

## II

*(Acts adopted under the EC Treaty/Euratom Treaty whose publication is not obligatory)*

## DECISIONS

## COMMISSION

## COMMISSION DECISION

of 23 May 2008

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

*(notified under document number C(2008) 2168)*

**(Only the Danish text is authentic)**

(2008/448/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community, and in particular Article 95(6) thereof,

Whereas:

## I. FACTS AND PROCEDURE

- (1) By letter of 21 November 2007, which reached the Commission on 23 November 2007, the Permanent Representation of the Kingdom of Denmark to the European Union, notified to the Commission its national provisions concerning the addition of nitrites to certain meat products, pursuant to Article 95(4) of the Treaty establishing the European Community. The Kingdom of Denmark considers it necessary to maintain these provisions in spite of the adoption of 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 <sup>(1)</sup> and intends not to transpose Directive 2006/52/EC into national law insofar as it concerns the addition of nitrite to meat products.

## 1. COMMUNITY LEGISLATION

## 1.1. ARTICLE 95(4) AND (6) OF THE EC TREATY

- (2) Article 95(4) of the EC Treaty provides that 'If, after the adoption by the Council or by the Commission of a harmonisation measure, a Member State deems it necessary to maintain national provisions on grounds of major needs referred to in Article 30, 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.'
- (3) According to Article 95(6) of the EC Treaty, 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.

<sup>(1)</sup> OJ L 204, 26.7.2006, p. 10.

## 1.2. DIRECTIVE 2006/52/EC

- (4) Under the general principles of 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 <sup>(1)</sup>, 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.
- (5) Nitrites have been used in meat and 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.
- (6) Directive 95/2/EC of the European Parliament and of the Council of 20 February 1995 on food additives other than colours and sweeteners <sup>(2)</sup>, 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).
- (7) 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 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.
- (8) This approach follows opinions from the Scientific Committee for Food (hereinafter SCF) of 1990 <sup>(3)</sup> and 1995 <sup>(4)</sup> as well as from the European Food Safety Authority (hereinafter EFSA) of 26 November 2003 <sup>(5)</sup>, 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 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 <sup>(6)</sup>.
- (9) 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 <sup>(7)</sup>.

<sup>(1)</sup> OJ L 40, 11.2.1989, p. 27. Directive as last amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

<sup>(2)</sup> OJ L 61, 18.3.1995, p. 1. The Directive was last amended by Directive 2006/52/EC (OJ L 204, 26.7.2006, p. 10).

<sup>(3)</sup> Opinion on nitrates and nitrites expressed on 19 October 1990, European Commission — Reports of the Scientific Committee for Food (26th series), p. 21.

<sup>(4)</sup> Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission — Reports of the Scientific Committee for Food (38th series), p. 1.

<sup>(5)</sup> 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, 1-34.

<sup>(6)</sup> Judgment of 20 March 2003, in particular points 109-115.

<sup>(7)</sup> Directive 2006/52/EC as corrected by Corrigendum (OJ L 78, 17.3.2007, p. 32).

E No	Name	Foodstuff	Maximum amount that may be added during manufacture (expressed as NaNO <sub>2</sub> )	Maximum residual level (expressed as NaNO <sub>2</sub> )
E249	Potassium nitrite (⁸)	Meat products	150 mg/kg	
E250	Sodium nitrite (⁸)	Sterilised meat products (Fo > 3,00) (⁹)	100 mg/kg	
		Traditional immersion cured meat products (1):		
		Wiltshire bacon (1.1); <i>Entremeada, entrecosto, chispe, orelheira e cabeça (salgados)</i> 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); <i>Jamón curado, paleta curada, lomo embuchado y cecina</i> (2.2); <i>Presunto, presunto da pá and paio do lombo</i> (2.3); and similar products		100 mg/kg
		Rohschinken, trocken-gepökelt (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	
		Rohschinken, trocken-/nassgepökelt (3.1); and similar products <i>Jellied veal and brisket</i> (3.2)		50 mg/kg

- (10) 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 Community, the Community legislator held that it was, for the moment, not possible to specify the appropriate level of nitrite for each product.
- (11) 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.
- (12) 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 within this Directive by 15 February 2008 and prohibit trade in and use of products which are not in compliance by 15 August 2008.

## 2. NATIONAL PROVISIONS NOTIFIED

- (13) The national provisions notified by Denmark are 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'*).
- (14) 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<sup>(1)</sup>. 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<sup>(2)</sup>. 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.

<sup>(1)</sup> See paragraph 13 of Order No 22 'Use of additives'.

<sup>(2)</sup> See paragraph 20 of Order No 22.

- (15) With regard to the use of nitrites E249 and E250 in meat and 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-based 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-based products derived from whole pieces of meat, including slices of products (in general)	60
<i>Rullepølse</i> (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-based products derived from minced meat, including slices of products (in general)	60
Fermented salamis	100
Entirely preserved or semi-preserved non-heat-treated meat-based products derived from minced meat	150
8.3.2. Heat-treated meat-based products derived from minced meat	60
Meatballs and liver paté ( <i>kødboller</i> and <i>leverpostej</i> )	0
Entirely preserved or semi-preserved heat-treated meat-based products derived from minced meat	150

- (16) It appears, therefore, that the limit of 60 mg/kg<sup>(3)</sup> applies to many types of meat products, whereas the corresponding maximum limits of Directive 2006/52/EC are 100 or 150 mg/kg. For certain sausages the accepted maximum in Denmark is 100 mg/kg. For specific entirely or semi-preserved meat products, including 'bacon of the Wiltshire type and related cuts', the maximum is 150 mg/kg.

<sup>(3)</sup> For *kødboller* and *leverpostej* the use of nitrite is banned in accordance with Decision 292/97/EC.

## 3. PROCEDURE

- (17) On 17 August 2007 the Commission received a first communication from the Kingdom of Denmark, dated 14 August 2007, in which Denmark criticised different aspects of Directive 2006/52/EC and informed the Commission that it does not intend to transpose Directive 2006/52/EC in relation to nitrites in meat products. However, Denmark did not notify the national provisions which it wishes to maintain. By letter of 13 November 2007 the Commission pointed this out to the Danish Government. By letter of 21 November 2007, which reached the Commission on 23 November 2007, the Permanent Representation of the Kingdom of Denmark to the European Union, notified to the Commission the relevant national provisions. In an additional correspondence of 22 November 2007, which was received by the Commission on 27 November 2007 and which contains a report of the National Food Institute of 30 October 2007, Denmark substantiated its application.
- (18) By letter of 21 December 2007 the Commission confirmed that it had received the notification and that the six-month period for its examination under Article 95(6) started on 24 November 2007, the day following the day on which the notification was received.
- (19) By letter of 31 March 2008 Denmark provided data on the consumption of meat products in Denmark.
- (20) By letter of 31 January 2008 the Commission informed the other Member States and the EFTA States on the notification and gave them the opportunity to submit comments thereon within 30 days. The Commission also published a notice regarding the notification in the *Official Journal of the European Union* <sup>(1)</sup> in order to inform other interested parties of Denmark's national provisions, as well as the grounds invoked to support the request. The Commission received comments from Estonia, France, Hungary and Norway <sup>(2)</sup>.

— Estonia emphasises that, given the restrictive effect of the Danish legislation on trade, it is essential that the restrictions are scientifically justified,

— France stresses that nitrites are a powerful inhibitor against the proliferation of certain bacteria, including *Clostridium botulinum* and, therefore, significant in the prevention of food poisoning and that there is no

alternative in relation to meat products. In its view, Directive 2006/52/EC is based on the EFSA opinion of 26 November 2003 and limits as much as possible the concentration of nitrosamines while securing the microbiological safety. As recommended by EFSA, it regulates added amounts. It refers to maximum residual values only as an exception and only where it was not possible to lay down maximum added amounts. A new analysis should be undertaken only once the results of studies in the Member States on the consumption of additives on the basis of the new rules are available.

— Hungary, while supporting the decrease in the exposure to nitrites and nitrosamines with all possibly available means, emphasises the need to regulate appropriate nitrite levels for the whole EU, including for traditional cured meat products, which may differ from the Danish meat products and where the addition of higher nitrite levels may be justified. It questions Denmark's claim that the transposition of Directive 2006/2052 could lead to a 2,3 to 2,4-fold increase in nitrite in Denmark, having regard to the fact that manufacturers are obliged to apply less than the maximum permitted amount if they can guarantee the required microbiological safety. European culture would grow poorer if traditional cured meat products had to disappear from the market.

— Norway considers that the Danish measure is justified on grounds of major needs referred to in Article 30. In its view, the measure is intended to ensure a high level of human health protection based on scientific advice and is not an arbitrary discrimination or a disguised restriction on trade. It contends that the obstacle to the functioning of the internal market created by it is necessary and proportionate. Norway agrees with Denmark that, in relation to nitrites in meat products, Directive 2006/52/EC does not fully reflect scientific advice in that it does not ensure that the lowest level of nitrites necessary to achieve the desired effect is applied and the application of residual levels in relation to a number of meat products.

## 4. REQUEST TO EFSA

- (21) By letter of 10 March 2008 the Directorate-General for Health and Consumer Protection requested EFSA to provide a scientific opinion on whether the previous opinions of the SCF of 1990 and 1995 and EFSA of 2003 are still valid in light of the information submitted by Denmark. In its reply of 28 March 2008 EFSA concluded that the previous opinions of the SCF and EFSA are still valid in light of the information provided by Denmark.

<sup>(1)</sup> OJ C 30, 2.2.2008, p. 5.

<sup>(2)</sup> In addition, the Commission received comments from Ireland on 1 May 2008, i.e. outside the time limit fixed by the Commission.



(22) With regard to the effects of nitrites/nitrates on the microbiological safety of meat products EFSA refers to the opinion of its Scientific Panel on Biological Hazards of 26 November 2003. In this 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). EFSA also refers to the fact that its 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*.

## II. ASSESSMENT

### 1. ADMISSIBILITY

(23) Under Article 95(4) and (6) of the EC Treaty a Member State may, after the adoption of a harmonisation measure, maintain national provisions on grounds of major needs referred to in Article 30, or relating to the protection of the environment or the working environment, if it notifies these national provisions to the Commission and if the Commission approves the application.

(24) 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 and E250. The current Danish provisions already existed at the time of the adoption of Directive 2006/52/EC.

(25) Order No 22 and the Danish positive list contain more stringent provisions in relation to the use of nitrites in meat and meat products than 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 insofar 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.

(26) In accordance with Article 95(4), the notification was supplemented by a description of the grounds relating to one or more of the major needs referred to in Article 30 or to the protection of the environment or the working environment, in this case the protection of health and life of humans. The Danish position is explained in more detail in a report of the Danish Food Institute of 30 October 2007, which was submitted on 27 November 2007, as well as in the other documents referred to in points 17 and 19 above.

(27) 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 and meat products is admissible under Article 95(4) of the EC Treaty.

### 2. ASSESSMENT OF MERITS

(28) In accordance with Article 95(4) and (6), first subparagraph, of the EC Treaty, the Commission must ascertain that all the conditions enabling a Member State to maintain its national provisions derogating from a Community harmonisation measure provided for in that Article are fulfilled.

(29) In particular, the Commission has to assess whether or not the national provisions are justified by the major needs referred to in Article 30 of the EC Treaty 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 fulfill the above conditions, it must verify, pursuant to Article 95(6), 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.

(30) It has to be noted that, in the light of the time frame established by Article 95(6) of the EC Treaty, the Commission, when examining whether the national measures notified under Article 95(4) of the EC Treaty 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 which seeks to maintain them. Given the procedural framework established by Article 95 paragraphs 4 and 6 of the EC Treaty, 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.

(31) However, where the Commission is in the possession of information in the light of which the Community 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

- (32) The Kingdom of Denmark claims that its legislation ensures a higher level of protection of health and life of human in that it 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 the European Food Safety Authority (EFSA) of 26 November 2003, since they contain no exceptions to the principle of establishing maximum 'added amounts' as opposed to residual levels and lay down more differentiated maximum levels related to particular groups of meat products.
- (33) Denmark acknowledges that in certain respects Directive 2006/52/EC complies with the scientific recommendations from the SCF and EFSA, in particular where, unlike the original version of Directive 95/2/EC it provides for 'maximum added amounts', as opposed to residual amounts and 'indicative added amounts'. It criticises, however, that there are exceptions to this principle, with the consequence that various traditionally produced meat products are still regulated from the point of view of residual amounts and considers that this can be a hazard to human health. It stresses that the concentration of residual nitrite is a very uncertain marker of added nitrite and refers to studies which have shown that residual values may even mask extremely high additions of nitrites, leading to an unpredictably high formation of N-nitroso compounds.
- (34) Denmark also emphasises that nitrosamines, whose formation depends on the presence of nitrite in meat products, are genotoxic and carcinogenic, which is why the use of nitrites should be allowed only in the amounts that are absolutely necessary. Denmark considers that the maximum added amounts set out in Directive 2006/52/EC are too high from a health point of view and that a technological need for these values has not been documented. It contends that, in light of the advice given by the Community scientific bodies, the inhibition of growth of *Clostridium botulinum* could be achieved by keeping the limits within the range of 50-150 mg/kg nitrite and specifying the limits for categories of meat products depending on the scientifically based needs.
- (35) Given that approximately 90 % of the intake of cured meat products in Denmark consists of products to which a maximum amount of 60 mg/kg of added nitrite currently applies in Denmark, Denmark points out that the transposition of the Directive and the introduction of a general limit of 150 mg/kg for all cured meat products could lead to the intake of nitrites in Denmark rising by a factor of 2,3-2,4, which may imply a corresponding rise in the intake of preformed nitrosamines.
- (36) Denmark stresses that, despite the fact that its rules providing for lower levels of nitrites which may be added have been in place for many years, they have proved adequate to prevent botulism. The Danish Government points out that these rules have never given rise to problems with the preservation of the products concerned and that Denmark has a very low rate of food poisoning cases caused by sausages compared with other Member States. It states that there are fewer cases of botulism than in most other Member States. According to the European Communicable Disease Bulletin, Eurosurveillance, of January 1999, which is a special issue on botulism in Europe, botulism is very rare in Denmark. The Danish health surveillance institution, the *Statens Serum Institute*, states on its website that after 1980 there have only occurred five cases of botulism amongst the Danish population, none of these being caused by the consumption of meat products.
- (37) Moreover, 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 been increasing in recent years.
- (38) 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.

## 2.2. EVALUATION OF THE DANISH POSITION

2.2.1. *Justification on grounds of major needs referred to in Article 30*

- (39) 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 many meat products and not allowing the placing on the market of products for which only maximum residual levels can be established.

(40) 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.

(41) In the light of the preceding considerations and those under points (9) and (10) before, 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 Community.

(42) 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.

(43) The Commission notes that the Danish legislation is compatible with the relevant scientific opinions of the Community'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.

(44) In addition, it must be considered that, according to information provided by Denmark, the bulk of the meat products consumed by the Danish population, approximately 90 %, 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.

(45) On the basis of the information available at the moment, the Commission considers that the request to maintain more stringent measures than those contained in Directive 2006/52/EC 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**

(46) Article 95(6) 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.

(47) 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**

(48) National measures which restrict the use of products to a greater extent than a Community Directive would normally constitute a barrier to trade, insofar as products that are legally placed on the market and used in the rest of the Community 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 95(6) of the EC Treaty 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.



(49) Given that the Danish rules impose stricter standards on the addition of nitrites to 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 95(6) of the EC Treaty 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 have been taking place in spite of its legislation and have even been increasing in recent years.

(50) 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

(51) 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 95 of the EC Treaty, the concept of obstacle to the functioning of the internal market must, in the context of Article 95(6) of the EC Treaty, be understood as a disproportionate effect in relation to the pursued objective.

(52) 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 95(6) of the EC Treaty.

(53) 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

(54) The above conclusions are based on the currently available information and, in particular, on figures indi-

cating that Denmark has been able to control botulism despite lower maximum levels of nitrite added to particular types of meat products, while not disrupting trade in a disproportionate fashion.

(55) 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.

(56) Since it cannot be predicted with a sufficient degree of certainty that these factors will not change significantly in the course of time, the Commission considers it appropriate to re-examine the situation at the latest in two years' time on the basis of updated information.

(57) The two-year period will permit the Danish Government to introduce a renewed application, in due time, and to supply further relevant data concerning the fact that the application of the levels laid down in Directive 2006/52/EC does not achieve the required level of protection and would lead to an unacceptable risk to human health.

(58) In order to be able to submit such data Denmark will have 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.

(59) In its renewed application Denmark would also have to provide a full justification for the continued maintenance of its legislation.

(60) At the same time, the two-year period will allow the Commission to check and analyse the transposition of Directive 2006/52/EC in the Member States, and to re-examine Directive 2006/52/EC under the terms of Article 95(7) of the EC Treaty, including further consultations of the Member States and EFSA.

(61) Against this background, the Commission considers that the national provisions, to the extent specified above, can be approved for a limited period. The approval should extend to the time needed to gather and to carefully evaluate the necessary information. The Commission considers that a period of two years from the date of the present decision is necessary to that effect. The decision will expire on that date.

- (62) Denmark remains obliged to transpose the other provisions of Directive 2006/52/EC into its national law,

### III. CONCLUSION

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, submitted on 23 November 2007, for maintaining its national provisions on the addition of nitrites, which are more stringent than those of Directive 2006/52/EC, can be approved for a period of two years from the date of adoption of the present decision, pending the demonstration by the Danish authorities that the levels laid down in Directive 2006/52/EC would lead to an unacceptable risk,

HAS ADOPTED THIS DECISION:

#### Article 1

The national provisions on the addition of nitrites to meat and 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 the Kingdom of Denmark notified to the Commission by letter of 21 November 2007, pursuant to Article 95(4) of the EC Treaty, are approved.

#### Article 2

This Decision shall expire on 23 May 2010.

#### Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 23 May 2008.

*For the Commission*

Androulla VASSILIOU  
*Member of the Commission*