DECISIONS

COMMISSION DECISION (EU) 2015/826

of 22 May 2015

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

(notified under document C(2015) 3526)

(Only the Danish text is authentic)

THE EUROPEAN COMMISSION,

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

Whereas:

I. FACTS AND PROCEDURE

(1) Commission Decision 2010/561/EU ([1]) approved Danish national provisions on the addition of potassium nitrite, E 249, and sodium nitrite, E 250, (nitrites) to meat products contained in Order No 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 20 November 2009, pursuant to Article 114(4) of the Treaty on the Functioning of the European Union (TFEU). These national provisions are approved until 25 May 2015.

(2) Denmark was not required to transpose Directive 2006/52/EC of the European Parliament and of the Council ([2]) into national law in so far as it relates to the use of nitrites in meat products. Decision 2010/561/EU required Denmark systematically to 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. At the same time, the Decision required the Commission 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 to consult with the Member States, stakeholders and EFSA.

(3) Commission Regulation (EU) No 1129/2011 ([3]) transferred the levels and other conditions of use of nitrites in meat products laid down by Directive 2006/52/EC into Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council ([4]) which applies since 1 June 2013.

(4) By letter of 25 November 2014, Denmark notified the Commission of its wish to continue to maintain national provisions on the use of nitrite additives in meat products that differ from Regulation (EC) No 1333/2008. Order No 542 of 27 May 2013 on food additives etc. in foodstuffs (BEK nr 542 af 27.5.2013 (tilsætningbekendtgørelsen), Offentliggørelsedato: 31.5.2013, Fødevareministeriet). In support of its notification, Denmark submitted additional information that includes data on consumption and imports of meat products, exposure to nitrites, prevalence of botulism and the formation of nitrosamines in processed meat products.

([1]) 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).

([2]) 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).

([3]) 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]) 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).

1. UNION LEGISLATION

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

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

(6) 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.

1.2. **Regulation (EC) No 1333/2008**

(7) Under the general principles of Regulation (EC) No 1333/2008 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.

(8) Annex II to Regulation (EC) No 1333/2008 lays down a Union list of food additives approved for use in foods and their conditions of use. Only food additives included in the Union list may be placed on the market as such and used in foods under the conditions of use specified therein.

(9) Nitrites have been used in meat products for many decades, inter alia, to secure, in conjunction with other factors, the preservation and microbiological safety of meat products, in particular cured meat products, inhibiting, amongst other things, the multiplication of Clostridium botulinum, the bacteria responsible for life-threatening botulism. At the same time, it is recognised that the presence of nitrites in meat products can give rise to the formation of nitrosamines, which have been found to be carcinogenic. Legislation in this field must, therefore, strike a balance between the risk of the formation of nitrosamines through the presence of nitrites in meat products, on the one hand, and the protective effects of nitrites against the multiplication of bacteria, in particular those responsible for botulism on the other.

(10) Regulation (EC) No 1333/2008, Annex II, Part E, Categories under 08.3: 'Meat products' contains maximum amounts for potassium nitrite (E249) and sodium nitrite (E250) 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.

(11) By way of exception to the general rule, Regulation (EC) No 1333/2008, Annex II, Part E, Categories under 08.3.4: 'Traditionally cured meat products with specific provisions concerning nitrites and nitrates' 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 Regulation to enable identification of 'similar products' and to make clear which products are covered by the different maximum levels.

(12) The maximum levels in Regulation (EC) No 1333/2008 are based on the opinions from the Scientific Committee for Food (hereinafter 'SCF') of 1990 ([1]) and 1995 ([2]) as well as from the European Food Safety Authority (hereinafter 'EFSA') of 26 November 2003 ([3]). The maximum amounts that may be added reflect the ranges

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

([2]) Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission — Reports of the Scientific Committee for Food (thirty-eighth series), p. 1.

([3]) 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.

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.

2. NATIONAL PROVISIONS NOTIFIED

(14) The national provisions notified by Denmark on 25 November 2014 are Order No 542 of 27 May 2013 on food additives etc. in foodstuffs (BEK nr 542 af 27.5.2013 (tilsætningbekendtgørelsen), Offentliggørelsedato: 31.5.2013, Fødevareministeriet). In the context of Decision 2010/561/EU, the Commission has already assessed the more stringent rules applied by Denmark with respect to E249 and E250.

Order No 542, provides that nitrites (E249-250) in meat products may only be used under the conditions specified in its Annex 3. Based on Commission Decision 2010/561/EU, [the following] conditions and restrictions have been laid down for the use of nitrites (E249-250). The groups of foodstuffs referred to in the table match the groups listed in Annex II to Regulation (EC) No 1333/2008 on food additives and supersede the usages arising from it:

Foodstuff	Amount of nitrites added (mg/kg)
08.3.1 Non-heat-treated processed meat	Total 60 mg/kg, but in fermented salamis, total 100 mg/kg and in entirely preserved or semi-preserved products, total 150 mg/kg
08.3.2 Heat-treated processed meat	Total 60 mg/kg, but not in traditional Danish meatballs and liver paté. In entirely preserved or semi-preserved products, total 150 mg/kg, in rullepølse (rolled-meat sausage), total 100 mg/kg, and in entirely preserved or semi-preserved products and salt cured ham, total 150 mg/kg
08.3.4 Traditional cured meat products covered by special provisions relating to nitrites and nitrates	Total 60 mg/kg, but in bacon of the Wiltshire type and related cuts, total 150 mg/kg

(15) Therefore, the 60 mg/kg limit applies for many types of meat products, whereas the corresponding maximum limits of Regulation (EC) No 1333/2008 are 100 or 150 mg/kg.

3. PROCEDURE

(16) By letter of 25 November 2014, Denmark notified the Commission of its wish to maintain national provisions on the use of nitrite additives in meat products that differ from Regulation (EC) No 1333/2008. In support of its notification, Denmark submitted additional information that includes data on consumption and imports of meat products, exposure to nitrites, prevalence of botulism and the formation of nitrosamines in processed meat products.

(17) The Commission published a notice regarding the notification in the *Official Journal of the European Union* ([1]) in order to inform interested parties of Denmark's national provisions, as well as the grounds invoked to support the request. By letter of 30 March 2015, the Commission also informed the other Member States on the

([1]) OJ C 93, 20.3.2015, p. 18.

notification and gave them the opportunity to submit comments thereon within 30 days. The Commission received comments within this deadline from Czech Republic and Sweden.

— The Czech Republic respects setting of stricter limits for using nitrites as additives in meat products in frame of national requirements for Danish producers. But as it concerns the products from other Member States the Czech Republic requires keeping current limits for content of nitrites in meat products, which are laid down by the Regulation (EC) No 1333/2008 on food additives.

— Sweden is of the view that the national provisions of Denmark appear to be well founded and does not seem to have a significant impact on conditions in Sweden. On the basis of what Denmark has indicated in the notification Sweden sees no reason not to accept an extension of the existing national provisions. A further extension would also have the benefit of providing the EU with time for a review of the levels of nitrites, making it possible to incorporate EFSA's ongoing work on nitrites as food additives.

4. RE-EVALUATION OF NITRITES

(18) Commission Regulation (EU) No 257/2010 ([1]) requires that the European Food Safety Authority shall re-evaluate potassium nitrite (E 249) and sodium nitrite (E 250) by end of 2015. For this re-evaluation, EFSA shall examine the earlier opinions of the SCF and EFSA, where available, the original dossier, data submitted by the interested business operator(s) and/or any other interested party and data made available by the Commission and Member States and identify any relevant literature published since the last evaluation of each food additive.

(19) The data that was provided by Denmark in support of its notification on consumption of meat products, the exposure to nitrites, the prevalence of botulism and the formation of nitrosamines in processed meat products was submitted to EFSA with a request to take this into account during the ongoing re-evaluation.

5. MONITORING BY THE COMMISSION

(20) 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. In the report it was concluded that the possibility of reviewing the current maximum levels of nitrites should be further explored ([2]).

(21) The Commission therefore launched an ad hoc study regarding the use of nitrites by industry in different categories of meat products. This study will include literature research, organisation of a workshop with experts in meat technology and a survey within the EU meat industry on the actual use and use levels of nitrites according to the different types of meat products identified. Conclusions from this study should be available by the end of 2015.

II. **ASSESSMENT**

1. ADMISSIBILITY

(22) 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.

(23) The Danish notification relates to national provisions derogating from those of Annex II, Part E to Regulation (EC) No 1333/2008 in relation to potassium nitrite (E 249) and sodium nitrite (E 250). The current Danish provisions already existed in substance at the time these maximum levels were originally laid down in Directive 2006/52/EC.

([1]) 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).

([2]) https://webgate.ec.europa.eu/sanco_foods/main/index.cfm?event=document.edit&identifier=5924&documentTypeIdentifier=57

(24) The Danish Order No 542 allows the addition of the nitrites to meat products only in so far as specific added amounts are not exceeded. Depending on the products in question these maximum amounts are 60, 100 or 150 mg/kg, which are lower for certain products than the ones laid down in Regulation (EC) No 1333/2008. Moreover, unlike Regulation (EC) No 1333/2008, the Danish provisions do not contain any exceptions to the principle of fixing maximum added amounts for nitrites, thereby not permitting the placing on the market of certain traditionally manufactured meat products from other Member States.

(25) The Danish provisions are therefore more stringent than the provisions of Regulation (EC) No 1333/2008 in so far that they lay down lower maximum added amounts than for several types of products (in many cases 60 mg/kg) and in so far as they do not allow the placing on the market of certain traditional meat products on the basis of maximum residual values.

(26) 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 imports of meat products, exposure to nitrites, prevalence of botulism and the formation of nitrosamines in processed meat products.

(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 products is admissible under Article 114(4) TFEU.

2. ASSESSMENT OF MERITS

(28) 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.

(29) In particular, the Commission has to assess whether or not the national provisions are justified by the major needs referred to in Article 36 TFEU or relating to the protection of the environment or the working environment and do not exceed what is necessary to attain the legitimate objective pursued. In addition, when the Commission considers that the national provisions fulfil the above conditions, it must verify, pursuant to Article 114(6) TFEU, whether or not the national provisions are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they constitute an obstacle to the functioning of the internal market.

(30) 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 TFEU, the responsibility of proving that the national measures are justified lies with the requesting Member State that seeks to maintain them.

(31) 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**

(32) Denmark claims that its legislation ensures a higher level of protection of health and life of humans in that it lays down lower maximum added amounts for nitrites than the ones provided for in Regulation (EC) No 1333/2008, 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 SCF made in 1990 and 1995, as well as with the opinion of EFSA of 26 November 2003.

(33) 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 acceptable daily intake (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.

(34) Thus, in its opinion, the overall scientific assessment demonstrates that (a) the use should be reduced as far as possible by using differentiated amounts in line with the technical needs related to different foodstuffs, (b) the use of nitrites and nitrates should be regulated in terms of the amounts that are added rather than the residual amounts, 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 Regulation (EC) No 1333/2008 does not as far as nitrites are concerned.

(35) 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. Denmark notes that no cases of botulism have been recorded in Denmark since 2006. Thus, the Danish provisions on the use of nitrites in meat products are still considered as providing comprehensive protection against food poisoning.

(36) 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 is stable over the years.

(37) As regards the exposure to nitrites, the Report of the Danish Ministry of Food, Agriculture and Fisheries provides estimates based on 384 nitrite analyses in processed meat and meat cold cuts and on consumption data from dietary surveys. Based on these estimates, the mean exposure remains below the ADI for nitrites. Children aged 4-5 years are exposed to a three-fold higher exposure per kg body weight compared to adults.

(38) As regards the formation of nitrosamines in processed meat products, the Danish Ministry of Food, Agriculture and Fisheries provided summary report on the presence of N-nitrosamines in processed meat products, prepared by the DTU National Food Institute, which concludes that low levels of nitrosamines are best achieved by using as little nitrite as possible and to use it in combination with erythorbic acid, ascorbic acid or ascorbate as this would prevent the possible formation of nitrosamines.

(39) Furthermore, Denmark maintains that its provisions on nitrites 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 2010.

(40) In sum, Denmark considers it legitimate to reduce the risk to human health stemming from the exposure to nitrosamines beyond the requirements of Regulation (EC) No 1333/2008 through the continued application of its legislation. According to Denmark, the monitoring, which it undertook pursuant to Decision 2010/561/EU, demonstrates that the health considerations previously taken into account are still valid. Finally, it contends that the data available show that the Danish provisions do not constitute an obstacle to trade in the products concerned.

2.2. **Evaluation of the Danish position**

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

(41) 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 Regulation (EC) No 1333/2008 and not allowing the placing on the market of products for which only maximum residual levels can be established.

(42) 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 presence of nitrosamines in meat products on the one hand, and the microbiological safety of meat products on the other.

The latter aspect is more than a mere technological need, but a highly relevant health concern in its own right. While it is recognised that the levels of nitrites in meat products 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.

(43) In the light of the preceding considerations and those under recitals 10 and 11 above, the Commission considers that, in principle, Regulation (EC) No 1333/2008 constitutes an adequate response to the challenge of reconciling two conflicting health risks in light of the diversity of meat products across the Union.

(44) Nevertheless, the Commission has to evaluate the specific choices made by the Danish regulator and the experience made with these rules, which have been in force for a considerable period of time. Through the figures it provided on the occurrence of food poisoning and, in particular, botulism, Denmark has demonstrated that it has achieved satisfactory results with its legislation so far. 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.

(45) 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 Regulation, in light of the types of meat products and manufacturing methods prevailing in Denmark.

(46) 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. Although Danish manufacturers, like manufacturers in other Member States, would not be obliged to raise the amounts of nitrites currently added to their products to the maximum levels referred to in Regulation (EC) No 1333/2008, an increase of the actual exposure of the Danish population to nitrites cannot be excluded.

(47) 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

(48) 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.

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

2.2.2.2. Absence of a disguised restriction on trade

(50) National measures which restrict the use of products to a greater extent than a Union Regulation would normally constitute a barrier to trade, in so far as products that are legally placed on the market and used in the rest of the Union are not 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.

(51) Given that the Danish rules also impose stricter standards on the addition of nitrites to certain meat products 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 since 2010.

(52) 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

(53) 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 aimed at the establishment and operation of the internal market constitutes in substance a measure likely to affect the internal market. Consequently, in order to preserve the useful character of the procedure laid down in Article 114 TFEU, the concept of obstacle to the functioning of the internal market must, in the context of Article 114(6) TFEU, be understood as a disproportionate effect in relation to the pursued objective.

(54) 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 not appear to be affected at all or only to a very limited extent, the Commission considers that the notified Danish rules may temporarily continue to be maintained on grounds relating to the protection of health and life of humans having regard to the fact that they are not disproportionate and do, therefore, not constitute an obstacle to the functioning of the internal market in the sense of Article 114(6) TFEU.

(55) 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*

(56) 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, while not disrupting trade in a disproportionate fashion.

(57) Another important factor is the rate of consumption in Denmark of meat products in relation to which the application of Regulation (EC) No 1333/2008 could lead to an increase of the exposure of the Danish population to nitrites and thereby nitrosamines.

(58) Denmark would need to continue to monitor the situation and collect data on whether the application of the levels laid down in Regulation (EC) No 1333/2008 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. In addition Denmark would need to continue to collect data on imports of meat products from other Member States. Denmark would be required to report the collected data to the Commission within two years from the date of adoption of the present Decision. Moreover, the Commission should consider the conclusions of the re-evaluation of nitrites by EFSA in accordance with Regulation (EU) No 257/2010 and of the ad hoc study as regards the use of nitrites by industry in different categories of meat products.

(59) Against this background, the Commission considers that the national provisions, to the extent specified above, can be approved for a limited period of 3 years.

III. **CONCLUSION**

(60) 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 25 November 2014, for maintaining its national provisions on the addition of nitrites, which are more stringent than those of Regulation (EC) No 1333/2008, can be approved for a period of 3 years from the date of adoption of the present Decision. Denmark would need to continue to monitor the situation and collect data on whether the application of the levels laid down in Regulation (EC) No 1333/2008 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 542 of 27 May 2013 on food additives etc. in foodstuffs *(BEK nr 542 af 27.5.2013 (tilsætningbekendtgørelsen), Offentliggørelsedato: 31.5.2013, Fødevarerministeriet)*, which the Kingdom of Denmark notified to the Commission by letter of 25 November 2014, pursuant to Article 114(4) TFEU, are approved.

Article 2

This Decision shall expire on 22 May 2018.

Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 22 May 2015.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission