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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)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2021/736

of 4 May 2021

allowing Poland to authorise biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage*(notified under document C(2021) 3014)***(Only the Polish text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(3) thereof,

After consulting the Standing Committee for Biocidal Products,

Whereas:

- (1) Annex I to Regulation (EU) No 528/2012 contains active substances which have a more favourable environmental or human or animal health profile. Products containing these active substances may therefore be authorised under a simplified procedure. Nitrogen is included in Annex I to Regulation (EU) No 528/2012, subject to the restriction that it is used in limited quantities in ready-for-use canisters.
- (2) Pursuant to Article 86 of Regulation (EU) No 528/2012, nitrogen is approved as active substance for use in biocidal products of product-type 18, insecticides ⁽²⁾. Biocidal products consisting of nitrogen as approved are authorised in several Member States and are supplied in gas cylinders ⁽³⁾.
- (3) Nitrogen can also be generated in-situ from ambient air. In-situ generated nitrogen is currently not approved for use in the Union and it is neither listed in Annex I to Regulation (EU) No 528/2012, nor inserted in the list of active substances included in the review programme of existing active substances in biocidal products in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽⁴⁾.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Directive 2009/89/EC of 30 July 2009 amending Directive 98/8/EC of the European Parliament and of the Council to include nitrogen as an active substance in Annex I thereto (OJ L 199, 31.7.2009, p. 19).

⁽³⁾ List of authorised products available at <https://echa.europa.eu/fr/information-on-chemicals/biocidal-products>

⁽⁴⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (4) Pursuant to Article 55(3) of Regulation (EU) No 528/2012, on 26 November 2020 Poland submitted to the Commission an application for derogation from Article 19(1)(a) of that Regulation asking to allow it to authorise biocidal products consisting of nitrogen generated in-situ from ambient air for the protection of cultural heritage ('the application').
- (5) Cultural heritage can be damaged by a wide range of harmful organisms, from insects to microorganisms. The presence of those organisms not only can lead to the loss of the cultural good itself, but also poses the risk of those harmful organisms being spread to other objects nearby. Without an appropriate treatment, objects could be irretrievably damaged, putting the cultural heritage at serious risk.
- (6) In-situ generated nitrogen is used to create a controlled atmosphere with a very low concentration of oxygen (anoxia) in permanent or temporary sealed treatment tents or chambers for the control of harmful organisms on cultural heritage objects. Nitrogen is separated from the ambient air and is pumped into the treatment tent or chamber, where the nitrogen content of the atmosphere is increased to 99 % approximately and consequently oxygen is almost completely depleted. The humidity of the nitrogen pumped into the treatment area is set according to the demands of the object to be treated. Harmful organisms cannot survive under the conditions created in the treatment tent or chamber.
- (7) According to the information submitted by Poland, the use of in-situ generated nitrogen appears to be the only effective technique for the control of harmful organisms that can be used for all types of materials and combinations of materials present in cultural institutions without damaging them. The treatment can be performed at room temperature, leaves no residues on the objects and can be performed in museums and historic buildings without moving the collections.
- (8) The method of anoxia or modified or controlled atmosphere is listed in the standard EN 16790:2016 'Conservation of cultural heritage – Integrated pest management (IPM) for protection of cultural heritage' and nitrogen is described in this standard as 'most used' for creating anoxia.
- (9) Other techniques for the control of harmful organisms are available, such as thermal shock techniques (high or low temperatures). In addition, biocidal products containing other active substances can be used for that purpose. However, according to Poland, each of those techniques has limitations in terms of damage that could occur to certain materials during treatment.
- (10) According to the information in the application, thermal shock processes (freezing or heat treatments) have undesired effects on several materials. Low temperature treatments are not suitable for a variety of objects, including oil and acrylic paintings on canvas, early photographic materials, especially photographic plates, combinations of wood and metal or glass. Furthermore, objects need to be moved to freezers, since there is no possibility of in-situ treatments, and freezers may not accommodate large-size objects.
- (11) High temperature treatments are not suitable for a number of materials, including many polymers and wax and for ethnographic objects containing leather.
- (12) As stated in the application, other active substances are seldom used in cultural institutions due to their hazard profile. After treatment with those substances, the residues on the treated objects can be progressively released to the environment, which poses a risk to human health. Moreover, those substances may react with the materials of the heritage objects causing irreversible changes, especially of their surface.
- (13) According to the information in the application, the use of nitrogen in cylinders is not an appropriate alternative for cultural institutions, as it presents practical disadvantages. The limited quantities in cylinders require frequent transport and a separate storage facility. The treatment with nitrogen in cylinders would also generate high costs for the cultural institutions.

- (14) Requesting cultural institutions to use several techniques to control harmful organisms – each of them suitable for specific materials and objects – instead of using one technique already used and suitable to all materials, would involve additional costs for cultural institutions and make it more complicated for them to reach the objective of moving away from the use of more hazardous active substances in their IPM. In addition, the abandonment of facilities and equipment acquired for in-situ generated nitrogen anoxia would represent a loss of previous investments.
- (15) Discussions related to a possible derogation pursuant to Article 55(3) of Regulation (EU) No 528/2012 for in-situ generated nitrogen took place in several meetings ⁽ⁱ⁾ of the Commission expert group of Competent Authorities for Biocidal Products in 2019.
- (16) In addition, at the request of the Commission, following the first, similar application for derogation for products consisting of in-situ generated nitrogen from Austria, the European Chemicals Agency conducted a public consultation on that application, allowing all interested parties to provide their views. The vast majority of the 1487 comments received were in favour of the derogation. Many contributors outlined the disadvantages of the alternative techniques available: thermal treatments may damage certain materials; the use of other active substances leaves toxic residues on artefacts that are progressively released to the environment; the use of nitrogen in cylinders does not allow the control of the relative humidity in the treatment area, which is needed for the treatment of some materials.
- (17) Two international organisations representing museums and cultural heritage sites – International Council of Museums and International Council on Monuments and Sites – have expressed their intention to submit an application for inclusion of in-situ generated nitrogen in Annex I to Regulation (EU) No 528/2012, which would allow Member States to authorise products consisting of in-situ generated nitrogen without the need for a derogation in accordance with Article 55(3) of that Regulation. However, performing the evaluation of such an application, including the substance into Annex I to Regulation (EU) No 528/2012 and obtaining product authorisations require time.
- (18) The application shows that no appropriate alternatives are available in Poland, since all the alternative techniques currently available present disadvantages either due to non-suitability for the treatment of all materials or practical disadvantages.
- (19) Based on all those arguments it is appropriate to conclude that in-situ generated nitrogen is essential for the protection of cultural heritage in Poland and that no appropriate alternatives are available. Poland should therefore be allowed to authorise the making available on the market and use of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage.
- (20) The possible inclusion of in-situ generated nitrogen into Annex I to Regulation (EU) No 528/2012 and the subsequent authorisation by Member States of products consisting of in-situ generated nitrogen requires time. It is therefore appropriate to allow a derogation for a period that would allow the completion of the underlying procedures,

HAS ADOPTED THIS DECISION:

Article 1

Poland may authorise the making available on the market and use of biocidal products consisting of in-situ generated nitrogen for the protection of cultural heritage until 31 December 2024.

⁽ⁱ⁾ 83rd, 84th, 85th and 86th meeting of the Commission Expert Group of representatives of Member States Competent Authorities for the implementation of Regulation (EU) No 528/2012, held in May 2019, July 2019, September 2019 and November 2019, respectively. The minutes of the meetings are available at https://ec.europa.eu/health/biocides/events_en#anchor0

Article 2

This Decision is addressed to the Republic of Poland.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/737**of 4 May 2021**

concerning the extension of the action taken by the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 3015)

(Only the German text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof,

Whereas:

- (1) On 24 June 2020 the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems until 22 December 2020 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. The microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The Covid-19 pandemic and the ensuing flight restrictions led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor of microbiological contamination.
- (3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8), active substances for use in biocidal products of product-type 6 as preservatives for products during storage as defined in Annex V to Regulation (EU) No 528/2012. As those active substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾, they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to them and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.
- (4) On 7 December 2020, the Commission received a reasoned request from the competent authority to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems after 22 December 2020 and the claim that Biobor JF is essential in order to control such microbiological contamination.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (5) According to the information provided by the competent authority, Biobor JF is the only product available for the treatment of microbiological contamination. The only alternative biocidal product recommended by aircraft and engine manufacturers for that use (Kathon™ FP 1.5) is no longer made available on the market.
- (6) As indicated by the competent authority, mechanical treatment of the fuel tanks and fuel systems is possible only to a limited extent and, according to manufacturers' specifications, it often has to be accompanied by the addition of a biocidal product after the cleaning of the tank. Mechanical tank treatment could take up to over 200 person-hours, depending on the aircraft type, meaning a maintenance downtime of the aircraft of several days.
- (7) In addition, mechanical treatment implies that aircraft mechanics have to work in a tight tank with numerous safety precautions, which is extremely demanding physically and mentally, and should be reduced to a minimum.
- (8) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product and an application for approval of the active substances it contains is expected to be submitted in the near future. The approval of the active substances and subsequent authorisation of the biocidal product would constitute a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.
- (9) The lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the competent authority to extend the action.
- (10) Considering that the action expired on 22 December 2020, this Decision should have retroactive effect.
- (11) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology may extend the action to permit the making available on the market and use of the biocidal product Biobor JF for antimicrobial treatment of aircraft fuel tanks and fuel systems until 26 June 2022.

Article 2

This Decision is addressed to the Austrian Federal Ministry for Climate Action, Environment, Energy, Mobility, Innovation and Technology.

It shall apply from 23 December 2020.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/738**of 4 May 2021****concerning the extension of the action taken by German Federal Office for Chemicals permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2021) 3016)***(Only the German text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof,

Whereas:

- (1) On 15 September 2020 the German Federal Office for Chemicals ('the competent authority') adopted a decision, applicable from 5 October 2020, in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the antimicrobial treatment of aircraft fuel tanks and fuel systems until 3 April 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. The microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The COVID-19 pandemic and the ensuing flight restrictions led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor of microbiological contamination.
- (3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8), active substances for use in biocidal products of product-type 6 as preservatives for products during storage as defined in Annex V to Regulation (EU) No 528/2012. As those active substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾, they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to them and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.
- (4) On 20 January 2021, the Commission received a reasoned request from the competent authority to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems after 3 April 2021 and the claim that Biobor JF is essential in order to control such microbiological contamination.
- (5) According to the information provided by the competent authority, the only alternative biocidal product recommended by aircraft and engine manufacturers for the treatment of microbiological contamination (Kathon™ FP 1.5) was withdrawn from the market due to safety-related incidents noticed after the treatment with that product.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (6) As indicated by the competent authority, manual cleaning of the fuel tanks is possible only when it is in accordance with the manufacturer's specifications. However, manual cleaning is often carried out in combination with biocidal treatment, as required by agreed aviation procedures, and requires the complete disposal of the contaminated aviation fuel as well as physically and mentally demanding work in the narrow fuel tank under numerous safety precautions. Manual cleaning of fuel tanks should therefore be avoided as far as possible.
- (7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product and an application for approval of the active substances it contains is expected to be submitted in the near future. The approval of the active substances and subsequent authorisation of the biocidal product would be a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.
- (8) The lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the competent authority to extend the action.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The German Federal Office for Chemicals may extend until 6 October 2022 the action to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the antimicrobial treatment of aircraft fuel tanks and fuel systems .

Article 2

This Decision is addressed to the German Federal Office for Chemicals.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/739**of 4 May 2021****concerning the extension of the action taken by the Dutch Ministry of Infrastructure and Water Management permitting the making available on the market and use of the biocidal product Biobor JF in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council***(notified under document C(2021) 3020)***(Only the Dutch text is authentic)**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof,

Whereas:

- (1) On 21 October 2020 the Dutch Ministry of Infrastructure and Water Management ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems until 19 April 2021 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. The microbiological contamination of aircraft fuel tanks and fuel systems can lead to malfunctions of the aircraft engine and endanger its airworthiness, thus endangering the safety of passengers and crew. The COVID-19 pandemic and the ensuing flight restrictions led to numerous aircraft being temporarily parked. The immobility of aircraft is an aggravating factor of microbiological contamination.
- (3) Biobor JF contains 2,2'-(1-methyltrimethylenedioxy)bis-(4-methyl-1,3,2-dioxaborinane) (CAS number 2665-13-6) and 2,2'-oxybis (4,4,6-trimethyl-1,3,2-dioxaborinane) (CAS number 14697-50-8), active substances for use in biocidal products of product-type 6 as preservatives for products during storage as defined in Annex V to Regulation (EU) No 528/2012. As those active substances are not listed in Annex II to Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾, they are not included in the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012. Article 89 of that Regulation therefore does not apply to them and they have to be assessed and approved before biocidal products containing them can be authorised also at national level.
- (4) On 12 January 2021, the Commission received a reasoned request from the competent authority to extend the action in accordance with the Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that air transport safety might continue to be endangered by microbiological contamination of aircraft fuel tanks and fuel systems after 19 April 2021 and the claim that Biobor JF is essential in order to control such microbiological contamination.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

⁽²⁾ Commission Delegated Regulation (EU) No 1062/2014 of 4 August 2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

- (5) According to the information provided by the competent authority, the only alternative biocidal product recommended by aircraft and engine manufacturers for the treatment of microbiological contamination (Kathon™ FP 1.5) was withdrawn from the market in March 2020 due to safety incidents that occurred after the treatment with that product.
- (6) According to the competent authority, there are no alternatives for the treatment of microbiological contamination of aircraft fuel tanks and fuel systems.
- (7) According to the information available to the Commission, the manufacturer of Biobor JF has taken steps towards the regular authorisation of the product and an application for approval of the active substances it contains is expected to be submitted in the near future. The approval of the active substances and subsequent authorisation of the biocidal product would constitute a permanent solution for the future, but a significant amount of time would be needed for the completion of those procedures.
- (8) The lack of control of microbiological contamination of aircraft fuel tanks and fuel systems might endanger the air transport safety and that danger cannot be adequately contained by using another biocidal product or by other means. It is therefore appropriate to allow the competent authority to extend the action.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The Dutch Ministry of Infrastructure and Water Management may extend until 22 October 2022 the action to permit the making available on the market for, and use by, professional users of the biocidal product Biobor JF for the preventive and curative antimicrobial treatment of aircraft fuel tanks and fuel systems.

Article 2

This Decision is addressed to the Dutch Ministry of Infrastructure and Water Management.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2021/740**of 4 May 2021**

concerning the extension of the action taken by the United Kingdom Health and Safety Executive permitting the making available on the market and use of the biocidal product Isopropanol Solution in accordance with Article 55(1) of Regulation (EU) No 528/2012 of the European Parliament and of the Council

(notified under document C(2021) 3037)

(Only the English text is authentic)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products ⁽¹⁾, and in particular Article 55(1), third subparagraph, thereof, in conjunction with Article 131 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community,

Whereas:

- (1) On 26 June 2020, the United Kingdom Health and Safety Executive ('the competent authority') adopted a decision in accordance with Article 55(1), first subparagraph, of Regulation (EU) No 528/2012 to permit the making available on the market and use of the biocidal product Isopropanol Solution, until 23 December 2020 ('the action'). The competent authority informed the Commission and the competent authorities of the other Member States about the action and the justification for it, in accordance with Article 55(1), second subparagraph, of that Regulation.
- (2) According to the information provided by the competent authority, the action was necessary in order to protect public health. On 11 March 2020, the World Health Organisation (WHO) declared that the outbreak of the coronavirus disease (COVID-19) could be characterised as a pandemic. The United Kingdom Government declared the risk to the United Kingdom as 'high' and on 23 March 2020 restrictive measures came into effect. The use of alcohol-based hand disinfectants is recommended by the WHO as a preventive measure against the spread of COVID-19, as an alternative to washing hands with soap and water.
- (3) Isopropanol Solution contains propan-2-ol as an active substance. Propan-2-ol is approved for use in biocidal products of product-type 1 (human hygiene) as defined in Annex V to Regulation (EU) No 528/2012.
- (4) Since the outbreak of the COVID-19 pandemic hand disinfectants have been in extremely high demand in the United Kingdom, which led to unprecedented supply shortages of such products. Prior to the action, there were very few hand disinfectants authorised in the United Kingdom under Regulation (EU) No 528/2012. COVID-19 represents a serious threat to public health in the United Kingdom and additional hand disinfectants are crucial for the control of its spread.
- (5) On 9 December 2020, the Commission received a reasoned request from the competent authority to extend the action in accordance with Article 55(1), third subparagraph, of Regulation (EU) No 528/2012. The reasoned request was made on the basis of concerns that public health might be endangered by COVID-19 beyond 23 December 2020 and taking into account that allowing additional hand disinfectants on the market is crucial in order to contain the danger posed by COVID-19.
- (6) The infection rate has been increasing in the United Kingdom and, according to the competent authority, a further increase in the demand of hand disinfectants is expected. The extension of the action is necessary in view of the expected increase in the demand.

⁽¹⁾ OJ L 167, 27.6.2012, p. 1.

- (7) The competent authority has encouraged companies that received derogations for hand disinfectants after 11 March 2020 to seek regular product authorisation as soon as possible. However, no new applications for regular product authorisation have been received by the competent authority to date.
- (8) As COVID-19 continues to pose a danger to public health and the fact that such danger cannot be adequately contained in the United Kingdom, in the absence of additional hand disinfectants allowed on the market, it is appropriate to allow the competent authority to extend the action.
- (9) Taking into account the end of the transition period referred to in Article 126 of the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (the Withdrawal Agreement), this Decision should apply until 31 December 2020. As regards the United Kingdom in respect of Northern Ireland, however, Union law continues to apply beyond the transition period in accordance with Article 5(4) of the Protocol on Ireland/Northern Ireland to the Withdrawal Agreement. Considering that the action expired on 23 December 2020, this Decision should have retroactive effect.
- (10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS DECISION:

Article 1

The United Kingdom Health and Safety Executive may extend the action to permit the making available on the market and use of the biocidal product Isopropanol Solution until 31 December 2020.

For the United Kingdom in respect of Northern Ireland, however, it may extend the action until 27 June 2022.

Article 2

This Decision is addressed to the United Kingdom Health and Safety Executive.

It shall apply from 24 December 2020.

Done at Brussels, 4 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

COMMISSION DECISION (EU) 2021/741**of 5 May 2021****concerning national provisions notified by Denmark on the addition of nitrite to certain meat products***(notified under document C(2021) 3045)***(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) 2018/702 ⁽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 1044 of 4 September 2015 on additives in foodstuffs (*BEK nr 1044 af 4.9.2015, Udskriftsdato: 25.9.2017, Fødevarerministeriet*), which the Kingdom of Denmark notified to the Commission by letter of 10 November 2017, pursuant to Article 114(4) of the Treaty on the Functioning of the European Union (TFEU). These national provisions are approved until 8 May 2021.
- (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 Commission Decision (EU) 2018/702 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 6 November 2020, 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 six months of the notification, approve or reject the national provisions involved after having verified whether or not they are a means of arbitrary discrimination or a disguised restriction on trade between Member States and whether or not they shall constitute an obstacle to the functioning of the internal market.

⁽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 safety 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 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 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 currently laid down in Regulation (EC) No 1333/2008, and before in Directive 2006/52/EC of the European Parliament and of the Council ⁽³⁾, are based on the opinions from the Scientific Committee for Food (hereinafter 'SCF') of 1990 ⁽⁴⁾ and 1995 ⁽⁵⁾ as well as from the European Food Safety Authority (hereinafter 'EFSA') of 26 November 2003 ⁽⁶⁾. The maximum amounts that may be added reflect the ranges referred to in these scientific opinions. Given the vast variety of (cured) meat products and manufacturing methods within the Union, the Union legislator held that it was not possible to specify the appropriate level of nitrite for each product.

⁽³⁾ 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).

⁽⁴⁾ Opinion on nitrates and nitrites expressed on 19 October 1990, European Commission — Reports of the Scientific Committee for Food (twenty-sixth series), p. 21.

⁽⁵⁾ Opinion on nitrates and nitrite expressed on 22 September 1995, European Commission — Reports of the Scientific Committee for Food (thirty eighth series), p. 1.

⁽⁶⁾ Opinion of the Scientific Panel on Biological Hazards on a request from the Commission related to the effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products, The EFSA Journal (2003) 14, p. 1.

2. NATIONAL PROVISIONS NOTIFIED

- (14) The national provisions notified by Denmark on 6 November 2020 are contained in Order No 1247 of 30 October 2018 on additives in foodstuffs (BEK nr 1247 af 30.10.2018, Udskriftsdato: 3.9.2020, Miljø- og Fødevarerministeriet). That Order amends Order No 1044 of 4.9.2015, which had been previously notified to the Commission and assessed in the context of Decision (EU) 2018/702.
- (15) Order No 1247 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 6 November 2020, 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.
- (18) The Commission published a notice regarding the notification in the *Official Journal of the European Union* ⁽⁷⁾ in order to inform interested parties of Denmark's national provisions, as well as the grounds invoked to support the request. By letter of 13 January 2021, 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 Finland, Latvia and Malta.

— Finland considers that Denmark has been able to prove the benefits of its national lower nitrite levels in terms of protecting public health from the high intake of nitrites and nitrosamines as well as an adequate protection against the possible growth of *Clostridium botulinum*. Finland refers to the ongoing work on the revision of the provisions for nitrites and nitrates, laid down in Regulation (EC) No 1333/2008, to reduce their current maximum levels and to add new requirements as regards residual amounts in meat products. Finland has no information on any complaints concerning the national nitrite rules maintained by Denmark, such as complications related to exports. Finland thus can accept the Danish national derogation on a temporary basis. However, it should be reviewed, at the latest, after the reform of the Union legislation by using, e.g. the common methodology to be applied to the monitoring of additives that is under development.

⁽⁷⁾ OJ C 47, 10.2.2021, p. 7.

- Latvia can support the request of Denmark taking into account the arguments provided and the fact that the national regulations imposing stricter requirements for the use of nitrites in meat products have been in place for several years and the Latvian exporting producers have had no objections on it.
- Malta has no objections from a health perspective or risk assessment point of view on the lower levels for nitrites set by Denmark.

4. RE-EVALUATION OF NITRITES

- (19) Commission Regulation (EU) No 257/2010 ⁽⁸⁾ 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, the original dossier, data submitted by the interested business operators and other interested parties 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 ⁽⁹⁾ 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.
- (21) EFSA delivered a Scientific Opinion on the re-evaluation of potassium nitrite (E 249) and sodium nitrite (E 250) on 15 June 2017 ⁽¹⁰⁾. 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 exposure and for all age groups at the 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 and 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, EFSA 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, EFSA took into account the overall exposure although such exposure does not result only from the use of nitrite as food additive. EFSA considered that 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 dietary nitrite with gastric cancers and to link the combination of nitrite plus nitrate from processed meat with 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 Union 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 Union maximum amount, but higher than the Danish levels. In the report, the Commission concluded that the possibility of reviewing the current maximum levels of nitrites should be further explored.

⁽⁸⁾ 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).

⁽⁹⁾ The notification by Denmark to the Commission by letter of 25 November 2014.

⁽¹⁰⁾ EFSA Journal 2017;15(6):4786

- (25) The Commission therefore launched an ad hoc study regarding the use of nitrites by the industry in different categories of meat products. The study, completed in 2016, also concluded that there is a possibility to review the current maximum levels of nitrites authorised in the Union 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. This revision of the maximum levels of nitrites is currently under discussion with the Member States.

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 the Union provisions were originally laid down in Directive 2006/52/EC.
- (29) The Danish Order No 1247 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.
- (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 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 of 3 April 2020 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 national provisions 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 finds the link only for the latter. It argues that 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. It considers that this lends support to restrictions on the use of nitrites as additives. Denmark also points out that whilst results from the most recent intake estimation for the Danish population show that the nitrite intake from processed meat is well below the ADI, the total dietary intake, according to the EFSA opinion, exceeds the ADI for a sizeable part of the Danish population. According to Denmark, this also represents an argument for upholding a restrictive use of nitrite as food additive.
- (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 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 of 3 April 2020 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 most recent data, captured in that memorandum, demonstrate that the consumption patterns have not changed significantly. The consumption of meat products is not increasing and remains stable. Out of meat products to which nitrite may be added, by far the majority of the consumption relates to those products covered by the low limit value of 60 mg/kg.
- (43) As regards trade, Denmark concludes that maintaining the special Danish rules have not had a negative impact on imports of the selected products from other Member States, showing that total imports increased by around 4 % from 2017 to 2019. Based on the analysis of nitrite in meat products, Denmark points out that in general, the current more restrictive Danish limit values are being complied with, including the use of nitrite in brine-cured meat products at retail butchers whose monitoring was required by the Commission in Decision (EU) 2018/702.
- (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) 2018/702 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

- (45) The Danish national provisions aim 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 national provisions are 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 national provisions 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) The Commission notes that the Danish national provisions, which are compatible with the relevant scientific opinions of the Union's scientific bodies, are based on a regulation of maximum added amounts and respect 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.

- (49) 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.
- (50) 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

- (51) 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.
- (52) 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

- (53) 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.
- (54) 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 1994-2019.
- (55) 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

- (56) 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.

- (57) Given the health benefits invoked by Denmark 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.
- (58) 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*

- (59) 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.
- (60) 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.
- (61) 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. 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 three years.

III. CONCLUSION

- (62) In the light of the above considerations, and taking account of comments provided by Finland, Latvia and Malta on the notification submitted by the Danish authorities, the Commission is of the opinion that the request by Denmark, received by the Commission on 6 November 2020, 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 three 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 1247 of 30 October 2018 on additives in foodstuffs (*BEK nr 1247 af 30.10.2018, Udskriftsdato: 3.9.2020, Miljø- og Fødevarerministeriet*), which the Kingdom of Denmark notified to the Commission by letter of 6 November 2020, pursuant to Article 114(4) TFEU, are approved.

Article 2

This Decision shall expire on 5 May 2024.

Article 3

This Decision is addressed to the Kingdom of Denmark.

Done at Brussels, 5 May 2021.

For the Commission
Stella KYRIAKIDES
Member of the Commission

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