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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION DELEGATED REGULATION (EU) 2020/1758

of 28 August 2020

amending Delegated Regulation (EU) 2019/2238 as regards high survivability and *de minimis* exemptions applicable to certain demersal fisheries in the North Sea

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2018/973 of the European Parliament and of the Council of 4 July 2018 establishing a multiannual plan for demersal stocks in the North Sea and the fisheries exploiting those stocks, specifying details of the implementation of the landing obligation in the North Sea and repealing Council Regulations (EC) No 676/2007 and (EC) No 1342/2008 ⁽¹⁾, and in particular Article 11 thereof,

Whereas:

- (1) Regulation (EU) No 1380/2013 of the European Parliament and of the Council ⁽²⁾ aims to progressively eliminate discards in all Union fisheries through the introduction of a landing obligation for catches of species subject to catch limits.
- (2) Article 9 of Regulation (EU) No 1380/2013 provides for the adoption of multiannual plans containing conservation measures for fisheries exploiting certain stocks in a relevant geographical area. Such multiannual plans specify details of the implementation of the landing obligation and may empower the Commission to further specify those details on the basis of joint recommendations developed by Member States.
- (3) Regulation (EU) 2018/973, which establishes a multiannual plan for demersal stocks in the North Sea also empowers the Commission to adopt delegated acts specifying details of the landing obligation on the basis of joint recommendations developed by Member States.
- (4) Belgium, Denmark, Germany, France, the Netherlands and Sweden have a direct fisheries management interest in the North Sea. After consulting the North Sea Advisory Council and the Pelagic Advisory Council, those Member States and the United Kingdom submitted on 29 May 2019 a joint recommendation to the Commission concerning details of the implementation of the landing obligation for demersal fisheries in the North Sea. The joint recommendation was amended on 7 August 2019. Following those joint recommendations, the Commission adopted Delegated Regulation (EU) 2019/2238 ⁽³⁾.

⁽¹⁾ OJ L 179, 16.7.2018, p. 1.

⁽²⁾ Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC (OJ L 354, 28.12.2013, p. 22).

⁽³⁾ Commission Delegated Regulation (EU) 2019/2238 of 1 October 2019 specifying details of implementation of the landing obligation for certain demersal fisheries in the North Sea for the period 2020-2021 (OJ L 336, 30.12.2019, p. 34).

- (5) On 8 November 2019 the Member States concerned and the United Kingdom submitted a new joint recommendation to correct some errors and unintentional omissions in Delegated Regulation (EU) 2019/2238.
- (6) The joint recommendation of 8 November 2019 suggested to grant the exemption for Norway lobster caught with bottom trawls equipped with a cod-end with a mesh size of at least 70 mm equipped with a species selective grid with a bar spacing of maximums 35 mm until 31 December 2021. This is an exemption with a positive scientific assessment ⁽⁴⁾ that had also been included in previous discard plans. In 2018, the Scientific, Technical and Economic Committee for Fisheries (STECF) pointed out that the supporting scientific information for that exemption was based on a robust approach and the validation technique used in the context of the wider fleets was reasonable ⁽⁵⁾. In spite of this positive scientific background, Delegated Regulation (EU) 2019/2238 unintentionally limited that exemption until 31 December 2020, even though there were no scientific grounds for that. That exemption should therefore apply until 31 December 2021.
- (7) On the basis of the abovementioned STECF assessments, Delegated Regulation (EU) 2019/2238 also included erroneously a reporting obligation to be submitted no later than 1 May 2020 for the exemption for Norway lobster caught with bottom trawls equipped with a cod-end with a mesh size of at least 70 mm equipped with a species selective grid with a bar spacing of maximums 35 mm. Hence, this exemption should be excluded from the obligation to submit additional data.
- (8) Delegated Regulation (EU) 2019/2238 contains an unintentional omission concerning the survivability exemption for catch and by-catch of plaice. The Joint Recommendation submitted on 7 August 2019 suggested an exemption for plaice caught with certain trawls targeting flatfish or roundfish, equipped with a mesh size of at least 90-99 mm and with seltra panel; or a mesh size of at least 80-99 mm. The STECF observed that survivability rates were variable between relevant studies (18-75 %), with particularly lower levels registered for smaller plaice ⁽⁶⁾. For this reason the exemption should have been granted only until 31 December 2020, but Article 6(4) did not specify it by error. Furthermore, the reporting obligation to present additional data should also cover this exemption.
- (9) The joint recommendation of 8 November 2019 suggested the inclusion of a *de minimis* exemption for ling caught with certain bottom trawls with a mesh size greater than or equal to 120 mm.
- (10) Commission Delegated Regulation (EU) 2018/2035 ⁽⁷⁾ had granted a *de minimis* exemption for ling below minimum conservation reference size caught with certain bottom trawls with a mesh size equal or greater than 120 mm in ICES subarea 4. That exemption was granted on the basis of scientific evidence provided by the Member States and endorsed by the scientific assessment ⁽⁸⁾. The STECF noted that it was reasonable to assume that improvements in selectivity to reduce unwanted catches of ling were technically challenging giving the morphology of ling. That exemption was not carried over in Delegated Regulation (EU) 2019/2238 due to a miscommunication between the regional group of Member States and the Commission. Therefore, Article 10 of Delegated Regulation (EU) 2019/2238 should be amended to include it.
- (11) Delegated Regulation (EU) 2019/2238 should be amended accordingly.
- (12) As the measures provided for in this Regulation have a direct impact on the planning of the fishing season of Union vessels and on related economic activities, this Regulation should enter into force very shortly after its publication. Considering that Delegated Regulation (EU) 2019/2238 entered into force on 1 January 2020, this Regulation should also apply from that date,

⁽⁴⁾ https://stecf.jrc.ec.europa.eu/c/document_library/get_file?uuid=f2e28988-14e4-4fdf-9770-0619edd32e64&groupId=43805

⁽⁵⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2147402/STECF+PLEN+18-02.pdf>

⁽⁶⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2537709/STECF+PLEN+19-02.pdf/0b2566fa-f07c-4215-99a7-3b7aa1a5265e>

⁽⁷⁾ Commission Delegated Regulation (EU) 2018/2035 of 18 October 2018 specifying details of implementation of the landing obligation for certain demersal fisheries in the North Sea for the period 2019-2021 (OJ L 327, 21.12.2018, p. 17).

⁽⁸⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/2147402/STECF+PLEN+18-02.pdf/9798bf87-66be-467a-aeb9-4950cddbdfb>

HAS ADOPTED THIS REGULATION:

Article 1

Delegated Regulation (EU) 2019/2238 is amended as follows:

(1) Article 3(3) is replaced by the following:

'3. The exemption referred to in paragraph 1(b)(1) and (3) shall be provisionally applicable until 31 December 2020. Member States having a direct management interest shall submit as soon as possible and not later than on 1 May 2020, additional scientific information supporting the exemption laid down in paragraph 1(b) (1) and (3). The Scientific, Technical and Economic Committee for Fisheries (STECF) shall assess the provided scientific information by 31 July 2020.;

(2) Article 6(4) is replaced by the following:

'4. The exemptions referred to in paragraphs 1(c) and 2 shall be provisionally applicable until 31 December 2020. Member States having a direct management interest shall submit as soon as possible and not later than by 1 May 2020, additional scientific information supporting the exemption laid down in paragraph 1(c) and 2. The Scientific, Technical and Economic Committee for Fisheries (STECF) shall assess the provided scientific information by 31 July 2020.;

(3) Article 10 is amended as follows:

(a) in point (n), under the introductory phrase, the second subparagraph is replaced by the following:

'the *de minimis* exemption set out in this point shall be provisionally applicable until 31 December 2020. Member States having a direct management interest shall submit, as soon as possible and not later than by 1 May 2020, additional scientific information supporting the exemption. The STECF shall assess the provided scientific information by 31 July 2020.;

(b) the following point (o) is added:

'(o) in the demersal fisheries by vessels using bottom trawls (OTB, OTT, PTB) with a mesh size equal to or greater than 120 mm catching ling in Union waters of ICES subarea 4:
a quantity of ling below minimum conservation reference size, which shall not exceed 3 % of the total annual catches of ling in that fishery.'

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 28 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION DELEGATED REGULATION (EU) 2020/1759**of 28 August 2020****correcting Delegated Regulation (EU) No 1394/2014 establishing a discard plan for certain pelagic fisheries in South-Western waters**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1380/2013 of the European Parliament and of the Council of 11 December 2013 on the Common Fisheries Policy, amending Council Regulations (EC) No 1954/2003 and (EC) No 1224/2009 and repealing Council Regulations (EC) No 2371/2002 and (EC) No 639/2004 and Council Decision 2004/585/EC ⁽¹⁾, and in particular Article 15(6) and Article 18(1) and (3) thereof,

Whereas:

- (1) Regulation (EU) No 1380/2013 aims to progressively eliminate discards in all Union fisheries through the introduction of a landing obligation for catches of species subject to catch limits.
- (2) Article 15(6) of Regulation (EU) No 1380/2013 empowers the Commission to adopt discard plans by means of a delegated act for a period of no more than three years and renewable once on the basis of joint recommendations developed by Member States in consultation with the relevant Advisory Councils.
- (3) Belgium, Spain, France, the Netherlands and Portugal have a direct fisheries management interest in the South-Western waters. After consulting the South Western Waters Advisory Council and the Pelagic Advisory Council, those Member States submitted on 2 June 2017 a joint recommendation to the Commission to extend the duration of *de minimis* exemptions established in the discard plan.
- (4) Following that recommendation and a positive evaluation provided by Scientific, Technical and Economic Committee for Fisheries (STECF) ⁽²⁾, Commission Delegated Regulation (EU) 2018/188 ⁽³⁾ granted the extension of the *de minimis* exemption as regards catches of anchovy, mackerel and horse mackerel in International Council for the Exploration of the Sea ICES division 8 for otter trawls (OTM) and pair trawls (PTM) for the years 2018, 2019 and 2020. That exemption had already been granted in Commission Delegated Regulation (EU) No 1394/2014 ⁽⁴⁾ for OTM and PTM for the years 2015, 2016 and 2017 due to the reasoned argumentation on the difficulties to further increase selectivity.
- (5) Due to an error, PTM was unintentionally excluded in Delegated Regulation (EU) 2018/188 and the abovementioned Member States requested the Commission to correct the omission. The reference to just one gear should be deleted to cover all pelagic gears (OTM and PTM) as regards catches of anchovy, mackerel and horse mackerel.
- (6) Delegated Regulation (EU) No 1394/2014 should be amended accordingly.
- (7) As the measures provided for in this Regulation have a direct impact on the planning of the fishing season of Union vessels and on related economic activities, this Regulation should enter into force immediately after its publication. Considering that Delegated Regulation (EU) 2018/188 applies from 1 January 2018, this Regulation should apply from 1 January 2020,

⁽¹⁾ OJ L 354, 28.12.2013, p. 22.

⁽²⁾ <https://stecf.jrc.ec.europa.eu/documents/43805/812327/STECF+PLEN+14-02.pdf/e29cf181-8d63-40ef-8050-6d980b12528f>

⁽³⁾ Commission Delegated Regulation (EU) 2018/188 of 21 November 2017 amending Delegated Regulation (EU) No 1394/2014 establishing a discard plan for certain pelagic fisheries in South-Western waters (OJ L 36, 9.2.2018, p. 1).

⁽⁴⁾ Commission Delegated Regulation (EU) No 1394/2014 of 20 October 2014 establishing a discard plan for certain pelagic fisheries in south-western waters (OJ L 370, 30.12.2014, p. 31).

HAS ADOPTED THIS REGULATION:

Article 1

In Delegated Regulation (EU) No 1394/2014, point (c) of Article 3 is replaced by the following:

‘(c) up to a maximum of 4 % in 2018, 2019 and 2020 of the total annual catches of anchovy, mackerel and horse mackerel in the pelagic trawl fishery which targets anchovy, mackerel and horse mackerel in ICES division 8 using pelagic trawls;’.

Article 2

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

It shall apply from 1 January 2020.

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

Done at Brussels, 28 August 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1760**of 25 November 2020****concerning the authorisation of the preparation of *Bacillus subtilis* DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets (holder of authorisation Chr. Hansen A/S)****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, two applications were submitted for the authorisation of the preparation of *Bacillus subtilis* DSM 25841. Those applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The applications concern the authorisation of the preparation of *Bacillus subtilis* DSM 25841 as a feed additive for all porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets to be classified in the additive category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 20 February 2018 ⁽²⁾, 4 October 2019 ⁽³⁾ and 4 October 2019 ⁽⁴⁾, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 25841 does not have an adverse effect on animal health, consumer safety or the environment. It also stated that this preparation should be considered a potential respiratory sensitiser and that it cannot conclude on its irritancy potential to skin and eyes or its dermal sensitisation. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the preparation has the potential to be efficacious in improving zootechnical parameters in the target species. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of *Bacillus subtilis* DSM 25841 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2018;16(4):5199.

⁽³⁾ EFSA Journal 2019;17(11):5882.

⁽⁴⁾ EFSA Journal 2019;17(11):5884.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers' is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Entry into force

This Regulation shall enter into force on the twentieth 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1900	Chr. Hansen A/S	<i>Bacillus subtilis</i> DSM 25841	<p><i>Additive composition</i></p> <p>Preparation of <i>Bacillus subtilis</i> DSM 25841 containing a minimum of $1,25 \times 10^{10}$ CFU/g of additive</p> <p>Solid form</p>	All porcine species, including sows, other than lactating sows in order to have a benefit in suckling piglets	—	5×10^8	—	$1,7 \times 10^8$	—	<ol style="list-style-type: none"> In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. The additive may be used in water for drinking. For use of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use: a potential respiratory sensitiser, potential skin irritant and potential eyes or dermal sensitiser. Where those risks cannot be eliminated or reduced to a 	16.12.2030
<i>Characterisation of the active substance</i>											
Viable spores of <i>Bacillus subtilis</i> DSM 25841											
<i>Analytical method</i> ⁽¹⁾											
<p>For identification of <i>Bacillus subtilis</i> DSM 25841: Identification: Pulsed Field Gel Electrophoresis (PFGE)</p> <p>For enumeration of <i>Bacillus subtilis</i> DSM 25841 in the feed additive, premixtures and feedingstuffs: Spread plate method using tryptone soya agar – EN 15784</p>											

										minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment:	
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(⁴) Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1761**of 25 November 2020****concerning the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 as a feed additive for all animal species****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) This application concerns the authorisation of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.
- (4) The applicant requested the feed additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 in water for drinking should not be allowed. The fact that of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 19 March 2020 ⁽²⁾ that, under the proposed conditions of use L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 do not have adverse effects on animal health, consumer health or the environment. The Authority concluded for L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 that although users' exposure via inhalation is unlikely due to the low dusting potential, the product is proposed to be classified as respiratory irritant due to its low pH when in solution. In addition, based on the results of the studies provided, it should be classified as skin irritant and that it can cause serious eye damage. L-cysteine hydrochloride monohydrate is not a dermal sensitiser. The Authority also concluded, that since L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 is used in food as flavouring, it is to be expected that it can provide a similar function in feed and no further demonstration of efficacy is necessary when used in feed. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of L-cysteine hydrochloride monohydrate produced by fermentation with *Escherichia coli* KCCM 80109 and KCCM 80197 should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(4):6101.

- (7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) 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 substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b920i	-	L-cysteine hydrochloride monohydrate	<p>Additive composition L-cysteine hydrochloride monohydrate</p> <p>Characterisation of the active substance L-cysteine hydrochloride monohydrate Produced by fermentation with <i>Escherichia coli</i> KCCM 80109 and KCCM 80197 Purity: ≥ 98,5 % assay Chemical formula: C₃H₇NO₂S•HClH₂O CAS number: 7048-04-6. FLAVIS number: 17.032</p> <p>Method of analysis ⁽¹⁾ For the identification of L-cysteine hydrochloride monohydrate in the feed additive: ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Ph. Eur. 6.6-2.2.56-Method 1 For the quantification of L-cysteine hydrochloride monohydrate in the feed additive: ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FD) For the quantification of L-cysteine hydrochloride monohydrate in premixtures: ion-exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 ⁽²⁾Annex III, F)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> The additive shall be incorporated into the feed in the form of a premixture. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance of complete feedingstuff with a moisture content of 12 %: 25 mg/kg' The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 25 mg/kg. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those 	16.12.2030

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
								risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and pre-mixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves	

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

⁽²⁾ Commission Regulation (EC) No 152/2009 of 27 January 2009 laying down the methods of sampling and analysis for the official control of feed (OJ L 54, 26.2.2009, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1762

of 25 November 2020

concerning the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding (holder of authorisation Chr. Hansen A/S)

(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of a preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 as a feed additive for all poultry species for fattening or reared for laying or reared for breeding to be classified in the category 'zootechnical additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 20 March 2020 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 does not have an adverse effect on animal health, consumer safety or the environment. It also concluded that in the absence of data, no conclusions on the skin/eye irritancy or skin sensitisation of the additive can be made, and due to the proteinaceous nature of the active agents, the additive should be considered a respiratory sensitiser. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. The Authority also concluded that the product has the potential to be efficacious as zootechnical additive in feedingstuffs and water for drinking. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) The assessment of the preparation of *Bacillus subtilis* DSM 32324, *Bacillus subtilis* DSM 32325 and *Bacillus amyloliquefaciens* DSM 25840 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of product should be authorised as specified in the Annex to this Regulation.
- (6) 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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is authorised as an additive in animal nutrition, subject to the conditions laid down in that Annex.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2020;18(4):6094.

Article 2

This Regulation shall enter into force on the twentieth 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Minimum content	Maximum content	Other provisions	End of period of authorisation
						CFU/kg of complete feedingstuff with a moisture content of 12 %		CFU/l of water for drinking			

Category of zootechnical additives. Functional group: gut flora stabilisers

4b1894	Chr. Hansen A/S	<i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840	<p><i>Additive composition</i> Preparation of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840 containing a minimum of: 3,2 × 10⁹ CFU/g additive (1,6 × 10⁹ CFU <i>B. subtilis</i> DSM 32324/g; 1,0 × 10⁹ CFU <i>B. subtilis</i> DSM 32325/g and 0,6 × 10⁹ CFU <i>B. amyloliquefaciens</i> DSM 25840/g)</p> <p><i>Characterisation of the active substance</i> Viable spores of cells of <i>Bacillus subtilis</i> DSM 32324, <i>Bacillus subtilis</i> DSM 32325 and <i>Bacillus amyloliquefaciens</i> DSM 25840</p> <p><i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive, premixtures, feedingstuffs and water: Spread plate method on tryptone soya agar (EN 15784). Identification: Pulsed Field Gel Electrophoresis (PFGE) method.</p>	All poultry species for fattening or reared for laying or reared for breeding	—	1,6 × 10 ⁹	—	5,4 × 10 ⁸	—	<ol style="list-style-type: none"> 1. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 2. For use of the additive in water for drinking the homogenous dispersion of the additive shall be ensured. 3. May be used in feed containing the permitted coccidiostats: diclazuril, decoquinone and halofuginone. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, glasses and gloves. 	16.12.2030
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1763**of 25 November 2020****approving formaldehyde as an existing active substance for use in biocidal products of product-types 2 and 3****(Text with EEA relevance)**

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 the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes formaldehyde.
- (2) Formaldehyde has been evaluated for use in biocidal products of product-type 2, private area and public health area disinfectants and other biocidal products, and product-type 3, veterinary hygiene biocidal products, as described in Annex V to Directive 98/8/EC of the European Parliament and of the Council ⁽³⁾, which correspond respectively to product-types 2 and 3 as described in Annex V to Regulation (EU) No 528/2012.
- (3) The evaluating competent authority of Germany submitted the assessment reports together with its conclusions to the Commission on 29 July 2013.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the opinions of the European Chemicals Agency ⁽⁴⁾ (the 'Agency') were adopted on 10 December 2019 by the Biocidal Products Committee, having regard to the conclusions of the evaluating competent authority.
- (5) It can be derived from Article 90(2) of Regulation (EU) No 528/2012 that substances for which the Member States' evaluation has been completed by 1 September 2013 should be evaluated in accordance with the provisions of Directive 98/8/EC.
- (6) According to the opinions of the Agency, biocidal products of product-types 2 and 3 containing formaldehyde may be expected to satisfy the requirements of Article 5 of Directive 98/8/EC, provided that certain specifications and conditions concerning their use are complied with.
- (7) It is therefore appropriate to approve formaldehyde for use in biocidal products of product-types 2 and 3, subject to compliance with certain specifications and conditions.
- (8) The opinions of the Agency conclude that formaldehyde meets the criteria for classification as carcinogen category 1B in accordance with Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁵⁾.
- (9) Since formaldehyde should be approved under the terms of Directive 98/8/EC, taking into account that property, the period of approval should be considerably shorter than 10 years, in accordance with the latest practice established under that Directive. In addition, since formaldehyde has benefitted from the transitional period provided for in Article 89 of Regulation (EU) No 528/2012 since 14 May 2000 and has been under peer review since 29 July 2013,

⁽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).

⁽³⁾ Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁽⁴⁾ Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 2, ECHA/BPC/232/2019, adopted on 10 December 2019; Biocidal Products Committee (BPC) opinion on the application for approval of the active substance Formaldehyde, Product type: 3, ECHA/BPC/233/2019, adopted on 10 December 2019.

⁽⁵⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

and with the view to examine at Union level as soon as possible in the context of a potential renewal of approval whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied for formaldehyde, the period of approval should be three years.

- (10) Furthermore, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the competent authorities of the Member States should evaluate whether the conditions of Article 5(2) of that Regulation can be satisfied in their territories in order to decide whether a biocidal product containing formaldehyde can be authorised.
- (11) For the purposes of Article 23 of Regulation (EU) No 528/2012, formaldehyde meets the conditions laid down in point (a) of Article 10(1) of that Regulation and should therefore be considered a candidate for substitution. The competent authorities of the Member States should therefore perform a comparative assessment as part of the evaluation of an application for authorisation or for renewal of authorisation of a biocidal product containing formaldehyde.
- (12) Since, as concluded by the Agency, formaldehyde meets the criteria for classification as carcinogen category 1B and as skin sensitiser category 1 in accordance with Annex I to Regulation (EC) No 1272/2008, treated articles treated with or incorporating formaldehyde should be appropriately labelled when placed on the market.
- (13) This Regulation does not affect the application of Union law in the area of health and safety at work, in particular Council Directives 89/391/EEC ⁽⁶⁾ and 98/24/EC ⁽⁷⁾, and Directive 2004/37/EC of the European Parliament and of the Council ⁽⁸⁾.
- (14) A reasonable period should be allowed to elapse before an active substance is approved in order to permit interested parties to take the preparatory measures necessary to meet the new requirements.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Biocidal Products,

HAS ADOPTED THIS REGULATION:

Article 1

Formaldehyde is approved as an active substance for use in biocidal products of product-types 2 and 3, subject to the specifications and conditions set out in the Annex.

Article 2

This Regulation shall enter into force on the twentieth 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁶⁾ Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work (OJ L 183, 29.6.1989, p. 1).

⁽⁷⁾ Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC) (OJ L 131, 5.5.1998, p. 11).

⁽⁸⁾ Directive 2004/37/EC of the European Parliament and of the Council of 29 April 2004 on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16(1) of Council Directive 89/391/EEC) (OJ L 158, 30.4.2004, p. 50).

ANNEX

Common Name	IUPAC Name Identification Numbers	Minimum degree of purity of the active substance ⁽¹⁾	Date of approval	Expiry date of approval	Product type	Specific conditions
Formaldehyde	IUPAC Name: Methanal EC No: 200-001-8 CAS No: 50-00-0	25–55,5 % formaldehyde in aqueous solution (minimum purity 87,5 % w/w with regard to formaldehyde)	1 February 2022	31 January 2025	2	<p>Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10 of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to: <ol style="list-style-type: none"> professional users for products used for disinfection by mopping and wiping of surfaces; secondary exposure of the general public and children; the aquatic environment for products used for room disinfection by fumigation in epidemic cases. <p>The placing on the market of treated articles is subject to the following condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.</p>
					3	<p>Formaldehyde is considered a candidate for substitution in accordance with point (a) of Article 10(1) of Regulation (EU) No 528/2012.</p> <p>The authorisations of biocidal products are subject to the following conditions:</p> <ol style="list-style-type: none"> The product assessment shall pay particular attention to the exposures, the risks and the efficacy linked to any uses covered by an application for authorisation, but not addressed in the Union level risk assessment of the active substance. In addition, pursuant to point 10

					<p>of Annex VI to Regulation (EU) No 528/2012, the product assessment shall include an evaluation as to whether the conditions of Article 5(2) of Regulation (EU) No 528/2012 can be satisfied.</p> <p>2. Products shall only be authorised for use in Member States where at least one of the conditions set in Article 5(2) of Regulation (EU) No 528/2012 is met.</p> <p>3. In view of the risks identified for the uses assessed, the product assessment shall pay particular attention to:</p> <ul style="list-style-type: none"> (i) professional users for products used for disinfection by spraying of animal housing and of vehicles in epidemic cases; (ii) secondary exposure of the general public; (iii) surface water, sediment, soil and groundwater following use of products for disinfection of vehicles and disinfection of animal's feet by bathing or dipping. <p>4. For products that may lead to residues in food or feed, it shall be verified whether new maximum residue levels (MRLs) need to be set or the existing MRLs need to be amended in accordance with Regulation (EC) No 470/2009 of the European Parliament and of the Council ⁽²⁾ or Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾, and any appropriate risk mitigation measures shall be taken to ensure that the applicable MRLs are not exceeded.</p> <p>The placing on the market of treated articles is subject to the condition that the person responsible for the placing on the market of a treated article treated with or incorporating formaldehyde shall ensure that the label of that treated article provides the information listed in the second subparagraph of Article 58(3) of Regulation (EU) No 528/2012.</p>
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⁽¹⁾ The purity indicated in this column was the minimum degree of purity of the active substance evaluated. The active substance in the product placed on the market can be of equal or different purity if it has been proven to be technically equivalent to the evaluated active substance.

⁽²⁾ Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

⁽³⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1764**of 25 November 2020****concerning the authorisation of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 as a feed additive for all animal species****(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 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ⁽¹⁾, and in particular Article 9(2) thereof,

Whereas:

- (1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161. This application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) This application concerns the authorisation of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 as a feed additive for all animal species. The applicant requested this additive to be classified in the additive category 'sensory additives'.
- (4) The applicant requested the feed additive to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 in water for drinking should not be allowed. The fact that the additive is not authorised for use as a flavouring in water for drinking does not preclude its use in compound feed administered via water.
- (5) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 May 2020 ⁽²⁾ that, under the proposed conditions of use, disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 does not have adverse effects on animal health, consumer health or the environment. The Authority concluded in the opinion that the additive is not toxic by inhalation, not irritant to skin or eyes and is not a dermal sensitiser. The Authority also concluded that the effect of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 to increase the taste of food is well proven, and therefore, no further demonstration of its efficacy in feed is necessary. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) The assessment of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of disodium 5'-inosinate produced by fermentation with *Corynebacterium stationis* KCCM 80161 should be authorised as specified in the Annex to this Regulation.
- (7) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additive. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2020;18(5):6140.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'flavouring compounds', is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the twentieth 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, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			

Category: Sensory additives**Functional group: Flavouring compounds**

2b631i	-	Disodium 5'-inosinate	<p><i>Additive composition</i> Disodium 5'-inosinate</p> <p><i>Characterisation of the active substance</i> Disodium 5'-inosinate Produced by fermentation with <i>Corynebacterium stationis</i> (KCCM 80161) Purity: ≥ 97 % (% assay) Chemical formula: C₁₀H₁₁N₄Na₂O₈P·7.5H₂O CAS number 4691-65-0</p> <p><i>Method of analysis</i> ⁽¹⁾ For the identification of disodium 5'-inosinate in the feed additive: FAO JECFA monographs 'disodium 5'-inosinate' and 'disodium 5'-ribonucleotides'. For the determination of disodium 5'-inosinate (IMP) in the feed additive and flavouring premixtures: high performance liquid chromatography coupled to UV detection (HPLC-UV)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> The additive shall be incorporated into the feed in the form of a premixture. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. On the label of the additive the following shall be indicated: 'Recommended maximum content of the active substance alone or in combination with other authorised disodium 5'-ribonucleotides shall be: 50 mg/kg of complete feedingstuff with a moisture content of 12 %'. The functional group, the identification number, the name and the added amount of the active substance shall be indicated on the label of the premixtures, if the following content of the active substance in complete feedingstuff with a moisture content of 12 % is exceeded: 50 mg/kg. 	16.12.2030
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⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports>

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/1765

of 25 November 2020

not approving chlorophene as an existing active substance for use in biocidal products of product-type 2

(Text with EEA relevance)

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 the third subparagraph of Article 89(1) thereof,

Whereas:

- (1) Commission Delegated Regulation (EU) No 1062/2014 ⁽²⁾ establishes a list of existing active substances to be evaluated for their possible approval for use in biocidal products. That list includes chlorophene (EC No: 204-385-8; CAS No 120-32-1).
- (2) Chlorophene has been evaluated for use in biocidal products of product-type 2, disinfectants and algaecides not intended for direct application to humans or animals, as described in Annex V to Regulation (EU) No 528/2012.
- (3) Norway was designated as a rapporteur State and its evaluating competent authority submitted the assessment report together with its conclusions to the European Chemicals Agency ('Agency') on 22 December 2016.
- (4) In accordance with Article 7(2) of Delegated Regulation (EU) No 1062/2014, the Biocidal Products Committee adopted the opinion of the Agency on 4 March 2020 ⁽³⁾, having regard to the conclusions of the evaluating competent authority.
- (5) According to that opinion, biocidal products of product-type 2 containing chlorophene may not be expected to meet the criteria laid down in Article 19(1)(b) of Regulation (EU) No 528/2012 as the human health risk assessment identified unacceptable risks.
- (6) Taking into account the opinion of the Agency, it is not appropriate to approve chlorophene for use in biocidal products of product-type 2.
- (7) 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

Chlorophene (EC No: 204-385-8, CAS No: 120-32-1) is not approved as an active substance for use in biocidal products of product-type 2.

⁽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).

⁽³⁾ Biocidal Products Committee Opinion on the application for approval of the active substance: Chlorophene, Product type: 2, ECHA/BPC/238/2020, adopted on 4 March 2020.

Article 2

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

Done at Brussels, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

COMMISSION IMPLEMENTING DECISION (EU) 2020/1766**of 25 November 2020****determining, for a limited period of time, that the regulatory framework applicable to central securities depositories of the United Kingdom of Great Britain and Northern Ireland is equivalent in accordance with Regulation (EU) No 909/2014 of the European Parliament and of the Council**

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 909/2014 of the European Parliament and of the Council of 23 July 2014 on improving securities settlement in the European Union and on central securities depositories and amending Directives 98/26/EC and 2014/65/EU and Regulation (EU) No 236/2012 ⁽¹⁾ and in particular Article 25(9) thereof,

Whereas:

- (1) On 29 March 2017, the United Kingdom of Great Britain and Northern Ireland (the 'United Kingdom') submitted the notification of its intention to withdraw from the Union pursuant to Article 50 of the Treaty on European Union. On 17 October 2019, the Union and the United Kingdom reached an agreement on the withdrawal of the United Kingdom from the Union ⁽²⁾ ('the Withdrawal Agreement'), with a revised Protocol on Ireland/Northern Ireland, and a revised Political Declaration ⁽³⁾. Pursuant to the Withdrawal Agreement and following its ratification by the House of Commons in the United Kingdom, its adoption by the European Parliament and its conclusion by the Council, the United Kingdom became a third country on 1 February 2020 and Union law will cease to apply to and in the United Kingdom on 31 December 2020.
- (2) Central securities depositories ('CSDs') are instrumental to financial markets. The recording of securities in a book-entry system ('notary services') and the maintenance of securities accounts at the top tier level ('central maintenance services') increase transparency and protect investors, as they ensure the integrity of the securities issue by preventing the undue creation or reduction of issued securities. CSDs also operate securities settlement systems, which ensure that securities transactions are settled properly and in a timely manner. Those functions are critical in the post-trade clearing and settlement processes. Securities settlement systems are essential also to monetary policy as they are closely involved in securing collateral for monetary policy operations.
- (3) From 1 January 2021, CSDs established in the United Kingdom ('UK CSDs') will be considered third-country CSDs within the meaning of Regulation (EU) No 909/2014. As such, they may not provide notary and central maintenance services in relation to financial instruments constituted under the law of a Member State unless they are recognised by the European Securities and Markets Authority (ESMA) in accordance with Article 25 of that Regulation. In the absence of such recognition, Union issuers may not use UK CSDs to perform notary and central maintenance services concerning transferable securities constituted under the law of a Member State. Such a situation may result in temporary challenges for Union issuers to fulfil their legal obligations, as those services provided by UK CSDs in relation to corporate securities and exchange-traded funds constituted under the domestic law of Ireland ('Irish corporate securities and ETFs') are currently not provided by CSDs authorised in the Union ('Union CSDs'). It is therefore justified and in the interest of the Union and its Member States to ensure that UK CSDs may continue to provide services in the Union after 31 December 2020 for a limited period of time.
- (4) ESMA may only recognise a CSD established in a third country where the Commission has adopted an implementing act determining that the legal and supervisory arrangements governing that CSD are equivalent to the requirements laid down in Regulation (EU) No 909/2014. In view of the risk of the United Kingdom withdrawing from the Union

⁽¹⁾ OJ L 257, 28.8.2014, p. 1.

⁽²⁾ Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community (OJ L 29, 31.1.2020, p. 7).

⁽³⁾ Political declaration setting out the framework for the future relationship between the European Union and the United Kingdom (OJ C 34, 31.1.2020, p. 1).

without the conclusion of a withdrawal agreement, Commission Implementing Decision (EU) 2018/2030 (*) granted equivalence to the legal and supervisory framework of the United Kingdom for the period until 30 March 2021. As a consequence of the conclusion of the Withdrawal Agreement, that Implementing Decision never became applicable. Union CSDs are very advanced in the process of developing services in relation to Irish corporate securities and ETFs, to allow Union issuers to migrate their positions, but that work will not be fully finalised when Union law ceases to apply to and in the United Kingdom on 31 December 2020. It is therefore necessary and in the interest of the Union and its Member States that the legal and supervisory arrangements governing UK CSDs are determined as equivalent to the requirements laid down in Regulation (EU) No 909/2014 for a period of six months.

- (5) In accordance with Article 25(9) of Regulation (EU) No 909/2014, three conditions are to be fulfilled in order to determine that the legal and supervisory arrangements of a third country regarding CSDs established therein are equivalent to those laid down in that Regulation.
- (6) First, the legal and supervisory arrangements of the third country must ensure that CSDs in that third country comply with legally binding requirements which are in effect equivalent to the requirements laid down in Regulation (EU) No 909/2014. Until the end of the transition period on 31 December 2020, UK CSDs must comply with the requirements laid down in Regulation (EU) No 909/2014. On 26 June 2018, the United Kingdom incorporated the provisions of Regulation (EU) No 909/2014 into its domestic law with effect from the end of the transition period.
- (7) Second, the legal and supervisory arrangements of the third country must ensure that CSDs established in that third country are subject to effective supervision, oversight and enforcement on an ongoing basis. Until the end of the transition period on 31 December 2020, UK CSDs are under the supervision of the Bank of England, as determined in United Kingdom domestic law in accordance with Regulation (EU) No 909/2014. As part of the incorporation of the provisions set out in Regulation (EU) No 909/2014 into United Kingdom domestic law, the Bank of England will remain responsible for the supervision of CSDs from the end of the transition period and there are, for the moment, no indications that any important changes to that supervision are foreseen.
- (8) Third, the legal framework of the third country must provide for an effective equivalent system for the recognition of CSDs authorised under third-country legal regimes. This is ensured by the incorporation of the provisions set out in Article 25 of Regulation (EU) No 909/2014 into United Kingdom domestic law. Furthermore, the United Kingdom has introduced specific transitional provisions, which enable a third-country CSD to provide notary and central maintenance services in the United Kingdom during a period of at least six months after the United Kingdom has determined the equivalence of that third-country framework.
- (9) On that basis, it can be concluded that the legal and supervisory arrangements of the United Kingdom which will be applicable to UK CSDs after the end of the transition period referred to in Article 126 of the Withdrawal Agreement meet the conditions laid down in Article 25(9) of Regulation (EU) No 909/2014.
- (10) This Decision is based on the information currently available about the legal and supervisory arrangements applicable to UK CSDs from 1 January 2021. In view of the United Kingdom's announcement that certain requirements that will come into force under the Union legal framework in the future will not be incorporated in its domestic law, the legal and supervisory arrangements currently in place in the United Kingdom can only be deemed as equivalent for a limited period of time. Given the United Kingdom's announcement about the future divergence as regards the legal and supervisory arrangements applicable to UK CSDs, market participants are expected to prepare for a situation without a further equivalence decision in this area.
- (11) The conclusion of comprehensive and effective cooperation arrangements between ESMA and the Bank of England in accordance with Article 25(10) of Regulation (EU) No 909/2014 ensures the pro-active exchange of information and coordination of supervisory activities. In particular, those arrangements must ensure that ESMA on an ongoing basis has immediate access in all situations, including emergency situations, to all information requested by it.

(*) Commission Implementing Decision (EU) 2018/2030 of 19 December 2018 determining, for a limited period of time, that the regulatory framework applicable to central securities depositories of the United Kingdom of Great Britain and Northern Ireland is equivalent in accordance with Regulation (EU) No 909/2014 of the European Parliament and of the Council (OJ L 325, 20.12.2018, p. 47).

Those cooperation arrangements also ensure that ESMA may share all relevant information with the authorities referred to in Article 25(5) of Regulation (EU) No 909/2014 for the purpose of consulting them about the recognised status of UK CSDs or where that information is necessary for those authorities to carry out their supervisory tasks.

- (12) The United Kingdom's authorities are expected to inform the Union about all changes to the United Kingdom's legal or supervisory framework affecting the provision of notary and central maintenance services in the United Kingdom. The Commission, in cooperation with ESMA, will monitor any changes introduced in the legal and supervisory arrangements affecting the provision of such services in the United Kingdom, market developments as well as the effectiveness of supervisory cooperation, including prompt information exchange between ESMA and the Bank of England. The Commission may undertake a review at any time where relevant developments make it necessary for the Commission to re-assess the equivalence granted by this Decision, including where the United Kingdom's authorities do not effectively cooperate, do not allow for an effective assessment of the risk that UK CSDs pose to the Union or its Member States or the actions taken by UK CSDs or the Bank of England promote undue and unfair competition.
- (13) In the interest of the Union and its Member States, and in order to give Union CSDs the time needed to develop further their offer of services in relation to Irish corporate securities and ETFs, and Union issuers the time needed to migrate their positions to Union CSDs, this Decision should expire six months after its date of application.
- (14) This Decision should enter into force as a matter of urgency in order to ensure legal certainty for Union issuers ahead of the end of the transition period in accordance with the Withdrawal Agreement. It should apply from the day following that on which Union law ceases to apply to and in the United Kingdom.
- (15) The measures provided for in this Decision are in accordance with the opinion of the European Securities Committee,

HAS ADOPTED THIS DECISION:

Article 1

For the purposes of Article 25 of Regulation (EU) No 909/2014, the legal and supervisory arrangements of the United Kingdom of Great Britain and Northern Ireland applicable to central securities depositories already established and authorised in the United Kingdom of Great Britain and Northern Ireland shall be considered to be equivalent to the requirements laid down in Regulation (EU) No 909/2014.

Article 2

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

It shall apply from 1 January 2021.

It shall expire on 30 June 2021.

Done at Brussels, 25 November 2020.

For the Commission
The President
Ursula VON DER LEYEN

CORRIGENDA

Corrigendum to the Agreement between the European Union and the Government of the Republic of Indonesia on certain aspects of air services

(Official Journal of the European Union L 264 of 8 October 2011)

On page 6, in Annex 1, thirteenth indent:

for: 'Air Transport Agreement between the Government of the Kingdom of the Netherlands and the Government of the Republic of Indonesia, signed at The Hague on 23 November 1990, hereinafter referred to as the "Indonesia — Netherlands Agreement" in Annex 2;'

read: 'Air Transport Agreement between the Government of the Kingdom of the Netherlands and the Government of the Republic of Indonesia, signed at The Hague on 23 November 1990, as modified by the Memorandum of Understanding done at The Hague on 19 August 2009, hereinafter referred to as the "Indonesia — Netherlands Agreement" in Annex 2;'

On page 9, in Annex 2, Part (b) (Refusal, revocation, suspension of limitation of authorisations or permissions), twelfth indent:

for: 'Articles 3 and 4 of the Indonesia — Netherlands Agreement;'

read: 'Article 4 of the Indonesia — Netherlands Agreement;'

On page 9, in Annex 2, Part (c) (Safety), twelfth indent:

for: 'Annex IV of the Memorandum of Understanding between the aeronautical authorities of the Republic of Indonesia and the Kingdom of the Netherlands done at The Hague on 19 August 2009;'

read: 'Annex IV of the Memorandum of Understanding done at The Hague on 19 August 2009;'

Corrigendum to Commission Regulation (EU) 2020/1683 of 12 November 2020 amending Annexes II and III to Regulation (EC) No 1223/2009 of the European Parliament and of the Council on cosmetic products

(Official Journal of the European Union L 379 of 13 November 2020)

On page 38, Annex, point 2(b), the table is replaced as follows:

Reference number	Substance identification				Restrictions			Wordings of conditions of use and warnings
	Chemical name/INN	Name of Common Ingredients Glossary	CAS number	EC number	Product type, body parts	Maximum concentration in ready use preparation	Other	
a	b	c	d	e	f	g	h	i
315	4-(3-aminopyrazolo[1,5-A]pyridin-2-yl)-1,1-dimethylpiperazin-1-ium chloride hydrochloride	Dimethylpiperazinium Aminopyrazolopyridine HCl	1256553-33-9	813-255-5	Hair dye substance in oxidative hair dye products		As from 3 June 2021, after mixing under oxidative conditions the maximum concentration applied to hair must not exceed 2 % (calculated as free base)	As from 3 December 2021, to be printed on the label: The mixing ratio. ⚠ Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.’
316	1-(3-((4-Aminophenyl)amino)propyl)-3-methyl-1H-imidazol-3-ium chloride hydrochloride	Methylimidazoliumpropyl p-phenylenediamine HCl	220158-86-1		Hair dye substance in oxidative hair dye products		As from 3 June 2021, after mixing under oxidative conditions the maximum concentration	As from 3 December 2021, to be printed on the label: The mixing ratio. ⚠ Hair colorants can cause severe allergic reactions.

							applied to hair must not exceed 2 % (calculated as free base)	Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy. Do not colour your hair if: <ul style="list-style-type: none"> — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.’
317	Di-[2-[(E)-2-[4-[bis(2-hydroxyethyl)aminophenyl]vinyl]pyridin-1-ium]-ethyl]disulphide dimethanesulfonate	HC Orange No 6	1449653-83-1		Hair dye substance in non-oxidative hair dye products	As from 3 June 2021: 0,5 %	Methanesulfonates impurities, in particular ethyl methanesulfonate shall not be present.	
318	Sodium 4-[(2-hydroxy-1-naphthyl)azo]benzene sulfonate	Acid Orange 7	633-96-5	211-199-0	Hair dye substance in non-oxidative hair dye products	As from 3 June 2021: 0,5 %		
319	Phenol, 4,4'-(4,5,6,7-tetrabromo-1,1-dioxido-3H-2,1-benzoxathiol-3-ylidene)bis [2,6-dibromo-	Tetrabromophenol Blue	4430-25-5	224-622-9	(a) Hair dye substance in oxidative hair dye products (b) Hair dye substance in non-oxidative hair dye products	(b) As from 3 June 2021: 0,2 %	(a) As from 3 June 2021, after mixing under oxidative conditions the maximum concentration applied to hair must not exceed 0,2 % (calculated as free base)	(a) As from 3 December 2021, to be printed on the label: The mixing ratio.  Hair colorants can cause severe allergic reactions. Read and follow instructions. This product is not intended for use on persons under the age of 16. Temporary “black henna” tattoos may increase your risk of allergy.

								Do not colour your hair if: — you have a rash on your face or sensitive, irritated and damaged scalp, — you have ever experienced any reaction after colouring your hair, — you have experienced a reaction to a temporary “black henna” tattoo in the past.’
320	<i>Indigofera tinctoria</i> , dried and pulverised leaves of <i>Indigofera tinctoria</i> L	<i>Indigofera tinctoria</i> leaf <i>Indigofera tinctoria</i> leaf powder <i>Indigofera tinctoria</i> leaf extract <i>Indigofera tinctoria</i> extract	84775-63-3	283-892-6	Hair dye substance in non-oxidative hair dye products	As from 3 June 2021: 25 %		

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