

## NOTICES FROM MEMBER STATES

**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)

(2018/C 114/06)

1. By letter of 10 November 2017, which reached the Commission on 14 November 2017, 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> into Danish law. Order No 1044 of 4 September 2015 on food additives etc. in foodstuffs (BEK nr 1044 af 04.09.2015, Udskriftsdato: 25.09.2017, Fødevarerministeriet). 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 maximum levels 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 aims 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, in line with scientific advice received from the European Food Safety Authority (EFSA) and the Scientific Committee for Food (SCF).

European Parliament and Council Directive 95/2/EC <sup>(4)</sup> as it was adopted originally laid down maximum residual levels for nitrites and nitrates in various meat products. By contrast, Directive 2006/52/EC introduces the principle, recommended in an EFSA opinion from 2003, that the control of nitrites should be regulated 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 is 150 mg/kg for meat products in general and 100 mg/kg for sterilised meat products.

By way of exception, Directive 2006/52/EC contains maximum residual levels for certain specified traditionally produced meat products, where it was not possible to control the ingoing amounts 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>(5)</sup>.

3. The Danish Order No 1044 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. 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.

<sup>(1)</sup> An authorisation for 3 years was granted by Commission Decision (EU) 2015/826 (OJ L 130, 28.5.2015, p. 10).

<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> European Parliament and Council Directive 95/2/EC of 20 February 1995 on food additives other than colours and sweeteners (OJ L 61, 18.3.1995, p. 1).

<sup>(5)</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).

4. The Danish provisions are therefore more stringent than Regulation (EC) No 1333/2008 in relation to the addition of nitrites to meat products.

5. The Kingdom of Denmark considers that, unlike Regulation (EC) No 1333/2008, the current Danish provisions are fully consistent with the opinion of EFSA <sup>(1)</sup> that safe meat products generally can be produced by the addition of as little as 50 mg per kg nitrite.

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 preservation of the products concerned and that Denmark has a very low rate of botulism compared with other Member States, and not a single case caused by meat products has been recorded since before 1980.

The latest figures provided by Denmark show that the trend in consumption patterns has not changed significantly since the Commission Decisions 2010/561/EU <sup>(2)</sup> and (EU) 2015/826 <sup>(3)</sup>. Danes' consumption of meat is rising steadily including cold cuts which contained added nitrites, and imports of meat products from other Member States are increasing.

6. In 2014 the Commission finalised a desk study to monitor the implementation by the Member States of the EU rules on nitrites. The study was based on the responses to a questionnaire that was submitted to all Member States. It revealed that with some exceptions, the typical amount of nitrites added to non-sterilised meat products is lower than the EU maximum amount, but higher than the Danish levels. It was concluded that the possibility to review the current maximum levels of nitrites should be further explored.

The Commission therefore launched an ad hoc study, completed in January 2016, as regards the use and the need of nitrites by industry in different categories of meat products, including protection against *Clostridium botulinum*. Based on data collected through a literature review, a survey and an expert workshop conducted for this study, results indicate that there is a possibility to review the current maximum levels of nitrites authorised.

Furthermore, Commission Regulation (EU) No 257/2010 <sup>(4)</sup> requires that EFSA re-evaluates the safety of the use of nitrites. EFSA delivered a Scientific Opinion on the re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives on 15 June 2017 <sup>(5)</sup>. EFSA derived an Acceptable Daily Intake (ADI) of 0,07 mg nitrite ion/kg bw per day and clarified that the exposure to nitrite resulting from its use as food additive did not exceed this ADI for the general population, except for a slight exceedance in children at the highest percentile. However, if all sources of dietary nitrite exposure were considered together (food additives, natural presence and contamination), the ADI would be exceeded in infants, toddlers and children at the mean and for all age groups at highest exposure. The exposure to the endogenous nitrosamines was considered to be of low concern whilst there was some concern as regards the exposure to exogenous nitrosamines. The EFSA opinion also states that more research was needed to address uncertainties and knowledge gaps and that it was not possible to clearly discern nitrosamines produced from the nitrite added at the authorised levels from those found in the food matrix without addition of external nitrite. In epidemiological studies there was some evidence to link (i) dietary nitrite and gastric cancers; and (ii) the combination of nitrite plus nitrate from processed meat and colorectal cancers, and there was evidence to link preformed N-nitrosodimethylamine and colorectal cancers.

The conclusions of the desk study with the Member States, the ad hoc study as regards the use of nitrites by industry, the re-evaluation by EFSA and the data reported by Denmark, allows the Commission to further consider a potential review of the maximum levels of nitrites.

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

<sup>(2)</sup> Commission Decision 2010/561/EU of 25 May 2010 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products (OJ L 247, 21.9.2010, p. 55).

<sup>(3)</sup> Commission Decision (EU) 2015/826 of 22 May 2015 concerning national provisions notified by Denmark on the addition of nitrite to certain meat products (OJ L 130, 28.5.2015, p. 10).

<sup>(4)</sup> Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (OJ L 80, 26.3.2010, p. 19).

<sup>(5)</sup> EFSA Journal 2017;15(6):4786

7. 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.

8. 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.

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

European Commission  
Directorate-General for Health and Food Safety  
DG SANTE — Unit E2 Food Processing Technologies and Novel Foods  
Jiri Sochor

Tel. +32 22976930  
Email: [jiri.sochor@ec.europa.eu](mailto:jiri.sochor@ec.europa.eu)

---