



C/2024/794

12.1.2024

**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**

(Text with EEA relevance)

(C/2024/794)

1. By letter of 3 November 2023, which reached the Commission on 9 November 2023, Denmark notified the Commission of its wish to maintain <sup>(1)</sup> national provisions on the use of nitrite additives in meat products that differ from Regulation (EC) No 1333/2008 of the European Parliament and of the Council <sup>(2)</sup>, in Danish law 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 09/05/2023*). The notification concerns the substances potassium nitrite (E 249) and sodium nitrite (E 250) (nitrites) in Annex II Part E to the Regulation, food category 8 (EU list).

2. The existing EU harmonised maximum levels for nitrite additives were originally laid down in Directive 2006/52/EC of the European Parliament and of the Council <sup>(3)</sup>. This Directive was adopted by the European Parliament and the Council on 5 July 2006 and is based on Article 95 of the EC Treaty (now Article 114 of the Treaty on the Functioning of the European Union - TFEU). With regard to the use of nitrates and nitrites in meat products it aimed to strike a balance between the protective effects of nitrites against the multiplication of the bacteria responsible for life-threatening botulism and the risk of the formation of carcinogenic nitrosamines through the presence of nitrites in meat products, based on scientific advice received from the European Food Safety Authority <sup>(4)</sup> (EFSA) and the Scientific Committee for Food <sup>(5)</sup>.

In line with the EFSA opinion from 2003, Directive 2006/52/EC introduced the levels in the form of maximum amounts that may be added during the manufacture of meat products for potassium nitrite (E 249) and sodium nitrite (E 250). The amount, expressed as sodium nitrite, was 150 mg/kg for meat products in general and 100 mg/kg for sterilised meat products. By way of exception maximum residual levels were set up for certain specified traditionally produced meat products, where it was not possible to control the amounts added because of their traditional manufacturing process. This authorised use of nitrites was transferred in the new Union list of food additives approved for use in foods and conditions of use, in Annex II to Regulation (EC) No 1333/2008, which was established by Commission Regulation (EU) No 1129/2011 <sup>(6)</sup>.

Given the re-evaluation of nitrites as food additives by EFSA <sup>(7)</sup> and taking into account other relevant information and the extensive consultation of organisations representing the relevant food business operators, consumers and experts from competent authorities of Member States, the existing EU maximum levels were revised by Commission Regulation (EU) 2023/2108 <sup>(8)</sup>. The new EU maximum levels, applicable as from 9 October 2025, significantly lower the maximum amounts of nitrites that may be added to foods (by approximately 20 %), but overall remain above the Danish maximum

<sup>(1)</sup> An authorisation for 3 years was granted by Commission Decision (EU) 2021/741.

<sup>(2)</sup> 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).

<sup>(3)</sup> Directive 2006/52/EC of the European Parliament and of the Council of 5 July 2006 amending Directive 95/2/EC on food additives other than colours and sweeteners and Directive 94/35/EC on sweeteners for use in foodstuffs (OJ L 204, 26.7.2006, p. 10).

<sup>(4)</sup> The EFSA Journal (2003) 14, 1-31, The effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products.

<sup>(5)</sup> Reports of the Scientific Committee for Food, Twenty-sixth series, 1992, p. 21-28 and Thirty-eight series, 1997, p. 1-33.

<sup>(6)</sup> Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives (OJ L 295, 12.11.2011, p. 1).

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

<sup>(8)</sup> 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>).

levels while maintaining residual levels for some traditionally cured products that account for the variety of products available on the EU market, including many traditionally-produced food products, the diversity of distribution chains, producers and other variable conditions such as climate.

3. The Danish Order No 474 allows the addition of potassium nitrite (E 249) and sodium nitrite (E 250) to meat products only in so far as specific added amounts are not exceeded. Depending on the products in question these maximum amounts are 0, 60, 100 or 150 mg/kg expressed as sodium nitrite. 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. In so far as the 0 and the 60 mg/kg limits apply, the Danish legislation, in addition, contains lower limits for added amounts of nitrites than the Regulation for a number of meat products.

The Danish provisions are therefore more stringent than the existing and new maximum levels laid down in Annex II to Regulation (EC) No 1333/2008 in relation to the addition of nitrites to meat products.

4. The Kingdom of Denmark considers that amending the provisions to bring them into line with the existing EU maximum levels would lead to a considerable increase in the intake of nitrites. According to Denmark, even the new significantly lower EU maximum levels would lead to an increased intake of nitrites for Danish consumers as the majority of meat products under the Danish provisions are covered by a lower limit value of 60 mg/kg. Denmark also points out that, through the lower maximum added amounts, the Danish provisions further minimise the risk posed by nitrosamines which is its primary concern.

Denmark emphasises that, despite the fact that its rules providing for lower levels of nitrites which may be added to meat products have been in place for many years, they have never given rise to problems with the preservation of the products concerned and that there has not been a single case of botulism caused by meat products since 1980.

According to Denmark, the updated data also show that the Danish rules do not constitute an obstacle to trade in the products concerned, which are being imported into Denmark to an ever-increasing extent.

5. The Commission will process this notification in accordance with Article 114(4) and (6) TFEU. Article 114(4) provides that if, after the adoption of an EU harmonisation measure, a Member State wishes to 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, it shall notify them to the Commission indicating the reasons for maintaining them. Following the notification of the Danish provisions the Commission has 6 months to approve or reject them. In this period the Commission shall verify whether the maintenance of the Danish provisions is justified on grounds of major needs referred to in Article 36 or relating to the protection of the environment, and that they do not constitute a means of arbitrary discrimination or a disguised restriction on trade and that they do not create an unnecessary and disproportionate obstacle to the functioning of the internal market.

6. Any party who wishes to provide comments on this notification must send them to the Commission within 30 days from the publication of this notice. Any comment submitted after this period will not be taken into account.

7. Further details about the Danish notification can be obtained from:

European Commission  
Directorate-General Health and Food Safety  
DG SANTE – Unit E2 Food Processing Technologies and Novel Foods

SANTE-E2-Additives@ec.europa.eu