all sources was established to monitor better the overall exposure to nitrites vis-à-vis the Acceptable Daily Intake (ADI). For traditionally cured meat products, the approach of regulating only maximum residual levels was maintained as it was not considered practicable to determine amounts of nitrites added to such products. The revised maximum levels and new residual maximum levels of nitrites are expressed as nitrite ion in line with the ADI established by EFSA.
- (15) In accordance with Regulation (EU) 2023/2108, the revised maximum added amount of nitrites is 80 mg/kg for meat products in general and 55 mg/kg for sterilised meat products. This corresponds to 120 mg/kg and 82 mg/kg respectively when expressed as sodium nitrite, i.e. expressed on the same basis as the maximum levels in Annex II to Regulation (EC) No 1333/2008 applicable until 9 October 2025 and the national provisions notified by Denmark. For a few specified cured meat products made traditionally, the maximum added amount of nitrites is 100 or 105 mg/kg, corresponding to 150 or 157 mg/kg when expressed as sodium nitrite. The residual levels newly established to monitor better the overall exposure to nitrites in relation with the ADI are 25, 45 or 50 mg/kg. The revised maximum residual levels for traditionally cured products for which no maximum added amount is set out are 30, 65 or 105 mg/kg applying to different groups of traditionally cured products.
- (16) The revised maximum levels were set out taking into account the variety of products available on the Union market, including many traditionally-produced food products, the diversity of distribution chains, producers and other variable conditions such as climate. They will be applicable from 9 October 2025 to allow the food business operators, including small and medium enterprises, to adapt to the new more stringent conditions of use.

2. NATIONAL PROVISIONS NOTIFIED

- (17) The national provisions notified by Denmark on 3 November 2023 are contained in Order No 474 of 9 May 2023 on additives, and other substances added to foodstuffs and on criminal provisions for infringements of related EU acts (BEK nr 474 af 9.5.2023). That Order replaces Order No 1247 of 30 October 2018 on additives in foodstuffs (BEK nr 1247 af 30.10.2018, Udskriftsdato: 3.9.2020, Miljø- og Fødevareministeriet), which had been previously notified to the Commission and assessed in the context of Decision (EU) 2021/741.

⁽³⁾ Opinion on nitrates and nitrites expressed on 19 October 1990, European Commission – Reports of the Scientific Committee for Food (twenty-sixth series), p. 21.

⁽⁴⁾ Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission – Reports of the Scientific Committee for Food (thirty eighth series), p. 1.

⁽⁵⁾ 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, The EFSA Journal (2003) 14, p. 1.

⁽⁶⁾ EFSA Journal 2017;15(6):4786.

⁽⁷⁾ 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) (OJ L, 2023/2108, 9.10.2023, ELI: <http://data.europa.eu/eli/reg/2023/2108/oj>).

- (18) Order No 474 provides that nitrites in meat products may only be used in accordance with the conditions laid down in Annex 3 thereto. The food categories referred to in that Annex correspond to the food categories listed in Annex II to Regulation (EC) No 1333/2008 on food additives and the conditions therein intend to supersede the provisions for nitrites laid down in that Regulation as follows:

08.3.1 Non-heat-treated meat products	Total 60 mg/kg. In fermented salamis, however, total 100 mg/kg.
08.3.2 Heat-treated meat products	Total 60 mg/kg. In entirely preserved or semi-preserved products, total 150 mg/kg. In rullepølse (rolled-meat sausage), total 100 mg/kg. In traditional Danish meat balls and liver pâté, 0 mg/kg.
08.3.4 Traditional and traditionally cured meat products with specific provisions concerning nitrites and nitrates	Total 60 mg/kg. In bacon of the Wiltshire type and related products, total 150 mg/kg. In traditional cured ham (spegeskinke) and related products, 150 mg/kg.

- (19) The default maximum added amount of 60 mg/kg applies in Denmark to many types of meat products, whereas the corresponding maximum levels, expressed as sodium nitrite, set out in Regulation (EC) No 1333/2008 are 100 mg/kg and 150 mg/kg until 9 October 2025 and will be 82 mg/kg and 120 mg/kg after that date.
- (20) The maximum added amount of nitrites for entirely preserved or semi-preserved heat-treated meat products in Denmark is 150 mg/kg, while the revised maximum added amounts of nitrites set out in Regulation (EC) No 1333/2008, applicable from 9 October 2025, are lower, permitting, expressed as sodium nitrite, only 82 mg/kg for sterilised heat-treated meat products and 120 mg/kg for non-sterilised heat-treated meat products.
- (21) The Danish national provisions do not set any maximum residual levels to be applied in parallel with the maximum added amounts of nitrites and thus do not control the exposure to nitrites in relation to the ADI, unlike the maximum residual levels related to the maximum added amounts set out in Regulation (EC) No 1333/2008.

3. PROCEDURE

- (22) By letter of 3 November 2023, Denmark notified the Commission of its intention to maintain national provisions on the use of nitrite additives in meat products that differ from Regulation (EC) No 1333/2008.
- (23) The Commission published a notice regarding the notification in *the Official Journal of the European Union* (*) in order to inform interested parties of Denmark's national provisions, as well as the grounds invoked to support the request. By letter of 22 December 2023, the Commission also informed the other Member States on the notification and gave them the opportunity to submit comments thereon within 30 days. No comments on the notification were received.

(*) Notification pursuant to Article 114, paragraph 4 of the Treaty on the Functioning of the European Union – Authorisation to maintain national measures which are more stringent than provisions of an EU harmonisation measure (OJ C, C/2024/794, 12.1.2024, ELI: <http://data.europa.eu/eli/C/2024/794/oj>).

II. ASSESSMENT

1. ADMISSIBILITY

- (24) Under Article 114(4) and (6) TFEU a Member State may, after the adoption of a harmonisation measure, maintain its more stringent national provisions on grounds of major needs referred to in Article 36 TFEU, or relating to the protection of the environment or the working environment, provided that it notifies these national provisions to the Commission and the Commission approves them.
- (25) The Danish notification relates to national provisions derogating from those of Part E of Annex II to Regulation (EC) No 1333/2008 in relation to potassium nitrite (E 249) and sodium nitrite (E 250).
- (26) Danish Order No 474 allows the addition of nitrites to meat products only in so far as specific added amounts are not exceeded. Depending on the products in question these maximum added amounts are 0 mg/kg, 60 mg/kg, 100 mg/kg or 150 mg/kg, which for certain products are lower than the ones laid down in Regulation (EC) No 1333/2008. Moreover, unlike Regulation (EC) No 1333/2008, the Danish provisions do not contain any exceptions to the principle of fixing maximum added amounts for nitrites, thereby not permitting the placing on the market of certain traditionally manufactured meat products from other Member States for which only maximum residual levels are laid down in Regulation (EC) No 1333/2008.
- (27) The Danish provisions are therefore in general more stringent than the provisions of Regulation (EC) No 1333/2008 in so far as they lay down lower maximum added amounts of nitrites for several types of products (in many cases the default level of 60 mg/kg applies) and in so far as they do not allow the placing on the market of certain traditional meat products regulated only on the basis of maximum residual levels. For traditionally cured products, the Danish practice is to take samples as close as possible to the time of manufacture in order to obtain the most realistic picture of the added quantity of nitrites.
- (28) In accordance with Article 114(4) TFEU, the notification was supplemented by a description of the grounds relating to one or more of the major needs referred to in Article 36 TFEU, in particular, the protection of health and life of humans. A Memorandum from the Danish Ministry of Food, Agriculture and Fisheries of 17 April 2023 and an updated risk assessment from the DTU National Food Institute of 18 August 2023 provide additional information on the consumption and imports of meat products, exposure to nitrites, analysis of nitrites in meat products on the Danish market, prevalence of botulism and the formation of nitrosamines in processed meat products.
- (29) In light of the foregoing, the Commission considers that the application submitted by Denmark with a view to obtaining authorisation to maintain its national provisions on the use of nitrites in meat products is admissible under Article 114(4) TFEU.

2. ASSESSMENT OF MERITS

- (30) In accordance with Article 114(4) and Article 114(6), first subparagraph, TFEU, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Union harmonisation measure provided for in that Article are fulfilled.

- (31) In particular, the Commission has to assess whether or not the national provisions are justified by the major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment and do not exceed what is necessary to attain the legitimate objective pursued. In addition, when the Commission considers that the national provisions fulfil the above conditions, it must verify, pursuant to Article 114(6) TFEU, whether or not the national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.
- (32) It has to be noted that, in the light of the time frame established by Article 114(6) TFEU, the Commission, when examining whether the national measures notified under Article 114(4) TFEU are justified, has to take as a basis the justifications put forward by the notifying Member State. The burden of proof lies with the requesting Member State that seeks to maintain its national measures.
- (33) However, where the Commission is in possession of information in the light of which the Union harmonisation measure from which the notified national provisions derogate may need to be reviewed, it can take such information into consideration in the assessment of the notified national provisions.

2.1. The position of Denmark

- (34) Denmark claims that its national provisions ensure a higher level of protection of health and human life in that they lay down lower maximum added amounts for nitrites than the ones provided for in Regulation (EC) No 1333/2008 and do not allow the placing on the market of traditional meat products for which no added amounts are established. Denmark points out that its provisions were laid down in full compliance with the opinions of the SCF adopted in 1990 and 1995 and considers the provisions justified in light of the EFSA opinions of 26 November 2003 and 15 June 2017.
- (35) According to Denmark, the overall scientific assessment demonstrates that (a) the use of nitrites and nitrates needs to be reduced as far as possible by using differentiated amounts in line with the technical needs related to different foodstuffs, (b) the use of nitrites and nitrates needs to be regulated in terms of the amounts that are added, and (c) the necessary preservation is achieved by using the amounts recommended by EFSA in 2003. In that respect, Denmark considers that its national provisions systematically follow these recommendations.
- (36) In Denmark's view, the concern about using the amounts of nitrites permitted under Regulation (EC) No 1333/2008 relates in particular to the increased risk of nitrosamines formation. Contrary to EFSA's opinion of 2017, Denmark considers that the formation of both volatile and non-volatile nitrosamines depends on the amounts of nitrites added to foods, while EFSA finds the link only for non-volatile nitrosamines. It argues that it has been scientifically proven that many volatile nitrosamines are carcinogenic and genotoxic. It adds that the updated risk assessment from the DTU National Food Institute refers to the increasing body of epidemiological evidence linking processed meat to stomach and colorectal cancer that heightens concerns about the use of nitrites in meat products.
- (37) Denmark also stresses that its national provisions have been in place for many years and have never given rise to problems with the preservation of the products concerned. Moreover, it has a relatively low rate of botulism compared with other Member States, and not a single case caused by the consumption of meat products has been recorded since 1980. Denmark notes that no cases of botulism have been recorded in Denmark since 2006. Thus, Denmark considers that its national provisions on the use of nitrites in meat products guarantee comprehensive protection against food poisoning.
- (38) The Memorandum from the Danish Ministry of Food, Agriculture and Fisheries of 17 April 2023 provides additional data on the consumption and import of meat products, exposure to nitrites as well as on an analysis of nitrites in meat products on the Danish market.

- (39) According to the Danish authorities, the most recent data, captured in that memorandum, demonstrate that the consumption patterns have not changed significantly. The consumption of meat products remains stable. Out of meat products to which nitrites may be added, by far the majority of the consumption relates to those products covered by the low limit value of 60 mg/kg.
- (40) As regards trade, despite of a slight decrease in imports by 2,5 % in the period 2020-2022, Denmark considers, based on the data for the period 1994-2022 related to different types of meat products, that there is no indication that the Danish national provisions have adversely affected imports from Member States.
- (41) The analysis of 302 samples in the period 2020-2022 does not reveal any exceedance of the Danish levels. The results show that the content of nitrites of the non-Danish products sampled on the Danish market is typically no higher than that of the Danish meat products.
- (42) Denmark welcomes the amendment of the provisions in Regulation (EC) No 1333/2008, made by Regulation (EU) 2023/2108, to ensure that the maximum levels are set as low as possible, taking into account technological needs and consumer safety. However, it points out that the revised levels, although significantly lower, are still generally above the levels set out in the Danish national provisions.
- (43) Therefore, Denmark considers it legitimate to maintain its national provisions for the use of nitrites in meat products. According to Denmark, the health considerations previously taken into account are still valid. Finally, it contends that the data available show that the Danish provisions do not constitute an obstacle to trade in the products concerned.

2.2. Evaluation of the Danish position

2.2.1. Justification on grounds of major needs referred to in Article 36 TFEU

- (44) The Danish national provisions aim to achieve a higher level of protection of health and life of humans with regard to exposure to nitrites and the possible formation of nitrosamines in meat products, by laying down lower and more specific maximum added amounts of nitrites for use in certain meat products, when compared with the maximum levels provided under Regulation (EC) No 1333/2008, and not allowing the placing on the market of products complying with only maximum residual levels.
- (45) The Commission notes that the Danish national provisions are compatible with the scientific opinions of the Union's scientific bodies issued in the past (SFC, 1990 and 1995; EFSA, 2003 and 2017) and respect the ranges of added amounts of nitrite referred to in these opinions.
- (46) Nevertheless, it should be noted that Denmark specifies a higher maximum added amount of nitrites for entirely preserved or semi-preserved heat-treated meat products (150 mg/kg) while the corresponding revised maximum added amounts of nitrites set out in Regulation (EC) No 1333/2008, applicable from 9 October 2025, are, when expressed as sodium nitrite, only 82 mg/kg for sterilised and 120 mg/kg for non-sterilised heat-treated meat products.
- (47) In addition, the Danish provisions do not set any maximum residual levels for the maximum added amounts and therefore do not control the overall exposure to nitrites from meat products. Maximum residual levels, linked to the maximum added amounts, were introduced in Regulation (EC) No 1333/2008 as a follow-up to the EFSA opinion of 2017, showing the exceedance of the ADI when all sources of dietary exposure to nitrites were taken into account.

- (48) When assessing whether the Danish national provisions are actually adequate and necessary for achieving their objective, a number of factors need to be taken into account. In particular, two health risks need to be balanced, the presence of nitrosamines in meat products on the one hand, and the microbiological safety of meat products on the other. The latter aspect is more than a mere technological need, but a highly relevant health concern in its own right. While it is recognised that the levels of nitrites in meat products should be as low as possible, lower levels of nitrites in meat will not automatically lead to a higher protection of human health. The most appropriate level of nitrites depends on a number of factors acknowledged in the relevant opinions of the SCF and EFSA, such as the addition of salt, moisture, pH, shelf-life of the product, hygiene, temperature control.
- (49) The Commission has to evaluate the specific choices made by the Danish regulator and the experience made with these rules, which have been in force for a considerable period of time. Through the figures it provided on the occurrence of food poisoning and, in particular, botulism, Denmark has demonstrated that it has achieved satisfactory results with its national provisions. In general, the data show that the maximum levels specified in the Danish legislation appear to have been adequate to ensure the microbiological safety of the meat products and production methods in Denmark.
- (50) It must be considered that, according to information provided by Denmark, the bulk of the meat products consumed by the Danish population relates to meat products for which the maximum added amount is limited to 60 mg/kg and which would have to be replaced by substantially higher maximum levels laid down in Regulation (EC) No 1333/2008. Although Danish manufacturers, like manufacturers in other Member States, would not be obliged to raise the amounts of nitrites currently added to their products to the maximum levels referred to in Regulation (EC) No 1333/2008, an increase of the actual exposure of the Danish population to nitrites cannot be excluded.
- (51) Overall, considering the data and rationale provided in the notification, the request to maintain the Danish national provisions can be accepted on grounds of protection of public health in Denmark in so far as, and only as long as, those provisions lay down lower maximum added amounts of nitrites when compared to those in Regulation (EC) No 1333/2008. However, since the maximum residual levels established in Regulation (EC) No 1333/2008 in relation with the maximum added amounts and applicable from 9 October 2025, can be applied in parallel with the Danish national provisions, this derogation should be without prejudice to the application in Denmark of those maximum residual levels.

2.2.2. *Absence of any arbitrary discrimination, any disguised restriction of trade between Member States or any obstacle to the functioning of the internal market*

2.2.2.1. *Absence of arbitrary discrimination*

- (52) Article 114(6) TFEU obliges the Commission to verify that the envisaged measures are not a means of arbitrary discrimination. According to the jurisprudence of the Court of Justice, in order for there to be no discrimination, similar situations must not be treated in different ways and different situations must not be treated in the same way.
- (53) The Danish national provisions apply to both domestic products and products made in other Member States. In the absence of any evidence to the contrary, it can be concluded that they are not a means of arbitrary discrimination.

2.2.2.2. *Absence of a disguised restriction on trade*

- (54) National measures which restrict the use of products to a greater extent than a Union Regulation would normally constitute a barrier to trade, in so far as products that are legally placed on the market and used in the rest of the Union are not allowed, as a result of the prohibition on use, to be placed on the market in the Member State concerned. The pre-conditions laid down in Article 114(6) TFEU are intended to prevent restrictions based on the criteria set out in paragraphs (4) and (5) thereof from being applied for inappropriate reasons, and constituting in effect economic measures to impede the importation of products from other Member States, that is to say, a means of indirectly protecting national production.

- (55) Given that the Danish national provisions impose stricter standards on the addition of nitrites to certain meat products also on operators based in other Member States in an otherwise harmonised area, they are liable to constitute a disguised restriction of trade or an obstacle to the functioning of the internal market. It is recognised, however, that Article 114(6) TFEU must be read in the sense that only national measures constituting a disproportionate obstacle to the internal market may not be approved. In that regard, Denmark has repeatedly submitted figures which indicate that imports of selected meat products from other Member States have not been significantly affected since 1994 and have even increased during the period of 1994-2019.
- (56) In the absence of any evidence suggesting that the national provisions constitute in effect a measure intended to protect national production, it can be concluded that they are not a disguised restriction to trade between Member States.

2.2.2.3. Absence of obstacles to the functioning of the internal market

- (57) This condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the functioning of the internal market. Indeed, any national measure derogating from a harmonisation measure aimed at the establishment and operation of the internal market constitutes in substance a measure likely to affect the internal market. Consequently, in order to preserve the useful character of the procedure laid down in Article 114 TFEU, the concept of obstacle to the functioning of the internal market must, in the context of Article 114(6) TFEU, be understood as a disproportionate effect in relation to the pursued objective.
- (58) Given the health benefits invoked by Denmark due to lower maximum amounts of nitrites that may be added to certain meat products and the fact that, on the basis of currently available information, trade does not appear to be affected or only to a very limited extent, the Commission considers that the notified Danish national provisions may continue to be maintained on grounds relating to the protection of health and life of humans having regard to the fact that they are not disproportionate and do, therefore, not constitute an obstacle to the functioning of the internal market in the sense of Article 114(6) TFEU.
- (59) In the light of this analysis, the Commission considers that the condition relating to the absence of obstacles to the functioning of the internal market is fulfilled.

2.2.3. *Limitation in time*

- (60) The above conclusions are based on the available information and, in particular, on information indicating that Denmark has been able to control botulism despite lower maximum levels of nitrites added to particular types of meat products, while not disrupting trade in a disproportionate fashion.
- (61) Another important factor is the rate of consumption in Denmark of meat products in relation to which the application of Regulation (EC) No 1333/2008 could lead to an increase of the exposure of the Danish population to nitrites and possibly nitrosamines.
- (62) Against this background, the Commission considers that the notified national provisions can be approved in so far as they lay down lower maximum added amounts of nitrites when compared to those in Regulation (EC) No 1333/2008.
- (63) In order to ensure that the national provisions, and the potential obstacle to the functioning of the internal market, are limited to what is strictly necessary to achieve the objectives pursued by Denmark, the derogation granted by this Decision should be limited in time. The derogation would cease to be necessary if, in the future, the maximum added amounts of nitrites to meat products laid down in Regulation (EC) No 1333/2008 would be further revised and set at or below the Danish national levels.

III. CONCLUSION

- (64) In the light of the above considerations the Commission is of the opinion that the request by Denmark, received by the Commission on 3 November 2023, for maintaining its national provisions on the addition of nitrites to meat products may be approved in so far as they are more stringent than those of Regulation (EC) No 1333/2008.
- (65) Therefore, the Danish national provision concerning the use of nitrites in entirely preserved and semi-preserved heat-treated meat products should be approved only until 9 October 2025, when the more stringent provisions of Regulation (EC) No 1333/2008 will start applying. The rest of the Danish national provisions should be approved only until the harmonised provisions applicable at Union level set out maximum added amounts of nitrites that are equal to or lower than those set out by the Danish national provisions.
- (66) This Decision is without prejudice to the application in Denmark of the maximum residual levels for nitrites, laid down in Regulation (EC) No 1333/2008, to be applied in parallel with the maximum added amounts of nitrites in order to monitor better the overall exposure to nitrites in relation with the ADI, since those maximum residual levels and the Danish national provisions are complementary.

HAS ADOPTED THIS DECISION:

Article 1

The national provision on the use of nitrites in entirely preserved or semi-preserved heat-treated meat products contained in Order No 474 of 9 May 2023 on additives, etc. to foodstuffs and on criminal provisions for infringements of related EU acts (*BEK nr 474 af 9.5.2023*), which the Kingdom of Denmark notified to the Commission by letter of 3 November 2023, pursuant to Article 114(4) TFEU, is approved until 9 October 2025.

Article 2

The other national provisions on the addition of nitrites to meat products contained in Order No 474 of 9 May 2023 on additives, etc. to foodstuffs and on criminal provisions for infringements of related EU acts (*BEK nr 474 af 9.5.2023*), which the Kingdom of Denmark notified to the Commission by letter of 3 November 2023, pursuant to Article 114(4) TFEU, with the exception of the provision for the use of nitrites in entirely preserved and semi-preserved heat-treated meat products, are approved until revised harmonised provisions setting maximum added amounts equal to or lower than those set out in that Order are applicable at Union level.

Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 30 April 2024.

For the Commission
Stella KYRIAKIDES
Member of the Commission