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⁽¹⁾ Text with EEA relevance.

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2018/700

of 8 May 2018

amending the lists of third country establishments from which imports of specified products of animal origin are permitted, regarding certain establishments from Brazil**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption ⁽¹⁾, and in particular Article 12(4)(c) thereof,

Whereas:

- (1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin. In particular, Article 12(1) of that Regulation provides that products of animal origin are to be imported into the Union only if they originate from third country establishments that appear on lists drawn up and updated in accordance with that Article. Those lists can be consulted on the website of the Directorate-General for Health and Food Safety ⁽²⁾.
- (2) Article 12(2) of Regulation (EC) No 854/2004 requires that third country establishments are placed on these lists only if the competent authorities of the third country guarantee that these establishments comply with the conditions established in that Article. In addition, in accordance with Article 12(3) of Regulation (EC) No 854/2004, the competent authorities of the third country concerned should keep these lists of establishments updated and communicate them accordingly to the Commission.
- (3) Article 12(4)(c) of Regulation (EC) No 854/2004 requires the Commission to take the necessary action leading to the amendment of the lists of establishments, whenever it considers that such amendments are necessary in the light of relevant information such as Union inspection reports or notifications from the Member States through the Rapid Alert System for Food and Feed (RASFF) set up by Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽³⁾.
- (4) From March 2017, Member States notified the Commission, through the RASFF, of a significant number of serious and repeated cases of non-compliance due to the presence of *Salmonella* in poultry meat and poultry meat preparations, originating from several establishments in Brazil. The Brazilian competent authorities were informed about these cases of non-compliance with Union requirements and were requested to take the necessary corrective actions.

⁽¹⁾ OJ L 139, 30.4.2004, p. 206.

⁽²⁾ https://ec.europa.eu/food/safety/international_affairs/trade/non-eu-countries_en

⁽³⁾ Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

- (5) The information received from the Brazilian competent authorities and the results of official controls at the Union borders failed to demonstrate that the requisite corrective actions were taken to address the shortcomings identified. Consequently, there are no sufficient guarantees that those establishments comply to date with Union requirements and their products might therefore constitute a risk for public health. It is therefore necessary to remove them from the list of establishments from which imports of poultry products into the Union are authorised.
- (6) In March 2018, according to information provided by the Brazilian competent authorities, cases of fraud have been found in Brazil concerning laboratory certification for meat and meat products exported to the Union. In this regard, ongoing investigations and recent action of the judiciary in Brazil indicate that there are no sufficient guarantees that the establishments of the companies BRF S.A. and SHB S.A., authorised to export meat and meat products to the Union, comply with the relevant Union requirements. Their products might therefore constitute a risk for public health and it is appropriate to remove them from the list of establishments from which imports into the Union of meat and meat products are permitted.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The lists of establishments referred to in Article 12 of Regulation (EC) No 854/2004 from which imports into the Union of specified products of animal origin are permitted shall be amended as indicated in the Annex.

Article 2

This Regulation shall enter into force on the second day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 May 2018.

For the Commission
The President
Jean-Claude JUNCKER

ANNEX

- (1) In the list of establishments authorised to import meat of domestic ungulates from Brazil (section I), the following entry is removed:

Approval number	Name	City	Region	Activities	Remark
928	BRF S. A.	Ponta Grossa	Paraná	CS	2

- (2) In the list of establishments authorised to import meat from poultry and lagomorphs from Brazil (section II), the following entries are removed:

Approval number	Name	City	Region	Activities	Remark
1	BRF S. A.	Concordia	Santa Catarina	CP, CS, SH	A
18	BRF S. A.	Dourados	Mato Grosso do Sul	CP, SH	A
103	BRF S. A.	Serafina Correa	Rio Grande do Sul	CP, CS, SH	A
104	BRF S. A.	Chapeco	Santa Catarina	CP, CS, SH	A
466	BRF S. A.	Capinzal	Santa Catarina	CP, CS, SH	A
928	BRF S. A.	Ponta Grossa	Paraná	CS	2
1001	BRF S. A.	Rio Verde	Goiás	CP, CS, SH	A
2014	BRF S. A.	Marau	Rio Grande do Sul	CP, CS, SH	A
2518	SHB Comercio e Industria de Alimentos S. A.	Francisco Beltrao	Paraná	CP, CS, SH	A
4567	SHB Comercio e Industria de Alimentos S. A.	Nova Mutum	Mato Grosso	CP, CS, SH	A

- (3) In the list of establishments authorised to import minced meat, meat preparations and mechanically separated meat from Brazil (section V), the following entries are removed:

Approval number	Name	City	Region	Activities	Remark
1	BRF S. A.	Concordia	Santa Catarina	MP	48, A
18	BRF S. A.	Dourados	Mato Grosso do Sul	MP	48, A
103	BRF S. A.	Serafina Correa	Rio Grande do Sul	MP	48, A
104	BRF S. A.	Chapeco	Santa Catarina	MP	48, A
292	BRF S. A.	Varzea Grande	Mato Grosso	MP	48, A, B
466	BRF S. A.	Capinzal	Santa Catarina	MP	48, A
516	Copacol-Cooperativa Agroindustrial Consolata	Cafelandia	Paraná	MP	48, A
797	Cooperativa Agroindustrial — Copagril	Marechal Cândido Rondon	Paraná	MP	48, A
1001	BRF S. A.	Rio Verde	Goiás	MP	48, A
2014	BRF S. A.	Marau	Rio Grande do Sul	MP	48, A
2518	SHB Comercio e Industria de Alimentos S. A.	Francisco Beltrao	Paraná	MP	48, A
2758	Zanchetta Alimentos Ltda	Boituva	São Paulo	MP	48, A

Approval number	Name	City	Region	Activities	Remark
3404	Sao Salvador Alimentos S/A	Itaberaí	Goiás	MP	48, A
3409	Bello Alimentos Ltda	Itaquiraí	Mato Grosso do Sul	MP	A
3887	Coopavel — Cooperativa Agroindustrial	Cascavel	Paraná	MP	48, A
4232	Avenorte Avícola Cianorte Ltda	Cianorte	Paraná	MP	A
4444	LAR Cooperativa Agroindustrial	Matelandia	Paraná	MP	48, A
4567	SHB Comercio e Industria de Alimentos S. A.	Nova Mutum	Mato Grosso	MP	48, A

- (4) In the list of establishments authorised to import meat products from Brazil (section VI), the following entries are removed:

Approval number	Name	City	Region	Activities	Remark
104	BRF S. A.	Chapeco	Santa Catarina	PP	22, A
292	BRF S. A.	Varzea Grande	Mato Grosso	PP	22, A, B
466	BRF S. A.	Capinzal	Santa Catarina	PP	22, A
716	BRF S. A.	Toledo	Paraná	PP	22, A
1001	BRF S. A.	Rio Verde	Goiás	PP	22, A
2014	BRF S. A.	Marau	Rio Grande do Sul	PP	22, A

Activities legend:

CP Cutting Plant

CS Cold Stores

MP Meat Preparation Plant

PP Processing Plant

SH Slaughterhouse

Remarks legend:

2. Packaged meat only

48. Minced poultry meat and mechanically separated poultry meat are excluded.

A Poultry

B Bovinae

COMMISSION IMPLEMENTING REGULATION (EU) 2018/701**of 8 May 2018**

derogating from Implementing Regulation (EU) No 809/2014 as regards the final date of submission of the single application, aid applications or payment claims, the final date for notification of amendments to the single application or payment claim and the final date for applications for allocation of payment entitlements or the increase of the value of payment entitlements under the basic payment scheme for the year 2018

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1306/2013 of the European Parliament and of the Council of 17 December 2013 on the financing, management and monitoring of the common agricultural policy and repealing Council Regulations (EEC) No 352/78, (EC) No 165/94, (EC) No 2799/98, (EC) No 814/2000, (EC) No 1290/2005 and (EC) No 485/2008 ⁽¹⁾, and in particular point (b) of the first paragraph and the second paragraph of Article 78 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 809/2014 ⁽²⁾ provides for the final date of submission of the single application, aid applications or payment claims, for the final date for notification of amendments to the single application or payment claim and for the final date for submission of applications for allocation of payment entitlements or the increase of the value of payment entitlements under the basic payment scheme.
- (2) Member States are implementing changes to their administrative system for direct payments resulting from the amendments made by Regulation (EU) 2017/2393 of the European Parliament and of the Council ⁽³⁾, involving inter alia a reorganisation of the information technology systems, changes to procedures and awareness-raising activities towards beneficiaries to inform them of the new legal requirements. In addition, some Member States experience delays in the implementation of the geo-spatial aid application. As a result, exceptional administrative difficulties have been encountered in Member States.
- (3) That situation has affected the possibility of beneficiaries to submit the single application, aid applications or payment claims and applications for allocation of payment entitlements or the increase of the value of payment entitlements under the basic payment scheme within the time limits provided for in Articles 13(1) and 22(1) of Implementing Regulation (EU) No 809/2014.
- (4) In view of that situation, it is appropriate to provide for a derogation from Articles 13(1) and 22(1) of Implementing Regulation (EU) No 809/2014 which enables Member States to fix for the year 2018 a final date of submission of the single application, aid applications or payment claims and a final date for submission of applications for allocation of payment entitlements or the increase of the value of payments entitlements under the basic payment scheme that are later than those provided for in those Articles. Since the dates and periods referred to in Articles 11(4), 15(2) and (2a) of Implementing Regulation (EU) No 809/2014 are linked to the final date provided for in Article 13(1) of that Regulation, a similar derogation should be provided for the notification of the results of preliminary checks and of amendments to the single application or payment claim.
- (5) Since those derogations should cover the single application, aid applications and payment claims, amendments to the single application or payment claim and applications for allocation of payment entitlements for the year 2018, it is appropriate that this Regulation applies to applications and payment claims relating to the year 2018.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Committee for Direct Payments and the Committee for Rural Development,

⁽¹⁾ OJ L 347, 20.12.2013, p. 549.

⁽²⁾ Commission Implementing Regulation (EU) No 809/2014 of 17 July 2014 laying down rules for the application of Regulation (EU) No 1306/2013 of the European Parliament and of the Council with regard to the integrated administration and control system, rural development measures and cross compliance (OJ L 227, 31.7.2014, p. 69).

⁽³⁾ Regulation (EU) 2017/2393 of the European Parliament and of the Council of 13 December 2017 amending Regulations (EU) No 1305/2013 on support for rural development by the European Agricultural Fund for Rural Development (EAFRD), (EU) No 1306/2013 on the financing, management and monitoring of the common agricultural policy, (EU) No 1307/2013 establishing rules for direct payments to farmers under support schemes within the framework of the common agricultural policy, (EU) No 1308/2013 establishing a common organisation of the markets in agricultural products and (EU) No 652/2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material (OJ L 350, 29.12.2017, p. 15).

HAS ADOPTED THIS REGULATION:

Article 1

By way of derogation from the first subparagraph of Article 13(1) of Implementing Regulation (EU) No 809/2014, for the year 2018, the final dates to be fixed by Member States by which the single application, aid applications or payment claims have to be submitted shall not be later than 15 June.

Article 2

By way of derogation from Article 15(2) of Implementing Regulation (EU) No 809/2014, for the year 2018, in Member States using the derogation provided for in Article 1 of this Regulation the amendments made to the single application or payment claim in accordance with Article 15(1) of Implementing Regulation (EU) No 809/2014 shall be notified to the competent authority by 15 June.

Article 3

The derogations provided for in Articles 1 and 2 shall also apply in the Member States concerned for the purpose of calculating the periods of 26, 35 and 10 calendar days, respectively, after the final date of submission of the single application, aid application or payment claims and the final date for notification of amendments as referred to in Articles 11(4) and 15(2a) of Implementing Regulation (EU) No 809/2014.

Article 4

By way of derogation from Article 22(1) of Implementing Regulation (EU) No 809/2014, for the year 2018, the date to be fixed by Member States for the submission of applications for allocation of payment entitlements or the increase of the value of payment entitlements under the basic payment scheme shall not be later than 15 June.

Article 5

This Regulation shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply to applications and payment claims relating to the year 2018.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 May 2018.

For the Commission
The President
Jean-Claude JUNCKER

DECISIONS

COMMISSION DECISION (EU) 2018/702

of 8 May 2018

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

(notified under document C(2018) 2721)

(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 (EU) 2015/826 ⁽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 542 of 27 May 2013 on additives in foodstuffs (*BEK nr. 542 af 27.5.2013 (tilsætningbekendtgørelsen), Offentliggørelsesdato: 31.5.2013, Fødevareministeriet*), which the Kingdom of Denmark notified to the Commission by letter of 25 November 2014, pursuant to Article 114(4) of the Treaty on the Functioning of the European Union (TFEU). These national provisions are approved until 22 May 2018.
- (2) Regulation (EC) No 1333/2008 of the European Parliament and of the Council ⁽²⁾ lays down the levels and other conditions of use of nitrites in meat products.
- (3) According to Decision (EU) 2015/826 Denmark should 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.
- (4) By letter of 10 November 2017, Denmark notified the Commission of its intention 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 information that includes data on consumption and imports of meat products, exposure to nitrites, analysis of nitrites in meat products, prevalence of botulism and updated risk assessment from the Technical University of Denmark (DTU) National Food Institute.

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

⁽²⁾ 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).

1.2. 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, some of 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, food category 8.3: 'Meat products' lays down maximum amounts for potassium nitrite (E 249) and sodium nitrite (E 250) 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 added amount is 180 mg/kg.
- (11) By way of exception to the general rule, Regulation (EC) No 1333/2008, Annex II, Part E, food category under 8.3.4: 'Traditionally cured meat products with specific provisions concerning nitrites and nitrates' lays down maximum residual levels at the end of the production process 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.
- (12) Maximum residual levels are the exceptions to the general rule of applying maximum added amounts. Those levels only 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 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.
- (13) 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 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 not possible to specify the appropriate level of nitrite for each product.

2. NATIONAL PROVISIONS NOTIFIED

- (14) The national provisions notified by Denmark on 10 November 2017 are contained in Order No 1044 of 4 September 2015 on additives in foodstuffs (BEK nr. 1044 af 4.9.2015, Udskriftsdato: 25.9.2017, Fødevareministeriet). That Order amends Order No 542 of 27 May 2013 which had been previously notified to the Commission and assessed in the context of Decision (EU) 2015/826.

⁽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.

- (15) Order No 1044 provides that nitrites (E 249 – 250) in meat products may only be used under the conditions specified in Annex 3 thereto. The groups of foodstuffs referred to in that Annex correspond to the food categories 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)
8.3.1 Non-heat-treated meat products	Total 60 mg/kg. In fermented salamis, however, total 100 mg/kg.
8.3.2 Heat-treated meat products	Total 60 mg/kg. In entirely preserved or semi-preserved products, total 150 mg/kg. In rullepølse (rolled-meat sausage), total 100 mg/kg. In traditional Danish meat balls and liver pâté, 0 mg/kg.
8.3.4 Traditional cured meat products with specific provisions concerning nitrites and nitrates	Total 60 mg/kg. In bacon of the Wiltshire type and related products, total 150 mg/kg. In traditional cured ham (spegeskinke) and related products, 150 mg/kg.

- (16) Thus lower maximum level for nitrites (E 249 and E 250) of 60 mg/kg applies for many types of meat products, whereas the corresponding maximum limits of Regulation (EC) No 1333/2008 are 100 mg/kg or 150 mg/kg.

3. PROCEDURE

- (17) By letter of 10 November 2017, Denmark notified the Commission of its intention 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 information that includes data on consumption and imports of meat products, exposure to nitrites, analysis of nitrites in meat products, prevalence of botulism and updated risk assessment from the DTU National Food Institute.
- (18) 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 28 March 2018, the Commission also informed the other Member States on the notification and gave them the opportunity to submit comments thereon within 30 days. The Commission received comments within this deadline from Cyprus.

Cyprus does not oppose to the request of Denmark for maintaining more stringent national rules for the use of nitrites in meat products and acknowledges the Danish position that the requested rules are necessary for safeguarding the public health. Cyprus can accept the request on the condition that these rules would not constitute a trade barrier or a disproportionate obstacle to the functioning of internal market and possible discrimination against products produced in other Member State and traded in Denmark.

4. RE-EVALUATION OF NITRITES

- (19) Commission Regulation (EU) No 257/2010 ⁽²⁾ required EFSA to re-evaluate the safety of potassium nitrite (E 249) and sodium nitrite (E 250) as food additives. For this re-evaluation, EFSA examined 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 identified any relevant literature published since the last evaluation of each food additive.
- (20) The data that was provided by Denmark in support of its previous notification ⁽³⁾ 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 in the safety re-evaluation.

⁽¹⁾ OJ C 114, 28.3.2018, p. 11.

⁽²⁾ 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).

⁽³⁾ The notification by Denmark to the Commission by letter of 25 November 2014.

- (21) EFSA delivered a Scientific Opinion on the re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) on 15 June 2017 ⁽¹⁾. EFSA derived an Acceptable Daily Intake (ADI) of 0,07 mg nitrite ion/kg bw per day and estimated that the exposure to nitrite resulting from its use as food additive did not exceed this ADI for the general population, except for a slight exceedance in children at the highest percentile. If all sources of dietary nitrite exposure were considered together (food additives, natural presence and contamination), the ADI would be exceeded in infants, toddlers and children at the mean and for all age groups at highest exposure. The contribution of nitrites used as food additives represented approximately 17 % (range 1,5-36,0 %) of the overall exposure.
- (22) Further, EFSA concluded that the exposure to the endogenous nitrosamines was of low concern. As regards the exposure to exogenous nitrosamines EFSA, based on the results of the systematic review conducted to assess the relationship between nitrite added to meat products and the formation of some volatile nitrosamines of highest toxicological concern, concluded that it was not possible to clearly discern these N-nitroso compounds produced from the nitrite added at the legal limits, from those produced already at the food matrix where nitrite has not been added. Therefore, the overall exposure was calculated although it does not relate only to the use of nitrite as food additive. There was some concern for the overall exposure to exogenous nitrosamines at high levels for all age groups except for the elderly.
- (23) Finally, EFSA confirmed evidence to link preformed N-nitrosodimethylamine and colorectal cancers and some evidence to link (i) dietary nitrite and gastric cancers and (ii) the combination of nitrite plus nitrate from processed meat and colorectal cancers.

5. MONITORING BY THE COMMISSION

- (24) 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.
- (25) The Commission therefore launched an ad hoc study regarding the use of nitrites by industry in different categories of meat products. The study, completed in 2016, concluded that there is a possibility to review the current maximum levels of nitrites authorised in the EU legislation.
- (26) The conclusions of the desk study with the Member States, the ad-hoc study as regards the use of nitrites by industry, the re-evaluation by EFSA and the data reported by Denmark are to be taken into consideration by the Commission in the context of the potential revision of the maximum levels of nitrites under Regulation (EC) No 1333/2008.

II. ASSESSMENT

1. ADMISSIBILITY

- (27) 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.
- (28) 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 of the European Parliament and of the Council ⁽²⁾.
- (29) The Danish Order No 1044 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 0 mg/kg, 60 mg/kg, 100 mg/kg 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.

⁽¹⁾ EFSA Journal 2017;15(6):4786

⁽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).

- (30) 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 levels.
- (31) 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. A Memorandum of the Danish Ministry of Environment and Food and an updated risk assessment from the DTU National Food Institute provide additional information on the consumption and imports of meat products, exposure to nitrites, analysis of nitrites in meat products on the Danish market, prevalence of botulism and the formation of nitrosamines in processed meat products.
- (32) 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

- (33) 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.
- (34) 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.
- (35) 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 justifications put forward by the notifying Member State. The burden of proof lies with the requesting Member State that seeks to maintain its national measures.
- (36) 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

- (37) 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 points out that its provisions were laid down in full compliance with the opinions of the SCF made in 1990 and 1995 and also consider the provisions as justified in light of the opinion of EFSA of 26 November 2003 and of the Danish assessment of the most recent EFSA opinion of 15 June 2017.
- (38) According to Denmark, the overall scientific assessment demonstrates that (a) the use of nitrites and nitrates 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 (2003). 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.
- (39) Denmark considers that the concern about using the amounts of nitrites permitted under Regulation (EC) No 1333/2008 relates in particular to the increased risk of the nitrosamines formation. Contrary to the recent EFSA opinion, Denmark considers that the formation of both volatile and non-volatile nitrosamines depends on the amount of nitrites added whilst EFSA acknowledges the link only for the latter. It has been scientifically proven that many volatile nitrosamines are carcinogenic and genotoxic and more recent epidemiological studies refer to the link between the consumption of meat products and the development of various forms of cancer. This lends support to restrictions on the use of nitrites as additives. Denmark also points out that the margin up to the ADI is not large for young children, who have the highest exposure to nitrites under the current intake calculations for the Danish population.

- (40) 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.
- (41) The Memorandum of the Danish Ministry of Environment and Food provides additional data on the consumption and import of meat products, exposure to nitrites as well as on an analysis of nitrites in meat products on the Danish market.
- (42) According to the Danish authorities, the comparison of the most recent data, i.e. between 2012 and 2014, demonstrates an increase in the consumption of meat products, including cold cuts, which contained added nitrites. This has been in line with the trend observed since 2000 indicating that the Danes are becoming increasingly exposed to nitrites in meat products many of which are covered by the low limit value for nitrites of 60 mg/kg.
- (43) As regards trade, Denmark concludes that, during the period under review, the special Danish rules have not had a negative impact on imports of the selected products to Denmark, showing that imports increased by around 5 % from 2013 to 2016, if the figures for Germany are excluded ⁽¹⁾. Based on the analysis of nitrite in meat products, Denmark claims that nitrite content in products imported to Denmark is no higher than that of Danish products.
- (44) Therefore, Denmark considers it legitimate to maintain the national rules for the use of nitrites in meat products which are more restrictive than the requirements of Regulation (EC) No 1333/2008. According to Denmark, the monitoring carried out in accordance with Decision (EU) 2015/826 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 DANISH POSITION

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

- (45) 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.
- (46) 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.
- (47) 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. In general, the 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.
- (48) In contrast to Regulation (EC) No 1333/2008 which lays down maximum residual levels at the end of the production process for certain specified traditional cured meat products, the Danish provisions do not contain any exceptions to the principle of fixing maximum added amounts. This also applies to brine-cured meat

⁽¹⁾ Denmark informed the Commission that there is an error in the Memorandum as regards the import of cured pork meat (bacon) from Germany and that there are no major changes to the import of bacon from Germany to Denmark.

products for which it is usually not possible to control the ingoing amount of curing salts absorbed. According to the data submitted, Denmark monitors the addition of nitrites to brine-cured meat products by taking samples as close as possible to the point of manufacture in order to obtain the most realistic picture of the added quantity of nitrite. However, the results of two inspection campaigns at retail butchers show the Danish limits being exceeded in almost 35 % of the brine-cured samples in 2014 and 19 % in 2016. The Danish authorities therefore provide further guidance to retail butchers on the rules and factors that are significant to the absorption of nitrite during brine curing. This should be further followed up and monitored that Denmark can confirm the compliance and therefore adequacy of the national provisions for these products.

- (49) The Commission notes that the Danish legislation, which is compatible with the relevant scientific opinions of the Union's scientific bodies, 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.
- (50) 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.
- (51) 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*

- (52) 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.
- (53) 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*

- (54) 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.
- (55) 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 selected meat products from other Member States have increased during the period 1994-2016 and have been stable in the period 2013-2016.
- (56) 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

- (57) This condition cannot be interpreted in such a way that it precludes the approval of any national measure likely to affect the functioning 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.
- (58) 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 information, 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.
- (59) 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

- (60) The above conclusions are based on the currently available information and, in particular, on information 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.
- (61) 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 possibly nitrosamines.
- (62) Denmark should 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 and on the compliance with the Danish national provisions on nitrites, especially for brine-cured meat products. In addition, Denmark should continue collecting data on imports of meat products from other Member States. Denmark is required to report the collected data to the Commission within two years from the date of adoption of the present Decision.

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

- (63) In the light of the above considerations, and taking account of comments provided by Cyprus on the notification submitted by the Danish authorities, the Commission is of the opinion that the request by Denmark, received by the Commission on 14 November 2017, 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 should 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 1044 of 4 September 2015 on food additives etc. in foodstuffs (*BEK nr. 1044 af 4.9.2015, Udskriftsdato: 25.9.2017, Fødevareministeriet*), which the Kingdom of Denmark notified to the Commission by letter of 10 November 2017, pursuant to Article 114(4) TFEU, are approved.

Article 2

This Decision shall expire on 8 May 2021.

Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 8 May 2018.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2018/703**of 8 May 2018****on the compliance of the unit rate for the charging zone of Switzerland for 2015, 2016 and 2018
under Article 17 of Implementing Regulation (EU) No 391/2013***(notified under document C(2018) 2726)***(Only the German, French and Italian texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Agreement between the European Community and the Swiss Confederation on Air Transport ('the Agreement') ⁽¹⁾,

Having regard to Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky (the service provision Regulation) ⁽²⁾, and in particular Article 16(1) thereof, and to Commission Implementing Regulation (EU) No 391/2013 of 3 May 2013 laying down a common charging scheme for air navigation services ⁽³⁾, and in particular Article (17)(1)(d) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 391/2013 lays down a common charging scheme for air navigation services. The common charging scheme is an integral element in reaching the objectives of the performance scheme as established under Article 11 of Regulation (EC) No 549/2004 of the European Parliament and of the Council ⁽⁴⁾ and Commission Implementing Regulation (EU) No 390/2013 ⁽⁵⁾.
- (2) Commission Implementing Decision 2014/132/EU ⁽⁶⁾ sets the Union-wide performance targets, including a cost-efficiency target for *en route* air navigation services expressed in determined unit costs for the provision of those services, for the second reference period, which covers the years 2015 to 2019 inclusive.
- (3) Pursuant to Article 17(1)(b) and (c) of Implementing Regulation (EU) No 391/2013, the Commission is to assess the unit rates for charging zones for 2015 submitted by the Member States to the Commission by 1 June 2014 and the unit rates for charging zones for 2016 submitted to the Commission by 1 June 2015 following the requirements of Article 9(1) and 9(2) of that Regulation. That assessment concerns the compliance of those unit rates with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (4) The Commission has carried out its assessment of the unit rates with the support of Eurocontrol's Performance Review Unit and Eurocontrol's Central Route Charges Office, using the data and additional information provided by the Member States and Switzerland by 1 November 2017.
- (5) Given that FABEC performance targets had not been found consistent with EU-wide performance targets, Commission Implementing Decision (EU) 2016/421 ⁽⁷⁾ established that unit rates for the charging zone of Switzerland for 2015 and 2016 were not compliant.
- (6) Switzerland, as regards Functional Airspace Block (FABEC), submitted on 30 January 2017 revised performance targets, based on corrective measures, where required, including in the key performance area of cost-efficiency for

⁽¹⁾ OJ L 114, 30.4.2002, p. 73.

⁽²⁾ OJ L 96, 31.3.2004, p. 10.

⁽³⁾ OJ L 128, 9.5.2013, p. 31.

⁽⁴⁾ Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) (OJ L 196, 31.3.2004, p. 1).

⁽⁵⁾ Commission Implementing Regulation (EU) No 390/2013 of 3 May 2013 laying down a performance scheme for air navigation services and network functions (OJ L 128, 9.5.2013, p. 1).

⁽⁶⁾ Commission Implementing Decision 2014/132/EU of 11 March 2014 setting the Union-wide performance targets for the air traffic management network and alert thresholds for the second reference period 2015-19 (OJ L 71, 12.3.2014, p. 20).

⁽⁷⁾ Commission Implementing Decision (EU) 2016/421 of 18 March 2016 on the non-compliance of unit rates for the charging zone of Switzerland for 2015 and 2016 under Article 17 of Implementing Regulation (EU) No 391/2013 (OJ L 75, 22.3.2016, p. 66).

the second reference period. This submission finally allowed the Commission by Commission Implementing Decision (EU) 2017/552 ⁽¹⁾ to declare these targets as being consistent with Union-wide performance targets. As a result, Implementing Decision (EU) 2016/421 should be repealed.

- (7) On the basis of the assessment of unit rates and on the basis of the consistency of FABEC performance targets, the Commission has found, in accordance with Article 17(1)(d) of Implementing Regulation (EU) No 391/2013, that the unit rates for en route charging zones for 2015, 2016 and 2018 submitted by Switzerland are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (8) The finding and notification that unit rates for charging zones are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 is without prejudice to Article 16 of Regulation (EC) No 550/2004.
- (9) In accordance with the last paragraph of Article 17(1), unit rates are set in national currency. The unit rates contained in this Decision are therefore presented in Swiss Franc.
- (10) The Commission has consulted Switzerland on this Decision, in accordance with Article 19(2) of the Agreement,

HAS ADOPTED THIS DECISION:

Article 1

The 2015 unit rate of 118,97, the 2016 unit rate of 113,69 and the 2018 unit rate of 113,00 for the *en route* charging zone of Switzerland are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.

Article 2

Implementing Decision (EU) 2016/421 is repealed.

Article 3

This Decision is addressed to the Swiss Confederation.

Done at Brussels, 8 May 2018.

For the Commission

Violeta BULC

Member of the Commission

⁽¹⁾ Commission Implementing Decision (EU) 2017/552 of 22 March 2017 concerning the consistency of the targets in the key performance areas of capacity and cost-efficiency included in the revised functional airspace block plan submitted by Switzerland pursuant to Regulation (EC) No 549/2004 with the Union-wide performance targets for the second reference period (OJ L 79, 24.3.2017, p. 8).

COMMISSION IMPLEMENTING DECISION (EU) 2018/704**of 8 May 2018****on the compliance of unit rates for charging zones with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 pursuant to Article 17 of Implementing Regulation (EU) No 391/2013***(notified under document C(2018) 2729)***(Only the Bulgarian, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Irish, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovak, Slovenian, Spanish and Swedish texts are authentic)****(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 550/2004 of the European Parliament and of the Council of 10 March 2004 on the provision of air navigation services in the Single European Sky (the service provision Regulation) ⁽¹⁾, and in particular Article 15(4) thereof,Having regard to Commission Implementing Regulation (EU) No 391/2013 of 3 May 2013 laying down a common charging scheme for air navigation services ⁽²⁾, and in particular Article 17(1)(d) thereof,

Whereas:

- (1) Implementing Regulation (EU) No 391/2013 lays down a common charging scheme for air navigation services. The common charging scheme is an integral element in reaching the objectives of the performance scheme as established under Article 11 of Regulation (EC) No 549/2004 of the European Parliament and of the Council ⁽³⁾ and Commission Implementing Regulation (EU) No 390/2013 ⁽⁴⁾.
- (2) Commission Implementing Decision 2014/132/EU ⁽⁵⁾ sets the Union-wide performance targets, including a cost-efficiency target for *en route* air navigation services expressed in determined unit costs for the provision of those services, for the second reference period of 2015-2019.
- (3) Pursuant to Article 17(1)(b) and (c) of Implementing Regulation (EU) No 391/2013, the Commission is to assess the unit rates for charging zones submitted by the Member States in accordance with the requirements of Article 9(1) and (2) of that Regulation. That assessment concerns the compliance of those unit rates with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (4) The Commission has carried out its assessment of the unit rates with the support of Eurocontrol's Performance Review Unit and Eurocontrol's Central Route Charges Office, using the data and additional information provided by the Member States by 1 November 2017. The Commission assessment also took into account the explanations given, as well as the corrections made by Member States to the unit rates for 2018 for *en route* services following contacts with the Commission.
- (5) On the grounds of that assessment, the Commission has found that the unit rates for *en route* charging zones for 2018 submitted by Austria, Belgium, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Hungary, Ireland, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.

⁽¹⁾ OJ L 96, 31.3.2004, p. 10.

⁽²⁾ OJ L 128, 9.5.2013, p. 31.

⁽³⁾ Regulation (EC) No 549/2004 of the European Parliament and of the Council of 10 March 2004 laying down the framework for the creation of the single European sky (the framework Regulation) (OJ L 96, 31.3.2004, p. 1).

⁽⁴⁾ Commission Implementing Regulation (EU) No 390/2013 of 3 May 2013 laying down a performance scheme for air navigation services and network functions (OJ L 128, 9.5.2013, p. 1).

⁽⁵⁾ Commission Implementing Decision 2014/132/EU of 11 March 2014 setting the Union-wide performance targets for the air traffic management network and alert thresholds for the second reference period 2015-19 (OJ L 71, 12.3.2014, p. 20).

- (6) Bulgaria, Malta and Poland revised in 2016 their performance targets in the key performance area of cost-efficiency for the remaining years of the second reference period, that is, 2017, 2018 and 2019. By Commission Implementing Decision (EU) 2017/2376 ⁽¹⁾, the consistency of those revised targets with the Union-wide performance targets has been established. On the grounds of its assessment, taking account of those revised targets, the Commission has found that the unit rates for *en route* charging zones for 2017 submitted by Bulgaria, Malta and Poland are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (7) As regards Functional Airspace Block Europe Central (FABEC), Belgium, France, Luxembourg and the Netherlands submitted on 30 January 2017 revised performance targets, based on corrective measures, where required, including in the key performance area of cost-efficiency for the second reference period. That submission allowed the Commission, by its Implementing Decision (EU) 2017/553 ⁽²⁾, to declare those targets to be consistent with Union-wide performance targets. As a result, Commission Implementing Decisions (EU) 2016/420 ⁽³⁾ and (EU) 2016/419 ⁽⁴⁾, which established that unit rates for charging zones of Belgium-Luxembourg, France, Germany and the Netherlands for 2015 and 2016 had not been in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013, should be repealed.
- (8) On the grounds of the Commission's assessment and of the established consistency of performance targets submitted by the Member States of FABEC, the Commission has found that the unit rates for *en route* charging zones for 2015 and 2016 submitted by Belgium, France, Germany, Luxembourg and Netherlands are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
- (9) Pursuant to Article 17(1)(d) of Implementing Regulation (EU) No 391/2013, the Member States concerned should be notified of the Commission's findings.
- (10) The finding and notification that the unit rates for charging zones are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013 is without prejudice to the ongoing review and investigations provided for in Article 16 of Regulation (EC) No 550/2004,

HAS ADOPTED THIS DECISION:

Article 1

1. The 2018 unit rates for the *en route* charging zones set out in point 1 of the Annex are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
2. The 2017 unit rates *en route* charging zones set out in point 2 of the Annex are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.
3. The 2015 and 2016 unit rates for the *en route* charging zones set out in point 3 of the Annex are in compliance with Implementing Regulations (EU) No 390/2013 and (EU) No 391/2013.

Article 2

Implementing Decisions (EU) 2016/420 and (EU) 2016/419 are repealed.

⁽¹⁾ Commission Implementing Decision (EU) 2017/2376 of 15 December 2017 amending Implementing Decision (EU) 2015/348 as regards the consistency of the revised targets in the key performance area of cost-efficiency included in the amended national or functional airspace block plans submitted by Malta, Bulgaria and Poland (OJ L 337, 19.12.2017, p. 68).

⁽²⁾ Commission Implementing Decision (EU) 2017/553 of 22 March 2017 concerning the consistency of the targets in the key performance areas of capacity and cost-efficiency included in the revised functional airspace block plan submitted pursuant to Regulation (EC) No 549/2004 by Belgium, Germany, France, Luxembourg and the Netherlands with the Union-wide performance targets for the second reference period (OJ L 79, 24.3.2017, p. 11).

⁽³⁾ Commission Implementing Decision (EU) 2016/420 of 18 March 2016 on the non-compliance of unit rates for charging zones for 2015 under Article 17 of Implementing Regulation (EU) No 391/2013 (OJ L 75, 22.3.2016, p. 63).

⁽⁴⁾ Commission Implementing Decision (EU) 2016/419 of 18 March 2016 on the non-compliance of unit rates for charging zones for 2016 under Article 17 of Implementing Regulation (EU) No 391/2013 (OJ L 75, 22.3.2016, p. 60).

Article 3

This Decision is addressed to the Republic of Austria, the Kingdom of Belgium, Republic of Bulgaria, Republic of Croatia, the Republic of Cyprus, the Czech Republic, the Kingdom of Denmark, the Republic of Estonia, the Republic of Finland, the French Republic, the Federal Republic of Germany, Hungary, Ireland, the Republic of Latvia, Lithuania, the Grand Duchy of Luxembourg, Republic of Malta, the Kingdom of the Netherlands, Republic of Poland, the Portuguese Republic, Romania, the Slovak Republic, the Republic of Slovenia, the Kingdom of Spain, the Kingdom of Sweden and the United Kingdom of Great Britain and Northern Ireland.

Done at Brussels, 8 May 2018.

For the Commission

Violeta BULC

Member of the Commission

ANNEX

1. *En route* unit rates for 2018

	Charging zone	2018 <i>en route</i> unit rate in national currency (*)
1	Austria	71,35
2	Belgium-Luxembourg	67,66
3	Bulgaria	51,99
4	Croatia	334,13
5	Cyprus	34,95
6	Czech Republic	1 078,54
7	Denmark	443,44
8	Estonia	28,66
9	Finland	54,79
10	France	63,48
11	Germany	67,07
12	Hungary	10 064,17
13	Ireland	27,69
14	Latvia	27,47
15	Lithuania	43,59
16	Malta	15,89
17	The Netherlands	58,70
18	Poland	181,72
19	Portugal	36,84
20	Romania	149,30
21	Slovakia	51,53
22	Slovenia	61,71
23	Spain Canaries	56,61
24	Spain Continental	69,54
25	Sweden	562,58
26	United Kingdom	59,96

(*) These unit rates do not include the administrative unit rate referred to in Article 18(1) of Implementing Regulation (EU) No 391/2013 and which applies to States party to Eurocontrol's Multilateral Agreement relating to route charges.

2. *En route* unit rates for 2017

	Charging zone	Submitted <i>en route</i> unit rate ⁽¹⁾ 2017 in national currency
1	Bulgaria	52,60
2	Malta	18,79
3	Poland	185,47

⁽¹⁾ These unit rates do not include the administrative unit rate referred to in Article 18(1) of Implementing Regulation (EU) No 391/2013 and which applies to States party to Eurocontrol's Multilateral Agreement relating to route charges.

3. FABEC *en route* unit rates for 2015 and 2016

	Charging zone	Submitted <i>en route</i> unit rate ⁽¹⁾ in national currency	
		2015	2016
1	Belgium-Luxembourg	70,68	65,41
2	France	70,00	67,54
3	Germany	90,15	82,59
4	Netherlands	66,57	67,00

⁽¹⁾ These unit rates do not include the administrative unit rate referred to in Article 18(1) of Implementing Regulation (EU) No 391/2013 and which applies to States party to Eurocontrol's Multilateral Agreement relating to route charges.

