

DECISIONS

COMMISSION DECISION

of 25 May 2010

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

(notified under document C(2010) 3301)

(Only the Danish text is authentic)

(2010/561/EU)

THE EUROPEAN COMMISSION,

of a renewed notification — that the application of the levels laid down in Directive 2006/52/EC do not achieve the required level of protection and would lead to an unacceptable risk to human health.

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) By letter of 21 November 2007 and pursuant to Article 95(4) of the EC Treaty (now Article 114(4) of the Treaty on the Functioning of the European Union — TFEU), the Kingdom of Denmark (Denmark) notified to the Commission its national provisions on the addition of nitrites to certain meat products, contained in Order No 22 of 11 January 2005 on food additives (*Bekendtgørelse nr 22 af 11.1.2005 om tilsætningsstoffer til fødevarer*) and the Danish positive list of permitted food additives (*Liste over tilladte tilsætningsstoffer til fødevarer, 'Positivlisten'*)⁽¹⁾. Denmark considered necessary to maintain these provisions and therefore not to transpose 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⁽²⁾ into national law in so far as it relates to the use of nitrites in meat products.

(2) By Commission Decision 2008/448/EC⁽³⁾, these national provisions were approved until 23 May 2010, pending the demonstration by the Danish authorities — by means

(3) Accordingly, by letter of 20 November 2009, which reached the Commission on 26 November 2009, Denmark notified the Commission of its intention to continue not to transpose Directive 2006/52/EC into national law in so far as it relates to the use of nitrites in certain meat products and instead maintain its existing national legislation in this respect, i.e. Order No 22 of 11 January 2005 on food additives (*Bekendtgørelse nr 22 af 11.1.2005 om tilsætningsstoffer til fødevarer*) and the Danish positive list of permitted food additives (*Liste over tilladte tilsætningsstoffer til fødevarer, 'Positivlisten'*). In support of its notification, Denmark submitted additional information that includes data on consumption of meat products, imports of meat products, and analysis of nitrite in meat products on the Danish market.

1. UNION LEGISLATION

1.1. ARTICLE 114(4) AND (6) TFEU

(4) Article 114(4) TFEU provides that, '[i]f, 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.'

(5) According to Article 114(6) TFEU, the Commission shall, within 6 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⁾ The notification related to E249 potassium nitrite and E250 sodium nitrite.

⁽²⁾ OJ L 204, 26.7.2006, p. 10.

⁽³⁾ OJ L 157, 17.6.2008, p. 98.

1.2. DIRECTIVE 2006/52/EC

- (6) Under the general principles of Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives⁽¹⁾, the approval of a food additive is subject to a reasonable technological need, its acceptability from a health point of view and its use not being misleading for the consumer. The latter Regulation repealed, as of 20 January 2010, Council Directive 89/107/EEC of 21 December 1988 on the approximation of the laws of the Member States concerning food additives authorised for use in foodstuffs intended for human consumption⁽²⁾, which set out the same general principles.
- (7) 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, 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.
- (8) Pursuant to Articles 33 and 34 of Regulation (EC) No 1333/2008, European Parliament and Council Directive No 95/2/EC on food additives other than colours and sweeteners⁽³⁾ is repealed as of 20 January 2010, with the exception of certain provisions, including Annexes I to VI thereto, which continue to apply. Directive 95/2/EC, as it was adopted originally, laid down maximum residual levels of nitrites and nitrates for various meat products as well as 'indicative ingoing amounts'. Annex I(3)(c) to Directive 2006/52/EC amends Annex III Part C to Directive 95/2/EC in relation to E249 potassium nitrite and E250 sodium nitrite.
- (9) By contrast, as a general rule, Directive 2006/52/EC contains maximum amounts for E249 potassium nitrite and E250 sodium nitrite that may be added during manufacture. The maximum added amount is 150 mg/kg for most meat products in general and 100 mg/kg for sterilised meat products. For a few specified cured meat products made traditionally in specific Member States the maximum amount is 180 mg/kg.
- (10) This approach follows opinions from the Scientific Committee for Food (hereinafter 'SCF') of 1990⁽⁴⁾ and 1995⁽⁵⁾ as well as from the European Food Safety Authority (hereinafter 'EFSA') of 26 November 2003⁽⁶⁾, which established that the ingoing amount of nitrite, rather than the residual amount, contributes to the inhibitory effect against *C. botulinum* and recommended to replace 'indicative ingoing amounts' with 'maximum ingoing amounts'. It also takes account of the Court's ruling in Case C-3/00 *Denmark/Commission* relating to a previous Danish request under Article 95(4) of the EC Treaty (now Article 114(4) TFEU) and in which the Court held that, when rejecting the Danish request in relation to the use of nitrites in meat products, the Commission did not take sufficient account of the SCF's opinions of 1990 and 1995, which cast doubt on the appropriateness of the amounts of nitrite authorised by Directive 95/2/EC⁽⁷⁾.
- (11) By way of exception to the general rule, Directive 2006/52/EC contains maximum residual levels for certain specified traditional cured meat products, which are produced through 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, e.g. 175 mg/kg for *Wiltshire bacon*, *dry cured bacon* and similar products, and 100 mg/kg for *Wiltshire ham* and similar products. In relation to these products maximum residual values have been established since 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 the Directive to enable identification of 'similar products' and to make clear what products are covered by the different maximum levels. The table below contains the maximum levels established by Directive 2006/52/EC.
- (1) OJ L 354, 31.12.2008, p. 16.
 (2) OJ L 40, 11.2.1989, p. 27.
 (3) OJ L 61, 18.3.1995, p. 1.
 (4) Opinion on nitrates and nitrites expressed on 19 October 1990, European Commission — Reports of the Scientific Committee for Food (twenty-sixth series), p. 21.
 (5) Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission — Reports of the Scientific Committee for Food (thirty eighth series), p. 1.
 (6) 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.
 (7) Case C-3/00, *Kingdom of Denmark v Commission of European Communities*, ECR [2003] I-2643, in particular points 109-115.

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₃)	Maximum residual level (expressed as NaNO ₃)
E 249	Potassium nitrite (*)	Meat product	150 mg/kg	
E 250	Sodium nitrite (*)	Sterilised meat products (Fo > 3,00) (**)	100 mg/kg	
		Traditional immersion cured meat products (1):		
		Wiltshire bacon (1.1); Entrecosta, entrecosto, chispe, orelheira e cabeça (salgados) Toucinho fumado (1.2); and similar products		175 mg/kg
		Wiltshire ham (1.1); and similar products		100 mg/kg
		Rohschinken, nassgepökelt (1.6); and similar products		50 mg/kg
		Cured tongue (1.3)		50 mg/kg
		Traditional dry cured meat products (2):		
		Dry cured bacon (2.1); and similar products		175 mg/kg
		Dry cured ham (2.1); Jamón curado, paleta curada, lomo embuchado y cecina (2.2); Presunto, presunto da pá and paio do lombo (2.3); and similar products		100 mg/kg
		Rohschinken, trockengepökelt (2.5); and similar products		50 mg/kg
		Other traditionally cured meat products (3):		
		Vysočina Selský salám Turistický trvanlivý salám Poličan Herkules Lovecký salám Dunajská klobása Paprikáš (3.5); and similar products	180 mg/kg	

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO ₃)	Maximum residual level (expressed as NaNO ₃)
		Rohschinken, trocken-/nassgepökelt (3.1); and similar products Jellied veal and brisket (3.2)		50 mg/kg

(*) When labelled 'for food use', nitrite may be sold only in a mixture with salt or a salt substitute.

(**) Fo-value 3 is equivalent to 3 minutes heating at 121 °C (reduction of the bacterial load of one billion spores in each 1 000 cans to one spore in 1 000 cans).

(12) As recommended in the relevant opinions of the SCF and EFSA, Directive 2006/52/EC is based on the establishment of maximum added amounts and reflects the ranges referred to in these scientific opinions by specifying that up to 100 mg/kg of nitrite are permitted in sterilised meat products and 150 mg/kg in other meat products. Given the vast variety of (cured) meat products and manufacturing methods within the European Union, the Union legislator held that it was, for the moment, not possible to specify the appropriate level of nitrite for each product.

(13) The exceptions to the rule of applying maximum added amounts have a limited character. They 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 traditional products to which they apply are defined, in particular, through a description of the production method.

(14) Directive 2006/52/EC was due to be transposed by the Member States by 15 February 2008 in order to permit trade in and the use of products complying with this Directive by 15 February 2008 and prohibit trade in and use of products which are not in compliance by 15 August 2008.

(15) On 23 November 2007, pursuant to Article 95(4) EC Treaty (now Article 114(4) TFEU), Denmark requested to maintain its national provisions on the addition of nitrites to meat products contained in Order No 22 of 11 January 2005 on food additives (*Bekendtgørelse nr 22 af 11.1.2005 om tilsætningsstoffer til fødevarer*) and the Danish positive list of permitted food additives (*Liste over tilladte tilsætningsstoffer til fødevarer, 'Positivlisten'*), which are more stringent than those of Directive 2006/52/EC.

(16) By means of Commission Decision 2008/448/EC and in accordance with Article 95(6) EC Treaty (now Article 114(6) TFEU) the Commission approved these

national measures until 23 May 2010, pending the demonstration by the Danish authorities that the application of the levels laid down in Directive 2006/52/EC do not achieve the required level of protection and would lead to an unacceptable risk to human health. In order to be able to submit such data in a renewed application, Denmark was required to monitor the situation in particular with regard to the control of botulism, the share of meat products covered by the 60 mg/kg limit in the overall consumption of meat products in Denmark, including any other risk factor of typical dietary habits as relevant, as well as imports of meat products from other Member States.

2. NATIONAL PROVISIONS NOTIFIED

(17) The national provisions notified by Denmark on 20 November 2009 are Order No 22 of 11.1.2005 on food additives (*Bekendtgørelse nr 22 af 11.1.2005 om tilsætningsstoffer til fødevarer*) and the Danish positive list of permitted food additives (*Liste over tilladte tilsætningsstoffer til fødevarer, 'Positivlisten'*). In the context of Decision 2008/448/EC, the Commission has already assessed the more stringent rules applied by Denmark with respect to E249 and E250.

(18) Order No 22 contains the principle that only additives contained in a positive list may be used for the foodstuffs under specified conditions, and with the specified objectives and restrictions⁽¹⁾. It further provides that, unless otherwise specified, the maximum values set out in the positive list refer to the maximum amounts of the additive which may be present in a foodstuff in the form in which it is sold⁽²⁾. As a consequence, only foodstuffs which are in compliance with the requirements of Order No 22 and the positive list may be sold on the Danish market. The positive list established by the Danish Veterinary and Food Administration on the basis of Order No 22 states which additives may be used for the individual foodstuffs, and in what amounts. The version notified applies with effect from 29 January 2005.

⁽¹⁾ See paragraph 13 of Order No 22 'Use of additives'.

⁽²⁾ See paragraph 20 of Order No 22.

- (19) With regard to the use of nitrites E249 (potassium nitrite) and E250 (sodium nitrite) in meat products, the Danish positive list sets out exclusively added amounts and contains the following maximum level.

Foodstuff	Amount of nitrites added (mg/kg)
8.2.1. Non-heat-treated meat products derived from whole pieces of meat, including slices of products (in general)	60
Bacon of the Wiltshire type and related cuts, including salt-cured ham	150
8.2.2. Heat-treated meat products derived from whole pieces of meat, including slices of products (in general)	60
Rullepølse (rolled meat sausage)	100
Entirely preserved or semi-preserved products, bacon of the Wiltshire type and cuts thereof, including salt-cured ham	150
8.3.1. Non-heat-treated meat products derived from minced meat, including slices of products (in general)	60
Fermented salamis	100
Entirely preserved or semi-preserved non-heat-treated meat products derived from minced meat	150
8.3.2. Heat-treated meat products derived from minced meat	60
Meatballs and liver paté (kødboller and leverpostej) (*)	0
Entirely preserved or semi-preserved heat-treated meat products derived from minced meat	150

(*) Pursuant to Article 20 of Regulation (EC) No 1333/2008 read in conjunction with Annex IV thereto, Denmark may continue to prohibit the use of certain categories of food additives, including preservatives, in the traditional Danish 'Kødboller' (meatballs) and Traditional Danish 'Leverpostej' (liver paté).

- (20) Therefore, the limit 60 mg/kg applies for many types of meat products, whereas the corresponding maximum limits of Directive 2006/52/EC are 100 or 150 mg/kg.

- (21) However, as regards 'entirely preserved or semi-preserved heat-treated meat products derived from minced meat', the notified provisions provide for a maximum limit of 150 mg/kg, whereas the corresponding maximum limits of Directive 2006/52/EC for 'sterilised meat products' is set at 100 mg/kg.

3. PROCEDURE

- (22) By letter of 20 November 2009, which reached the Commission on 26 November 2009, Denmark notified to the Commission its intention to continue not to transpose Directive 2006/52/EC into Danish law in so far as it relates to the use of E249 potassium nitrite and E 250 sodium nitrite in meat products. In support of its notification, Denmark submitted a Report of the Danish Ministry of Food, Agriculture and Fisheries on consumption and import of meat products in Denmark, as well as a Report of the National Food Institute (NFI) on 'Nitrites as food additives — Health aspects and EU Regulation'.
- (23) By letter of 21 December 2009, the Commission confirmed that it had received the notification and that the 6-month period for its examination under Article 114(6) TFEU started on 27 November 2009, the day following the day on which the notification was received. By means of the same letter, the Commission requested the Danish authorities to provide the latest version of the positive list of permitted food additives ('Positivlisten').
- (24) By letter of 7 January 2010, Denmark provided the additional requested information.
- (25) The Commission published a notice regarding the notification in the *Official Journal of the European Union* ⁽¹⁾ in order to inform other interested parties of Denmark's national provisions, as well as the grounds invoked to support the request. By letter of 25 January 2010, the Commission also informed the other Member States and the EEA States on the notification and gave them the opportunity to submit comments thereon within 30 days. The Commission received comments within this deadline from the Czech Republic, Poland, the United Kingdom and Norway ⁽²⁾.

— The Czech Republic agrees to the maintaining of more stringent national measures but only until the adoption of the annexes to Regulation (EC) No 1333/2008. Following the adoption of the annexes on the use of additives in foodstuffs, the same conditions of use must apply to all Member States.

— Poland has no comments on the notification, but stressed the need to reconsider the levels of nitrites laid down in Directive 2006/52/EC, following a re-evaluation by EFSA.

⁽¹⁾ OJ C 7, 13.1.2010, p. 1.

⁽²⁾ In addition, the Commission received comments from Latvia and Lithuania on 1 March 2010 and 25 March 2010 respectively, i.e. outside the time limit fixed by the Commission.

— The United Kingdom refers to Denmark's stated motivation for maintaining national levels for use of nitrites in meat products to prevent its population from being exposed to an increased level of nitrosamines. It stresses that the same preservation of meat products, ensuring there are no outbreaks of botulism, relies upon a complex interaction between a number of factors including not only nitrites but also salt, pH and temperature control. In its view, the possibility of consumers being exposed to nitrosamines is not the only issue to be considered in deciding the appropriate levels of nitrites. In that respect, it emphasises that the framework agreed by 26 of the Member States, as part of the European Commission's High Level Group on Nutrition and Physical Activity, recommends a 16 % salt reduction in meat products to be achieved over 4 years (2008 to 2012). Therefore, it questions how it would be possible to simultaneously reduce salt and nitrite levels whilst still ensuring the production of safe meat products.

— Norway considers that the Danish measure is well documented and therefore has no objection to Denmark's request to maintain national provisions on the use of nitrites as additives in meat products. Against this background, it also encourages the Commission to re-examine Directive 2006/52/EC in relation to the use of nitrites in meat products.

- (26) A further meeting took place between the Commission services and Denmark on 19 March 2010. By means of a letter dated 12 April 2010, Denmark provided additional clarifications with respect to the different categories of meat products covered by the notified provisions as well as the carrying out of controls of imported meat products.

4. REQUEST TO EFSA

- (27) By letter of 29 January 2010, the Directorate-General for Health and Consumers requested EFSA to assess the data provided by the Danish authorities and in particular whether this information or any other new scientific developments indicate that there is scientific evidence for a revision of the maximum limits on nitrites adopted in Directive 2006/52/EC.
- (28) In its Opinion adopted on 11 March 2010 ⁽¹⁾, the EFSA Panel on Food Additives and Nutrient Sources added to Foods (ANS Panel) concluded that the data provided by the Danish authorities do not provide a basis to revise the 'acceptable daily intake' (ADI) of 0,07 mg/kg bw/day for nitrite, established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) in 2002. It also noted that this ADI might be exceeded by children. Finally, the ANS Panel concluded, in line with what had been concluded by the SCF in 1995, that exposure

to preformed nitrosamines in food should be minimised by appropriate technological practices, such as lowering the levels of nitrate and nitrite added to foods to the minimum required to achieve the necessary preservative effect and to ensure microbiological safety.

- (29) With regard to the effects of nitrites/nitrates on the microbiological safety of meat products, the ANS Panel noted that this had been addressed in the Opinion of EFSA Scientific Panel on Biological Hazards of 26 November 2003. In that Opinion, it was stated that several factors contribute to the safety of meat products (cooking process, salt/concentration, water activity etc. and that the ingoing amount of nitrites is important for microbiological safety, which is why ingoing amounts should be controlled (rather than the residual amount). Moreover, the Scientific Panel on Biological Hazards agreed with the view of the Scientific Committee for Food (SCF) that 50-100 mg added nitrite per kg of meat products may suffice for many products and in other products, especially those with a low salt content and having a prolonged shelf-life, addition of between 50-150 mg/kg nitrite is necessary to inhibit growth of *C. botulinum*. However, no detailed analysis per category of meat products was provided.

II. ASSESSMENT

1. ADMISSIBILITY

- (30) 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 these measures.
- (31) The Danish notification relates to national provisions derogating from those of Annex I (3) (c) to Directive 2006/52/EC amending Annex III Part C to Directive 95/2/EC in relation to E249 potassium nitrite and E250 sodium nitrite. The current Danish provisions already existed at the time of the adoption of Directive 2006/52/EC.
- (32) The Danish Order No 22 and the Danish positive list allows the addition of E249 potassium nitrite and E250 sodium nitrite 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, which are lower for certain products than, or differ from the ones laid down in Directive 2006/52/EC. Moreover, unlike Directive 2006/52/EC, the Danish provisions do not contain any

⁽¹⁾ Scientific Opinion on nitrite in meat products of the EFSA Panel on Food Additives and Nutrient Sources added to Food, *EFSA Journal* 2010, 8(3):1538.

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.

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.

(33) The Danish provisions are therefore more stringent than, or differ from the provisions of Directive 2006/52/EC in that they lay down lower maximum added amounts than Directive 2006/52/EC for several types of products (in many cases 60 mg/kg) and in so far as they do not, unlike Directive 2006/52/EC, allow the placing on the market of certain traditional meat products on the basis of maximum residual values.

(34) 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 this case the protection of health and life of humans. An accompanying Report of the Danish Ministry of Food, Agriculture and Fisheries provides additional data on the consumption and import of meat products as well as an analysis of nitrite in meat products on the Danish market. Finally, the Danish authorities have submitted a Report of the National Food Institute (NFI) on 'Nitrites as food additives — Health aspects and EU Regulation', dated 30 October 2007. According to submitted information, the latter report was re-evaluated in September 2009 and no new comments or knowledge has been added.

(35) 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

(36) In accordance with Article 114(4) and (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.

(37) 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

(38) 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 grounds' put forward by the notifying Member State. This means that, according to the provisions of the Treaty, the responsibility of proving that the national measures are justified lies with the requesting Member State that seeks to maintain them. Given the procedural framework established by Article 114(4) and (6) TFEU, including in particular a strict deadline for a decision to be adopted, the Commission normally has to limit itself to examining the relevance of the elements, which are submitted by the requesting Member State, without having to seek itself possible reasons of justifications.

(39) 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

(40) Denmark claims that its legislation ensures a higher level of protection of health and life of human in that it lays down lower maximum added amounts of E249 potassium nitrite and E250 sodium nitrite than the ones provided for in Directive 2006/52/EC, and does not allow the placing on the market of traditional meat products for which no ingoing amounts can be established. Denmark considers that the Danish provisions are fully consistent with the recommendations which the Scientific Committee on Food (SCF) made in 1990 and 1995, as well as with the opinion of EFSA of 26 November 2003.

(41) Denmark also considers that regulating the nitrite amounts used on the basis of whether they were considered to involve an intake in excess of the established relevant ADI does not provide the necessary protection of human health. The ADI established for nitrites does not take into account the formation of nitrosamines, which are associated with the use of nitrites in meat products. According to scientific evaluations, nitrosamines are genotoxic; as such, it is not possible to establish a limit under which they are not carcinogenic. Denmark further emphasises that the formation of nitrosamines depends on the nitrite amounts that are added, and not on the much lower residual amounts, which, due to the substance's transformation in the foodstuff, are typically present in the product at the time of consumption.

- (42) Thus, in its opinion, the overall scientific assessment demonstrates that (a) the use of nitrites and nitrates should be regulated in terms of the amounts that are added rather than the residual amounts, (b) their use should be reduced as far as possible by using differentiated amounts in line with the technical needs related to different foodstuffs, and (c) the necessary preservation is achieved by using the amounts recommended by EFSA. In that respect, Denmark considers that its national provisions systematically follow these recommendations, whereas Directive 2006/52/EC does not as far as nitrites are concerned.
- (43) 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 EU Member States, and not a single case caused by the consumption of meat products has been recorded since 1980. Following Decision 2008/448/EC, which required Denmark to monitor the situation with respect to, inter alia, botulism, Denmark notes that no cases of botulism have been recorded in Denmark since 2006. Thus, the Danish provisions on the use of nitrite in meat products are still considered as providing comprehensive protection against food poisoning.
- (44) As regards consumption patterns, the Report of the Danish Ministry of Food, Agriculture and Fisheries provides additional data on the consumption and import of meat products as well as an analysis of nitrite in meat products on the Danish market. According to the Danish authorities, this Report demonstrates that the consumption of meat products to which nitrites may be added has increased over the years, especially among children. Moreover, the meat products covered by the 60 mg/kg limit are by far the most frequently consumed products in Denmark. This demonstrates that any amendment to the national provisions to raise the maximum added amounts in accordance with Directive 2006/52/EC to 150 mg/kg could result in a significant rise in the intake of nitrite and thereby nitrosamines.
- (45) Furthermore, Denmark maintains that its provisions on nitrite do not act as an obstacle to trade, referring to figures showing that imports of meat products from other Member States have been taking place and have even increased since 2006.
- (46) Denmark also stresses that maintaining nitrite use to a minimum is justified in order to adhere to the ADI for nitrite in foodstuffs. Furthermore, Denmark refers to the 2007 Report of the Danish National Food Institute (NFI) on 'Nitrites as food additives — Health aspects and EU Regulation'. The latter report, which was re-evaluated in 2009, states that the implementation of Directive 2006/52/EC in Denmark could lead to an increase in nitrite intake by a factor of 2,3-2,4, which may imply a corresponding rise in the intake of preformed nitrosamines.
- (47) In sum, Denmark considers it legitimate to reduce the risk to human health stemming from the exposure to nitrosamines beyond the requirements of Directive 2006/52/EC through the continued application of its legislation. According to Denmark, the monitoring, which it undertook pursuant to Decision 2008/448/EC, demonstrates that the health considerations previously taken into account are still valid. Finally, it contends that the latest 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*
- (48) The Danish legislation aims 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 specifying lower maximum added amounts of nitrite in relation to certain meat products, when compared with the maximum levels provided under Directive 2006/52/EC and not allowing the placing on the market of products for which only maximum residual levels can be established. Moreover, the notified provisions set a maximum amount of 150 mg/kg as regards 'entirely preserved or semi-preserved heat-treated meat products derived from minced meat', which is higher than that specified for 'sterilised meat products' in Directive 2006/52/EC, i.e. 100 mg/kg.
- (49) When assessing whether the Danish legislation is actually adequate and necessary for achieving this objective a number of factors need to be taken into account. In particular, two health risks need to be balanced, the one related to the presence of nitrosamines in meat products, on the one hand, and the microbiological safety of meat products, on the other hand. 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 need to be limited, lower levels of nitrite in meat will not automatically lead to a higher protection of human health. The most appropriate level of nitrite

depends on a number of factors acknowledged in the relevant opinions of the SCF and EFSA, e.g. the addition of salt, moisture, pH, shelf-life of the product, hygiene, temperature control etc.

(50) In the light of the preceding considerations and those under recitals 11 and 12 above, the Commission considers that, in principle, Directive 2006/52/EC constitutes an adequate response to the challenge of reconciling two conflicting health risks in light of the diversity of meat products across the Union.

(51) On the other hand, 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 so far achieved satisfactory results with its legislation. These data show that the maximum levels specified in the Danish legislation appear to have been sufficient to ensure the microbiological safety of the meat products currently made in Denmark and the production methods currently used in Denmark.

(52) The Commission notes that the Danish legislation is compatible with the relevant scientific opinions of the Union's scientific bodies. It is based on a regulation of maximum added values and respects the ranges of added amounts of nitrite referred to in these opinions, i.e. 50-150 mg/kg. At the same time, Denmark has established more specific maximum added amounts for particular groups of meat products, compared with the Directive, in light of the types of meat products and manufacturing methods prevailing in Denmark.

(53) In addition, 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 there is currently a limit of 60 mg/kg and which would have to be replaced with a limit of 100 or 150 mg/kg. Since 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 Directive 2006/52/EC, it is unlikely that the actual exposure of the Danish population to nitrites in meat products would increase to the extent suggested in the Danish submission, i.e. by a factor of 2,3-2,4. However, an increase of the actual exposure of the Danish population, to nitrites cannot be excluded.

(54) On the basis of the information available at the moment, the Commission considers that the request to maintain the notified measures can be temporarily accepted on grounds of protection of public health in Denmark.

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**

(55) 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.

(56) The Danish national rules apply to both domestic products and products made in other Member States. In the absence of any evidence of the contrary, it can be concluded that the national provisions are not a means of arbitrary discrimination.

2.2.2.2. **Absence of a disguised restriction on trade**

(57) National measures which restrict the use of products to a greater extent than a Union Directive 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 expected, 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.

(58) Given that the Danish rules impose stricter standards on the addition of nitrites to certain meat products and for specific categories of meat products ('entirely preserved or semi-preserved heat-treated meat products derived from minced meat') a higher maximum added amount of nitrites than that of Directive 2006/52/EC 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 this connection, Denmark has submitted figures which indicate that imports of meat products from other Member States not only have been taking place in spite of its legislation, but they have even increased in the recent years.

- (59) 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

- (60) This condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the establishment of the internal market. Indeed, any national measure derogating from a harmonisation measure aiming 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.
- (61) Given the health benefits invoked by the Danish government in relation to the reduction of exposure to nitrites in meat products and the fact that, on the basis of currently available figures, trade does appear not to be affected at all or only to a very limited extent, the Commission considers that the notified Danish rules may be temporarily 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.
- (62) 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

- (63) The above conclusions are based on the currently available information and, in particular, on figures indicating that Denmark has been able to control botulism despite lower maximum levels of nitrite added to particular types of meat products and a higher maximum level as regards 'entirely preserved or semi-preserved heat-treated meat products derived from minced meat', while not disrupting trade in a disproportionate fashion.
- (64) Another important factor is the rate of consumption in Denmark of meat products in relation to which the application of Directive 2006/52/EC could lead to an increase of the exposure of the Danish population to nitrites and thereby nitrosamines.

- (65) Denmark would need to systematically monitor the situation and collect data on whether the application of the levels laid down in Directive 2006/52/EC achieve the required level of protection and if not, whether it would lead to an unacceptable risk to human health. The data collected should focus in particular on the control of botulism, the share of meat products covered by the 60 mg/kg limit in the overall consumption of meat products in Denmark, including any other risk factor of typical dietary habits as relevant, as well as imports of meat products from other Member States. Denmark would be required to report the collected data to the Commission every 2 years from the date of adoption of the present Decision.
- (66) Moreover, the Commission would have to monitor the implementation of Directive 2006/52/EC in the Member States as regards in particular the use of nitrites by the industry in the different categories of meat products and the organisation of national controls. Appropriate consultations must also be carried out with the Member States, stakeholders as well as with EFSA. On the basis of the collected information, the Commission would examine Directive 2006/52/EC, under the terms of Article 114(7) TFEU, to consider whether it is appropriate to propose an adaptation to the latter Directive, with respect to the maximum levels of nitrites that may be added to certain meat products.
- (67) Against this background, the Commission considers that the national provisions, to the extent specified above, can be approved for a limited period of 5 years. The approval should extend to the time needed to gather and to carefully evaluate the necessary information.
- (68) Denmark remains obliged to transpose the other provisions of Directive 2006/52/EC into its national law.

III. CONCLUSION

- (69) In the light of the above considerations, and taking account of comments provided by Member States on the notification submitted by the Danish authorities, the Commission is of the opinion that the request by Denmark, received by the Commission on 26 November 2009, for maintaining its national provisions on the addition of nitrites, which differ for 'entirely preserved or semi-preserved heat-treated meat products derived from minced meat' and are more stringent for all other meat products than those of Directive 2006/52/EC, can be approved for a period of 5 years from the date of adoption of the present Decision. Denmark would be required to systematically collect and report data to the Commission on whether the application of the levels laid down in Directive 2006/52/EC achieve the required level of protection and if not, whether it would lead to an unacceptable risk to human health,

HAS ADOPTED THIS DECISION:

Article 1

The national provisions on the addition of nitrites to meat products contained in Order No 22 of 11.1.2005 on food additives (*Bekendtgørelse nr 22 af 11.1.2005 om tilsætningsstoffer til fødevarer*) and the Danish positive list of permitted food additives (*Liste over tilladte tilsætningsstoffer til fødevarer, 'Positivlisten'*), which the Kingdom of Denmark notified to the Commission by letter of 20 November 2009, pursuant to Article 114(4) TFEU, are approved.

Article 2

This Decision shall expire on 25 May 2015.

Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 25 May 2010.

For the Commission

John DALLI

Member of the Commission
