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⁽¹⁾ Text with EEA relevance.

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⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1090

of 24 July 2020

concerning the authorisation of L-histidine monohydrochloride monohydrate 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 three applications were submitted for the authorisation of L-histidine monohydrochloride monohydrate. The applications were accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) The applications concern the authorisation of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives'. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 and *Corynebacterium glutamicum* KCCM 80179 are also applied for the additive category 'sensory additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinions of 2 July 2019 ⁽²⁾ ⁽³⁾ ⁽⁴⁾ that, under the proposed conditions of use, L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179, when supplemented at levels appropriate to the requirements of the target species, does not have an adverse effect on animal health, consumer safety or the environment. This conclusion covers also the use of L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 as sensory additive at the intended use level. With respect to the safety of the user of the additive, the Authority stated only a mild irritation risk to the eyes for L-histidine monohydrochloride monohydrate produced by *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179. For L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* NITE BP-02526, the Authority stated a risk by inhalation. Therefore, appropriate protective measures should be taken for this additive to prevent adverse effects on human health, in particular as regards the users of the additive. Further, the Authority concluded that L-histidine

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2019; 17(7):5783.⁽³⁾ EFSA Journal 2019; 17(7):5784.⁽⁴⁾ EFSA Journal 2019; 17(8):5785.

monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 is an efficacious source of the essential amino acid L-histidine for animal nutrition and that in order to be efficacious in ruminants, the additive should be protected against degradation in the rumen. Moreover, the Authority concluded that L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 is efficacious as feed flavouring compound.

- (5) 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.
- (6) Restrictions and conditions should be provided for to allow for a better control for those additives when used as flavourings. For these additives used as flavourings recommended contents should be indicated on the label. Where such contents are exceeded, certain information should be indicated on the label of premixtures. The use of L-histidine monohydrochloride monohydrate as a flavouring compound is not authorised in water for drinking. The fact that L-histidine monohydrochloride monohydrate is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.
- (7) The assessment of that substance 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 substance should be authorised as specified in the Annex to this Regulation.
- (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

1. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526, *Corynebacterium glutamicum* KCCM 80172 or *Corynebacterium glutamicum* KCCM 80179 specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues' are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.
2. L-histidine monohydrochloride monohydrate produced by *Escherichia coli* NITE BP-02526 or *Corynebacterium glutamicum* KCCM 80179 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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: amino acids, their salts and analogues

3c352	-	L-histidine monohydrochloride monohydrate	Additive composition: Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine	All animal species	-	-	-	1. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive can be also used via water for drinking. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m ³ air (?). 4. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks for the eyes and skin and by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment. 5. In the directions for use of the additive and premixture, the storage conditions, the stability to heat treatment and the stability in water for drinking shall be indicated.	16.8.2030
			Characterisation of the active substance: L-histidine monohydrochloride monohydrate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80172 or <i>Corynebacterium glutamicum</i> KCCM 80179 or <i>Escherichia coli</i> NITE BP-02526 Chemical formula: C ₃ H ₃ N ₂ -CH ₂ -CH(NH ₂)-COOH·HCl·H ₂ O CAS number: 5934-29-2						
			Analytical method ⁽¹⁾: For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV) — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD)						

			For the quantification of histidine in pre-mixtures, feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of histidine in water: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS/FLD)					6. Declaration to be made on the label of the additive and premixture: ‘The supplementation with L-histidine monohydrochloride monohydrate, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.’ — Histidine content.	
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Category: Sensory additives. Functional group: Flavouring compounds

3c352	-	L-histidine monohydrochloride monohydrate	Additive composition: Powder with a minimum content of 98 % L-histidine monohydrochloride monohydrate and 72 % histidine and a maximum content of 100 ppm histamine Characterisation of the active substance: L-histidine monohydrochloride monohydrate produced by fermentation with <i>Corynebacterium glutamicum</i> KCCM 80179 or <i>Escherichia coli</i> NITE BP-02526. Chemical formula: $C_3H_3N_2-CH_2-CH(NH_2-COOH \cdot HCl \cdot H_2O)$ CAS number: 5934-29-2 Analytical method ⁽¹⁾: For the quantification of histidine in the feed additive: — high performance liquid chromatography coupled with photometric detection (HPLC-UV)	All animal species	-	-	-	1. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 2. The additive shall be incorporated into the feed in the form of a premixture. 3. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1 600 IU endotoxins/m³ air ⁽²⁾. 4. For users of the additive and premixture, feed business operators shall establish operational procedures and organisational measures to address potential risks for the eyes and skin and by inhalation. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixture shall be used with personal protective equipment.	16.8.2030
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		— ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of histidine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) or — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F) For the quantification of histidine in feed materials and compound feed: — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F)					5. In the directions for use of the additive and premixture, the storage conditions and the stability to heat treatment shall be indicated. 6. 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 histidine content. 7. 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.	
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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>

⁽²⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

⁽³⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (EFSA Journal 2017;15(3):4705); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1091
of 24 July 2020
concerning the authorisation of L-threonine 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-threonine produced by *Escherichia coli* CGMCC 11473 as a feed additive for use in feed for all animal species. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation.
- (3) This application concerns the authorisation of L-threonine produced by *Escherichia coli* CGMCC 11473 as a feed additive for all animal species to be classified in the additive category 'nutritional additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 5 July 2017 ⁽²⁾ combined with the opinion of 4 October 2019 ⁽³⁾ that, under the proposed conditions of use, L-threonine produced by *Escherichia coli* CGMCC 11473 does not have an adverse effect on animal health, consumer health or the environment. It also could not conclude on the potential of L-threonine produced by *Escherichia coli* CGMCC 11473 to be a skin sensitiser and irritant to the skin and eyes, and stated an inhalation risk to endotoxins for the users of the additive. Therefore, 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 additive is an efficacious source of the amino acid L-threonine for all animal species and that in order to be as efficacious in ruminants as in non-ruminant species, the additive should be protected against degradation in the rumen. 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 L-threonine produced by *Escherichia coli* CGMCC 11473 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of this additive 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,

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2017;15(7):4939.

⁽³⁾ EFSA Journal 2019;17(11):5885.

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an 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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

Identifica- tion number of the additive	Name of the holder of authorisa- tion	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/kg of complete feed with a moisture content of 12 %			

Category of nutritional additives. Functional group: amino acids, their salts and analogues

3c411	-	L-threonine	Additive composition: Powder with a minimum of 98 % L-threonine and a maximum moisture content of 1 %	All species	-	-	-	1. L- threonine may be placed on the market and used as an additive consisting of a preparation. 2. L-threonine may be used via water for drinking. 3. 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 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, safety glasses and gloves. 4. The endotoxin content of the additive and its dusting potential shall ensure a maximal endotoxin exposure of 1600 IU endotoxins/m ³ air ⁽²⁾ .	16.8.2030
			Characterisation of the active substance: L-threonine produced by fermentation with <i>Escherichia coli</i> CGMCC 11473 Chemical formula: C ₄ H ₉ NO ₃ CAS Number: 72-19-5.						
			Analytical methods ⁽¹⁾: For the determination of L-threonine in the feed additive: — Food Chemical Codex 'L-threonine monograph' and — Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180. For the determination of threonine in premixtures: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) – EN ISO 17180 and — ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS), Commission Regulation (EC) No 152/2009 (Annex III, F).						

			For the determination of threonine in compound feed and feed materials: — Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS): Commission Regulation (EC) No 152/2009 (Annex III, F). For the determination of threonine in water: — ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD).					5. The labelling of the additive and premixtures shall indicate the following: ‘The supplementation with L-threonine, in particular via water for drinking, should take into account all essential and conditional essential amino acids in order to avoid imbalances.’	
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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>

⁽²⁾ Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by EFSA (*EFSA Journal* 2017;15(7):4939); analytical method: European Pharmacopoeia 2.6.14. (bacterial endotoxins).

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1092

of 24 July 2020

amending Implementing Regulation (EU) No 1263/2011 as regards the authorisation of *Lactococcus lactis* (NCIMB 30160) 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 13(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 or modifying such authorisation.
- (2) The use of *Lactococcus lactis* NCIMB 30160 as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) No 1263/2011 ⁽²⁾.
- (3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of *Lactococcus lactis* (NCIMB 30160) as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. The modification relates to the formulation of the additive, consisting of the inclusion of polyethylene glycol (PEG 4000) in the list of cryoprotectants that can be used for the manufacture of the additive. The request was accompanied by the relevant supporting data.
- (4) The Authority concluded in its opinions of 6 March 2018 ⁽³⁾ and 7 October 2019 ⁽⁴⁾ that, under the proposed conditions of use, preparations of PEG 4000 as an excipient in formulations with *Lactococcus lactis* (NCIMB 30160) do not modify the previous conclusions that the additive does not have an adverse effect on animal health, human health or the environment and that it is efficacious as silage additive. Therefore, no safety concerns are expected when PEG 4000 is used as a cryoprotectant in the additive *Lactococcus lactis* NCIMB 30160 up to a maximum concentration of 0,025 mg PEG 4000/kg silage. The Authority does not consider that there is a need for specific requirements of post-market monitoring.
- (5) The assessment of the proposed modification to the authorisation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.
- (6) Implementing Regulation (EU) No 1263/2011 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The Annex to Implementing Regulation (EU) No 1263/2011 is amended in accordance with the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation of *Lactobacillus buchneri* (DSM 16774), *Lactobacillus buchneri* (DSM 12856), *Lactobacillus paracasei* (DSM 16245), *Lactobacillus paracasei* (DSM 16773), *Lactobacillus plantarum* (DSM 12836), *Lactobacillus plantarum* (DSM 12837), *Lactobacillus brevis* (DSM 12835), *Lactobacillus rhamnosus* (NCIMB 30121), *Lactococcus lactis* (DSM 11037), *Lactococcus lactis* (NCIMB 30160), *Pediococcus acidilactici* (DSM 16243) and *Pediococcus pentosaceus* (DSM 12834) as feed additives for all animal species (OJ L 322, 6.12.2011, p. 3).⁽³⁾ EFSA Journal 2018; 16(3):5218.⁽⁴⁾ EFSA Journal 2019; 17(11):5890.

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

In the Annex to Implementing Regulation (EU) No 1263/2011, the entry concerning the additive with the identification number 1k2082 is replaced by the following:

Identification number of the additive	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
					CFU of additive/kg of fresh material			
Category of technological additives. Functional group: silage additives								
'1k2082	<i>Lactococcus lactis</i> (NCIMB 30160)	<i>Additive composition:</i> Preparation of <i>Lactococcus lactis</i> (NCIMB 30160) containing a minimum of 4 × 10 ¹¹ CFU/g additive One of the following cryoprotectants: ascorbic acid, lactose, mannitol, monosodium glutamate, sodium citrate, whey powder or polyethylene glycol (PEG 4000) <i>Characterisation of the active substance:</i> <i>Lactococcus lactis</i> (NCIMB 30160) <i>Analytical method</i> ⁽¹⁾ : Enumeration: pour plate method using MSR agar (ISO 15214) Identification: Pulsed-Field Gel Electrophoresis (PFGE)	All animal species	-	-	-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1 × 10⁸ CFU/kg fresh material. 3. If used as a cryoprotectant, polyethylene glycol (PEG 4000) shall be used up to a maximum concentration of 0,025 mg/kg silage. 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.	16.8.2030

⁽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) 2020/1093**of 24 July 2020****amending Implementing Regulation (EU) No 686/2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of active substances whose approval expires between 31 March 2025 and 27 December 2028****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC ⁽¹⁾, and in particular Article 19 thereof,

Whereas:

- (1) Commission Implementing Regulation (EU) No 686/2012 ⁽²⁾ allocates the evaluation of active substances to a rapporteur Member State and to a co-rapporteur Member State for the purposes of the renewal procedure. Since the evaluation of active substances whose approval expires between 31 March 2025 and 27 December 2028 has not yet been allocated to a Member State or to a co-rapporteur Member State, it is appropriate to proceed to such allocation.
- (2) That allocation should be made in such a way that a balance is achieved as regards the distribution of the responsibilities and the work between Member States.
- (3) Implementing Regulation (EU) No 686/2012 should therefore be amended accordingly.
- (4) 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

Implementing Regulation (EU) No 686/2012 is amended in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the third 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, 24 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) No 686/2012 of 26 July 2012 allocating to Member States, for the purposes of the renewal procedure, the evaluation of the active substances (OJ L 200, 27.7.2012, p. 5).

ANNEX

The Annex to Implementing Regulation (EU) No 686/2012 is amended as follows:

The following Part D is added:

PART D

Allocation of the evaluation of active substances whose approval expires between 31 March 2025 and 27 December 2028

Active substance	Rapporteur Member State	Co-rapporteur Member State
Alpha-cypermethrin	FR	AT
<i>Bacillus amyloliquefaciens</i> subsp. <i>plantarum</i> strain D747	NL	SK
<i>Bacillus amyloliquefaciens</i> strain MBI 600	NL	SK
<i>Beauveria bassiana</i> strain NPP111B005	BE	RO
<i>Beauveria bassiana</i> strain 147	BE	RO
Bentazone	PL	EL
Bordeaux mixture	IT	PL
Chromafenozide	CZ	MT
Copper hydroxide	IT	PL
Copper oxide	IT	PL
Copper oxychloride	IT	PL
Cyantraniliprole	ES	FI
Fenpicoxamid	SE	BG
Flupyradifurone	EL	PL
Gamma-cyhalothrin	DE	ES
Halauxifen-methyl	HU	SE
Isofetamid	PT	IE
Mandestrobin	SE	NO
Meptyldinocap	HR	DE
Methoxyfenozide	FR	HU
<i>Metschnikowia fructicola</i> strain NRRL Y-27328	NL	HR
Oxathiapiprolin	NO	CZ
Pinoxaden	FI	BE
Propyzamide	DK	DE
Rescalure	IE	PT
Sulfoxaflor	AT	ES
Terpenoid blend QRD 460	FR	DK
Tribasic copper sulphate	IT	PL

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1094**of 24 July 2020****concerning the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows and repealing Regulation (EC) No 896/2009 (holder of authorisation Prosol S.p.A.)****(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 and renewing such authorisation.
- (2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised for 10 years as a feed additive for sows by Commission Regulation (EC) No 896/2009 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of the preparation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 May 2019 ⁽³⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority concluded that *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect under the authorised conditions of use for the animal health, consumers, or the environment. The Authority also concluded that the additive is considered a potential skin and eye irritant and a potential skin and 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.
- (5) The assessment of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 896/2009 of 25 September 2009 concerning the authorisation of a new use of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for sows (holder of the authorisation Prosol SpA) (OJ L 256, 29.9.2009, p. 6).

⁽³⁾ EFSA Journal 2019; 17(6):5719.

- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EC) No 896/2009 should be repealed.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EC) No 896/2009 is repealed.

Article 3

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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
						CFU/kg of complete feedingstuff with a moisture content of 12%			
Category of zootechnical additives. Functional group: gut flora stabilisers.									
4b1710	Prosol S.p.A.	<i>Saccharomyces cerevisiae</i> MUCL 39885	Additive composition Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885 Powder and granulated form containing a minimum of 1 × 10 ⁹ CFU/g additive Characterisation of active substance Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885 Analytical method ⁽¹⁾ Enumeration: pour plate method using chloramphenicol glucose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method	Sows	-	6,4 × 10 ⁹	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	16.8.2030

⁽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) 2020/1095**of 24 July 2020****amending Implementing Regulation (EU) 2015/502 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows****(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 13(3) thereof,

Whereas:

- (1) In accordance with Regulation (EC) No 1831/2003, a preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows was authorised by Commission Implementing Regulation (EU) 2015/502 ⁽²⁾.
- (2) Implementing Regulation (EU) 2015/502 was amended by Commission Implementing Regulation (EU) 2019/146 ⁽³⁾.
- (3) On 8 January 2020, the holder of the authorisation, Micron Bio-systems Ltd, submitted an application pursuant to Article 13(3) of Regulation (EC) No 1831/2003 proposing to amend the name of its representative. The applicant submits that FF Chemicals BV will act as its representative in the Union for the feed additive concerned. The application was accompanied by the relevant supporting data.
- (4) The proposed change of the terms of the authorisation is purely administrative in nature and does not entail a fresh assessment of the additive concerned. The European Food Safety Authority was informed of the application.
- (5) To provide that FF Chemicals BV acts as the representative of the holder of the authorisation, it is necessary to change the terms of the authorisation concerned. Consequently, the name of the representative should be amended in the title of Implementing Regulation (EU) 2015/502 and in the Annex to that Regulation.
- (6) Implementing Regulation (EU) 2015/502 should therefore be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Implementing Regulation (EU) 2015/502

Implementing Regulation (EU) 2015/502 is amended as follows:

- (1) in the title, the words ‘Micron Bio-Systems Ltd, represented by FeedVision BV’ are replaced by the words ‘Micron Bio-Systems Ltd, represented by FF Chemicals BV’;

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) 2015/502 of 24 March 2015 concerning the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows (holder of the authorisation Micron Bio-Systems Ltd, represented by FeedVision BV) (OJ L 79, 25.3.2015, p. 57).

⁽³⁾ Commission Implementing Regulation (EU) 2019/146 of 30 January 2019 amending Implementing Regulation (EU) 2015/502, concerning the authorisation of the preparation of *Saccharomyces cerevisiae* NCYC R404 as a feed additive for dairy cows (OJ L 27, 31.1.2019, p. 12).

- (2) in the second column of the Annex entitled 'Name of the holder of authorisation', the words 'Micron Bio-Systems Ltd, represented by FeedVision BV.' are replaced by the words 'Micron Bio-Systems Ltd, represented by FF Chemicals BV.'.

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, 24 July 2020.

For the Commission

The President

Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1096**of 24 July 2020****concerning the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and repealing Regulation (EU) No 1119/2010 (holder of authorisation Prosol S.p.A.)****(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 and renewing such authorisation.
- (2) The preparation of *Saccharomyces cerevisiae* MUCL 39885 was authorised for 10 years as a feed additive for dairy cows and horses by Commission Regulation (EU) No 1119/2010 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted by the holder of that authorisation for the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses, requesting that additive to be classified in the additive category 'zootechnical additives'. That application was accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 12 November 2019 ⁽³⁾ that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation. The Authority concluded that *Saccharomyces cerevisiae* MUCL 39885 does not have an adverse effect under the authorised conditions of use for the animal health, consumers, and the environment. The Authority also concluded that the additive is considered a potential skin and eye irritant and skin/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.
- (5) The assessment of *Saccharomyces cerevisiae* MUCL 39885 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.
- (6) As a consequence of the renewal of the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive under the conditions laid down in the Annex to this Regulation, Regulation (EU) No 1119/2010 should be repealed.
- (7) 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⁾ Commission Regulation (EU) No 1119/2010 of 2 December 2010 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for dairy cows and horses and amending Regulation (EC) No 1520/2007 (holder of the authorisation Prosol SpA) (OJ L 317, 3.12.2010, p. 9).

⁽³⁾ EFSA Journal 2019; 17(11):5915.

HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'gut flora stabilisers', is renewed subject to the conditions laid down in that Annex.

Article 2

Regulation (EU) No 1119/2010 is repealed.

Article 3

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

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
						CFU/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: gut flora stabilisers									
4b1710	Prosol S.p.A.	Saccharomyces cerevisiae MUCL 39885	Additive composition Preparation of <i>Saccharomyces cerevisiae</i> MUCL 39885 Powder and granulated form containing a minimum of 1 × 10 ⁹ CFU/g additive	Horses	-	3 × 10 ⁹	-	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their 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 skin, eyes and breathing protection.	16.8.2030
			Characterisation of active substance Viable cells of <i>Saccharomyces cerevisiae</i> MUCL 39885	Dairy cows		2 × 10 ⁹			
			Analytical method ⁽¹⁾ Enumeration: pour plate method using chloramphenicol glucose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method						

⁽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) 2020/1097

of 24 July 2020

concerning the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and laying and for minor poultry species for fattening and laying

(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. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾ and Article 4 for the authorisation of a new use of an additive.
- (2) Lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for poultry belonging to the group 'colourants, including pigments', under the heading 'carotenoids and xanthophylls'. These two extracts were authorised under the common name 'lutein' and 'zeaxanthin' without any specification so the request for this two forms lutein-rich and lutein/zeaxanthin fell within the generic entries 'lutein' and 'zeaxanthin'. The additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.
- (3) In accordance with Articles 4 and 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the authorisation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and the re-evaluation of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* as feed additives for poultry (except turkeys) for fattening and for laying and minor poultry species for fattening and for laying. The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 3 April 2019 ⁽³⁾ that, under the proposed conditions of use, lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* do not have an adverse effect on animal health, consumer safety or the environment. It stated that the conclusion on the safety and efficacy of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* for poultry (except turkeys) for fattening and for laying can be extrapolated to minor poultry for fattening and for laying. It also concluded that the active substances are viscous substances, so operators will not be exposed by inhalation. The applicant recognises that the active substances may be irritant to skin and eyes. 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, including the use of the additives in the form of a preparation, where toxicity by inhalation or due to the potential skin/eye irritant nature of the substance cannot be excluded. The Authority further concluded that the additives concerned are effective in adding colour to food of animal origin. 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 European Union Reference Laboratory set up by Regulation (EC) No 1831/2003.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2019; 17(5):5698.

- (5) As regards the use in water for drinking, the Commission considers that the simultaneous use of the additives in water for drinking and feed is difficult to manage, as there are maximum levels established for safety reasons and there are also other additives containing xanthophylls and carotenoids that may be used in feed. The simultaneous use of lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta* in water for drinking and feed increases the ways of administration and the risk to exceed the maximum levels authorised for additives containing carotenoids and xanthophylls (for lutein-rich 80 mg/kg alone or with other carotenoids or xanthophylls and for lutein/zeaxanthin 50 mg/kg alone or with other carotenoids or xanthophylls). Consequently, the use in water for drinking is denied.
- (6) The assessment shows that the conditions for authorisation for lutein-rich and lutein/zeaxanthin extracts from *Tagetes erecta*, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those additives should be authorised as specified in the Annex to this Regulation.
- (7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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 substances specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'colourants: (ii) substances which, when fed to animals, add colours to food of animal origin', are authorised as feed additives in animal nutrition subject to the conditions laid down in that Annex.

Article 2

The authorised substances specified in the Annex shall not be used in water for drinking

Article 3

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 16 February 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 16 August 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

Article 4

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
2a161b	Lutein-rich extract	Additive composition: Lutein-rich extract of <i>Tagetes erecta</i> Benzene ≤ 2mg/kg	Poultry for fattening (except turkeys) and minor poultry for fattening	-	-	80	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein-rich extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein-rich extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 80 mg/kg of complete feed. 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 eye and skin protection	16.8.2030
		Characterisation of the active substance: Lutein from a saponified extract of <i>Tagetes erecta</i> (dried flowers petals) obtained via extraction and saponification: — Total carotenoids (TC):≥ 60g/kg — Lutein ≥ 75 % of total carotenoids (TC) — Zeaxanthin≥ 4 % of total carotenoids (TC) Chemical formula: C ₄₀ H ₅₆ O ₂ CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Liquid form Analytical method ⁽¹⁾ : — For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: high Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Regulation (EU) No 231/2012 referring to FAO JECFA monograph ‘	Poultry for laying (except turkeys) and minor poultry for laying	-	-	80		

		lutein from <i>Tagetes erecta</i> monograph No 3 (2006), Combined Compendium for Food Additive Specifications — For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: high Performance Liquid Chromatography with visible detection (HPLC-Vis) — For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64						
2a161bi	Lutein/zeaxanthin extract	<i>Additive composition:</i> Lutein/zeaxanthin extract of <i>Tagetes erecta</i>. Benzene ≤ 2mg/kg	Poultry for fattening (except turkeys) and minor poultry for fattening	-	-	50	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Lutein/zeaxanthin extract must be placed on the market and used as an additive consisting of a preparation. 3. The mixture of lutein/zeaxanthin extract with other authorised carotenoids and xanthophylls shall not exceed a total carotenoids and xanthophylls content of 50 mg/kg of complete feed 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential	16.8.2030
		<i>Characterisation of the active substance:</i> Lutein/zeaxanthin saponified/isomerised extract from dried flowers petals of <i>Tagetes erecta</i> obtained via extraction, saponification and isomerisation: — Total carotenoids (TC): ≥ 60g/kg — Lutein ≥ 37 % of TC; — Zeaxanthin ≥ 36 % of TC. Liquid form CAS number 127-40-2 (lutein) CAS number 144-68-3 (zeaxanthin) CoE number: 494 Chemical formula: C₄₀H₅₆O₂	Poultry for laying (except turkeys) and minor poultry for laying.	-	-	50		

		<i>Analytical method</i> ⁽¹⁾: For the determination of lutein (all-trans-lutein isomer only), zeaxanthin and total carotenoids and xanthophylls in the feed additive: — High Performance Liquid Chromatography (HPLC) with spectrophotometry – Commission Directive 2008/128/EC referring to FAO JECFA monograph 'lutein from <i>Tagetes erecta</i>' monograph No 3 (2006), Combined Compendium for Food Additive Specifications For the determination of lutein (all-trans-lutein isomer only) in premixtures and feedingstuffs: — High Performance Liquid Chromatography with visible detection (HPLC-Vis) For the determination of total carotenoids and xanthophylls in premixtures and feedingstuffs: — Liquid chromatography with visible detection (LC-Vis) – AOAC official method 970.64					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 eye and skin protection.	
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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) 2020/1098

of 24 July 2020

concerning the authorisation of cardamom essential oil from *Elettaria cardamomum* (L.) Maton 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. Article 10(2) of Regulation (EC) No 1831/2003 provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) Cardamom oil from *Elettaria cardamomum* (L.) Maton was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for all animal species under the group 'Flavouring and appetising substances'. The product was subsequently entered in the Register of feed additives as an existing product, in accordance with point (b) of Article 10(1) of Regulation (EC) No 1831/2003.
- (3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of cardamom oil from *Elettaria cardamomum* (L.) Maton as a feed additive for all animal species. The applicant requested the additive to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 14 May 2019 ⁽³⁾ that, under the proposed conditions of use, cardamom oil from *Elettaria cardamomum* (L.) Maton does not have an adverse effect on animal health, consumer safety or the environment. In the absence of studies to assess the safety for the user, the Authority could not conclude on the safety for the users when handling the additive. According to the opinion, the applicant produced a safety data sheet for cardamomum oil, where hazards have been identified. The hazards described in the safety data sheet are, in particular skin irritation, eye irritation, allergic skin reaction and fatal if swallowed. 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.
- (5) The Authority further concluded that since the substance concerned is used in food as a flavouring and its function in feed is the same as that in food, no further demonstration of 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 additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (6) Restrictions and conditions should be provided for to allow for a better control for this substance. For the feed additive concerned recommended contents should be indicated on the label. Where such contents are exceeded, certain information should be indicated on the label of premixtures containing the feed additive.
- (7) The assessment of cardamom essential oil from *Elettaria cardamomum* (L.) Maton 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 additive should be authorised as specified in the Annex to this Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs (OJ L 270, 14.12.1970, p. 1).⁽³⁾ EFSA Journal 2019; 17(6):5721.

- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from this authorisation.
- (9) The fact that cardamom essential oil from *Elettaria cardamomum* (L.) Maton is not authorised for use as a flavouring in water for drinking, does not preclude its use in compound feed, which is administered via water.
- (10) 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 an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 16 February 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 16 August 2021 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.
3. Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 16 August 2022 in accordance with the rules applicable before 16 August 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for non-food-producing animals.

Article 3

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	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 of kg of complete feedingstuff with a moisture content of 12 %			

Category: Sensory additives. Functional group: Flavouring compounds

2b180	Cardamom essential oil	<i>Additive composition:</i> Essential oil from the seeds of <i>Elettaria cardamomum</i> (L.) Maton. <i>Characterisation of the active substance:</i> Essential oil from the seeds of <i>Elettaria cardamomum</i> (L.) Maton as defined by the International Organisation for Standardization (ISO) 4733:2004 for Oil of Cardamom (<i>E. cardamomum</i> (L.) Maton). Terpineol acetate: 30-42 % of the essential oil. Methyleugenol ≤ 0,0002 % of the essential oil. Liquid form. CAS number 8000-66-6 Einecs number 288-922-1 FEMA number 2241 CoE: 180 <i>Analytical method ⁽¹⁾:</i> For the determination of terpineol acetate (phytochemical marker) in the feed additive (cardamom oil): — gas chromatography coupled with flame ionisation detection (GC-FID) – ISO 4733	All animal species	-	-	-	1. The additive shall be incorporated into the feed in the form of a premixture. 2. In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. 3. 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 %: 5 mg/kg feed'. 4. 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: 5 mg/kg. 5. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, swallowing, dermal contact or eyes contact 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 eye and skin protection.	16.8.2030
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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

POLITICAL AND SECURITY COMMITTEE DECISION (CFSP) 2020/1099

of 16 July 2020

on the acceptance of a third State's contribution to the European Union military operation in Bosnia and Herzegovina (EUFOR ALTHEA) (BiH/30/2020)

THE POLITICAL AND SECURITY COMMITTEE,

Having regard to the Treaty on European Union, and in particular the third paragraph of Article 38 thereof,

Having regard to Council Joint Action 2004/570/CFSP of 12 July 2004 on the European Union military operation in Bosnia and Herzegovina ⁽¹⁾, in particular Article 11 thereof,

Whereas:

- (1) Pursuant to Article 11(2) of Joint Action 2004/570/CFSP, the Council authorised the Political and Security Committee to take the relevant decisions on acceptance of the proposed contributions by third States to the European Union military operation in Bosnia and Herzegovina.
- (2) Following the recommendations regarding a contribution from Ukraine by the EU Operation Commander and by the European Union Military Committee, the contribution from Ukraine should be accepted and considered to be significant.
- (3) In accordance with Article 5 of Protocol No 22 on the position of Denmark, annexed to the Treaty on European Union and to the Treaty on the Functioning of the European Union, Denmark does not participate in the elaboration and implementation of decisions and actions of the Union which have defence implications. Consequently, Denmark is not participating in the adoption of this Decision and is neither bound by it nor subject to its application.
- (4) On 12 and 13 December 2002, the Copenhagen European Council adopted a declaration stating that the 'Berlin Plus' arrangements and the implementation thereof will apply only to those Member States of the Union which are also either NATO members or members of the 'Partnership for Peace' programme, and which have consequently concluded bilateral security agreements with NATO,

HAS ADOPTED THIS DECISION:

Article 1

1. The contribution from Ukraine to the European Union military operation in Bosnia and Herzegovina (EUFOR ALTHEA) is accepted and considered to be significant.
2. Ukraine is exempted from financial contributions to the budget of EUFOR ALTHEA.

Article 2

This Decision shall enter into force on the date of its adoption.

Done at Brussels, 16 July 2020.

For the Political and Security Committee
The Chairperson
S. FROM-EMMESBERGER

⁽¹⁾ OJ L 252, 28.7.2004, p. 10.

DECISION (EU) 2020/1100 OF THE EUROPEAN CENTRAL BANK**of 17 July 2020****amending Decision (EU) 2015/32 concerning derogations that may be granted under Regulation (EU) No 1073/2013 (ECB/2020/33)**

THE GOVERNING COUNCIL OF THE EUROPEAN CENTRAL BANK,

Having regard to Regulation (EU) No 1073/2013 of the European Central Bank of 18 October 2013 concerning statistics on the assets and liabilities of investment funds (ECB/2013/38) ⁽¹⁾, and in particular Article 8(2) thereof,

Whereas:

- (1) Article 8(2) of Regulation (EU) No 1073/2013 (ECB/2013/38) provides that derogations from statistical reporting requirements may be granted to investment funds (IFs) that are subject to national accounting rules which allow the valuation of their assets less frequently than quarterly. It further provides that the IF categories to which the national central banks (NCBs) have the discretion to grant derogations are to be decided by the Governing Council. The list of those IF categories is contained in a Decision adopted by the Governing Council.
- (2) In the course of the review prescribed by Article 1 of Decision (EU) 2015/32 of the European Central Bank (ECB/2014/62) ⁽²⁾, the Governing Council determined that it is necessary to include further investment fund categories for which derogations may be granted under Article 8(2) of Regulation (EU) No 1073/2013 (ECB/2013/38) for Austria, Latvia, Lithuania and Portugal, remove investment fund categories for France that no longer apply, and make minor amendments resulting from changes to certain national legal acts.
- (3) Therefore, Decision (EU) 2015/32 (ECB/2014/62) should be amended accordingly,

HAS ADOPTED THIS DECISION:

*Article 1***Amendment**

The Annex to Decision (EU) 2015/32 (ECB/2014/62) is replaced by the Annex to this Decision.

*Article 2***Taking effect**

This Decision shall take effect on the day of its notification to the addressees.

*Article 3***Addressees**

This Decision is addressed to the NCBs of the Member States whose currency is the euro.

Done at Frankfurt am Main, 17 July 2020.

The President of the ECB
Christine LAGARDE

⁽¹⁾ OJ L 297, 7.11.2013, p. 73.

⁽²⁾ Decision (EU) 2015/32 of the European Central Bank of 29 December 2014 concerning derogations that may be granted under Regulation (EU) No 1073/2013 concerning statistics on the assets and liabilities of investment funds (ECB/2013/38) (ECB/2014/62) (OJ L 5, 9.1.2015, p. 17).

The Annex to Decision (EU) 2015/32 (ECB/2014/62) is replaced by the following:

‘ANNEX

**INVESTMENT FUND CATEGORIES FOR WHICH DEROGATIONS MAY BE GRANTED UNDER ARTICLE 8(2) OF REGULATION (EU) No 1073/2013
(ECB/2013/38)**

Member State	Name of IF category	Legal act relating to the category			Legal act determining the frequency of valuation			Frequency of valuation under national legislation
		Title of legal act	Number/date of legal act	Relevant provisions	Title of legal act	Number/date of legal act	Relevant provisions	
Austria	<i>Alternative Investmentfonds</i> (Alternative investment funds for professional investors)	<i>Alternative Investmentfonds Manager-Gesetz – AIFMG 2013</i> (Law on alternative investment fund management companies)	BGBI. I Nr. 135/2013	AIFMG 2013 § 2 <u>and not</u> subject to AIFMG § 48	<i>Alternative Investmentfonds Manager-Gesetz – AIFMG 2013</i> (Law on alternative investment fund management companies)	BGBI. I Nr. 135/2013	AIFMG 2013 §17 (3)	Annual
Austria	<i>Immobilienfonds</i> (Real estate investment funds)	<i>Immobilien-Investmentfondsgesetz – ImmoInvFG 2003</i> (Law on real estate investment funds)	BGBI. I Nr. 80/2003	ImmoInvFG 2003 § 1	<i>Immobilien-Investmentfondsgesetz – ImmoInvFG 2003</i> (Law on real estate investment funds)	BGBI. I Nr. 80/2003	ImmoInvFG 2003 § 29 (2)	Annual
France	<i>Fonds commun de placement à risque</i> (Venture capital mutual funds)	<i>Code monétaire et financier</i> (Monetary and Financial Code)		Chapter IV, Section 2, Paragraph 2, L214-28 to L214-32	<i>Règlement général de l'Autorité des Marchés Financiers</i> (General Regulation of the Financial Markets Authority)		Book IV, Title II, Article 422-120-13	Biannual
Italy	<i>Fondi chiusi</i> (Closed funds)	<i>Decreto legislativo – Testo unico delle disposizioni in materia di intermediazione finanziaria</i> (Legislative decree – all provisions in the field of financial intermediation)	No 58 of 24 February 1998	Part I, Article 1 Part II, Articles 36, 37 and 39	<i>Provvedimento della Banca d'Italia – Regolamento sulla gestione collettiva del risparmio</i> (Act of the Banca d'Italia – Regulation on the collective management of savings)	23 December 2016	Title V, Chapter 1, Section II, paragraph 4.6	Annual

		Decreto ministeriale – Regolamento attuativo dell'articolo 37 del Decreto legislativo di 24 febbraio 1998, nr. 58 (Ministerial decree – Regulation implementing Article 37 of Legislative decree No 58 of 24 February 1998)	No 228 of 24 May 1999	Chapter II, Article 12				
Latvia	Alternatīvo ieguldījumu fondi (Alternative Investment Funds)	Alternatīvo ieguldījumu fondu un to pārvaldnieku likums (Law on Alternative Investment Funds and Managers Thereof)	Law of 9 July 2013	Chapter III, Part 6 of Section 27	Alternatīvo ieguldījumu fondu un to pārvaldnieku likums (Law on Alternative Investment Funds and Managers Thereof)	Law of 9 July 2013	Chapter III, Part 6 of Section 27	Annual
Lithuania	Informuotiesiems investuotojams skirti kolektyvinio investavimo subjektai (Collective investment undertakings intended for informed investors)	Informuotiesiems investuotojams skirtų kolektyvinio investavimo subjektų įstatymas (Law on Collective Investment Undertakings Intended for Informed Investors)	No XII-376 of 18 June 2013 (As last amended on 12 December 2019)	Article 2(5)	Informuotiesiems investuotojams skirtų kolektyvinio investavimo subjektų įstatymas (Law on Collective Investment Undertakings Intended for Informed Investors)	No XII-376 of 18 June 2013 (As last amended on 12 December 2019)	Article 42(2)	Biannual/annual
Lithuania	Alternatyvieji kolektyvinio investavimo subjektai (Alternative collective investment undertakings)	Alternatyviųjų kolektyvinio investavimo subjektų valdytojų įstatymas (Law on Managers of Alternative Collective Investment Undertakings)	No XII-1467 of 18 December 2014 (As last amended on 12 December 2019)	Article 3(13)	Alternatyviųjų kolektyvinio investavimo subjektų valdytojų įstatymas (Law on Managers of Alternative Collective Investment Undertakings)	No XII-1467 of 18 December 2014 (As last amended on 12 December 2019)	Article 16(1)	Biannual/annual

Portugal	<i>Fundos de capital de risco</i> (Private equity and Venture capital funds)	<i>Lei</i> (Law)	No 18/2015 of 4 March 2015	Article 1 and 3	<i>Regulamento da Comissão do Mercado de Valores Mobiliários</i> (Securities Market Commission Regulation) <i>Instrução da Comissão do Mercado de Valores Mobiliários</i> (Securities Market Commission Guideline)	No 3/2015 of 3 November 2015 No 7/2016 of 29 November 2016	Articles 2 and 15§1 Rule 2	Biannual
Portugal	<i>Fundos de empreendedorismo social</i> (Social entrepreneurship Funds) <i>Organismos de investimento alternativo especializado</i> (Specialised alternative investment funds)	<i>Lei</i> (Law)	No 18/2015 of 4 March 2015	Article 1 and 4 Article 1 and 5	<i>Regulamento da Comissão do Mercado de Valores Mobiliários</i> (Securities Market Commission Regulation)	No 3/2015 of 3 November 2015	Articles 2 and 15 §2	Annual'

COMMISSION DECISION (EU) 2020/1101**of 23 July 2020****amending Decision (EU) 2020/491 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020***(notified under document number C(2020) 4936)*

THE EUROPEAN COMMISSION,

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

Having regard to Council Directive 2009/132/EC of 19 October 2009 determining the scope of Article 143(b) and (c) of Directive 2006/112/EC as regards exemption from value added tax on the final importation of certain goods ⁽¹⁾, and in particular Article 53, first paragraph, 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,

Having regard to Council Regulation (EC) No 1186/2009 of 16 November 2009 setting up a Community system of reliefs from customs duty ⁽²⁾, and in particular Article 76, first paragraph, 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) Commission Decision (EU) 2020/491 ⁽³⁾ grants relief from import duties and exemption of VAT on importation of goods needed to combat the effects of the COVID-19 outbreak until 31 July 2020.
- (2) On 11 June 2020, the Commission consulted the Member States in accordance with recital (5) of Decision (EU) 2020/491 whether an extension was necessary, following which Member States requested the extension of the relief.
- (3) The imports made by Member States under Decision (EU) 2020/491 have been beneficial in providing State organisations or approved organisations by the competent authorities in the Member States access to needed medical equipment and personal protective equipment, for which a shortage exists. Trade statistics for such goods have indicated that importations are still high. Since the number of COVID-19 infections in Member States still poses public health risks and as shortages for goods needed to combat the COVID-19 pandemic are still reported in the Member States, it is necessary to extend the period of application provided in Decision (EU) 2020/491 by three months.
- (4) In order to allow a proper reporting by Member States of the obligations derived from Decision (EU) 2020/491, it is appropriate to extend the deadline provided for in Article 2 of Decision (EU) 2020/491.
- (5) On 24 June 2020, the Member States were consulted on the requested extension in accordance with Article 76 of Regulation (EC) No 1186/2009 and Article 53 of Directive 2009/132/EC.
- (6) Decision (EU) 2020/491 should therefore be amended accordingly,

⁽¹⁾ OJ L 292, 10.11.2009, p. 5.

⁽²⁾ OJ L 324, 10.12.2009, p. 23.

⁽³⁾ Commission Decision (EU) 2020/491 of 3 April 2020 on relief from import duties and VAT exemption on importation granted for goods needed to combat the effects of the COVID-19 outbreak during 2020 (OJ L 103, 3.4.2020, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Decision (EU) 2020/491 is amended as follows:

(1) in Article 2, the introductory part is replaced by the following:

‘Member States shall communicate by 31 December 2020 at the latest the following information to the Commission:’;

(2) Article 3 is replaced by the following:

‘Article 3

Article 1 shall apply to importations made from 30 January 2020 to 31 October 2020.’.

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 23 July 2020.

For the Commission
Paolo GENTILONI
Member of the Commission

COMMISSION IMPLEMENTING DECISION (EU) 2020/1102**of 24 July 2020**

on the approval of the technology used in a 48 Volt efficient motor-generator combined with a 48 Volt/12 Volt DC/DC converter for use in conventional combustion engine and certain hybrid electric passenger cars and light commercial vehicles as an innovative technology pursuant to Regulation (EU) 2019/631 of the European Parliament and of the Council and by reference to the New European Driving Cycle (NEDC)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2019/631 of the European Parliament and of the Council of 17 April 2019 setting CO₂ emission performance standards for new passenger cars and for new light commercial vehicles, and repealing Regulations (EC) No 443/2009 and (EU) No 510/2011 ⁽¹⁾, and in particular Article 11(4) thereof,

Whereas:

- (1) On 24 October 2019, the manufacturers Audi AG, Bayerische Motoren Werke AG, Daimler AG, FCA Italy S.p.A, Ford-Werke GmbH, Honda Motor Europe Ltd, Hyundai Motor Europe Technical Center GmbH, Jaguar Land Rover LTD., Renault, Volkswagen AG, Volkswagen Nutzfahrzeuge and the suppliers Valeo Electrical systems and Mitsubishi Electric Corporation submitted a joint application ('the first application') for the approval as an innovative technology of the technology used in a 48 Volt efficient motor-generator combined with a 48 Volt/12 Volt DC/DC converter for use in passenger cars and light commercial vehicles with an internal combustion engine powertrain running on petrol or diesel (conventional ICE powertrain) and in certain not-off-vehicle charging hybrid electric vehicles (NOVC-HEVs) of those categories.
- (2) On 8 November 2019, the supplier Valeo Electrical systems submitted an application ('the second application') for the approval of the same technology, i.e. the technology used in a 48 Volt efficient motor-generator combined with a 48 Volt/12 Volt DC/DC converter, for use in vehicles of the same categories and powertrains.
- (3) Both applications have been assessed in accordance with Article 11 of Regulation (EU) 2019/631, Commission Implementing Regulations (EU) No 725/2011 ⁽²⁾ and (EU) No 427/2014 ⁽³⁾ and the Technical Guidelines for the preparation of applications for the approval of innovative technologies pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council ⁽⁴⁾ and (EU) No 510/2011 of the European Parliament and of the Council ⁽⁵⁾ (July 2018 version ⁽⁶⁾). In accordance with Article 11(3) of Regulation (EU) 2019/631, the applications were accompanied by a verification report of an independent and certified body.
- (4) Both applications refer to CO₂ emission savings that may not be demonstrated by measurements performed in accordance with the New European Driving Cycle (NEDC) as set out in Commission Regulation (EC) No 692/2008 ⁽⁷⁾.

⁽¹⁾ OJ L 111, 25.4.2019, p. 13.

⁽²⁾ Commission Implementing Regulation (EU) No 725/2011 of 25 July 2011 establishing a procedure for the approval and certification of innovative technologies for reducing CO₂ emissions from passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council (OJ L 194, 26.7.2011, p. 19).

⁽³⁾ Commission Implementing Regulation (EU) No 427/2014 of 25 April 2014 establishing a procedure for the approval and certification of innovative technologies for reducing CO₂ emissions from light commercial vehicles pursuant to Regulation (EU) No 510/2011 of the European Parliament and of the Council (OJ L 125, 26.4.2014, p. 57).

⁽⁴⁾ Regulation (EC) No 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars as part of the Community's integrated approach to reduce CO₂ emissions from light-duty vehicles (OJ L 140, 5.6.2009, p. 1).

⁽⁵⁾ Regulation (EU) No 510/2011 of the European Parliament and of the Council of 11 May 2011 setting emission performance standards for new light commercial vehicles as part of the Union's integrated approach to reduce CO₂ emissions from light-duty vehicles (OJ L 145, 31.5.2011, p. 1).

⁽⁶⁾ <https://circabc.europa.eu/w/browse/f3927eae-29f8-4950-b3b3-d2e700598b52>

⁽⁷⁾ Commission Regulation (EC) No 692/2008 of 18 July 2008 implementing and amending Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information (OJ L 199, 28.7.2008, p. 1).

- (5) Considering that both applications refer to the same innovative technology and that the same conditions should apply for its use in the vehicles concerned, it is appropriate to address both applications in one single decision.
- (6) The 48 Volt motor-generator may operate as either an electric motor converting electrical energy into mechanical energy, or as a generator converting mechanical energy into electrical energy, i.e. as a standard alternator. The 48 Volt/12 Volt DC/DC converter enables the 48 Volt motor-generator to provide electric energy at the voltage required to power the 12 Volt electric power board of the vehicle and/or charging the 12 Volt battery.
- (7) The Commission has already approved the high efficient 48 Volt motor-generator combined with a 48 Volt/12 Volt DC/DC converter supplied by SEG Automotive Germany GmbH as an innovative technology for use in conventional ICE powered passenger cars and light commercial vehicles and certain NOVC-HEVs of those categories by its Implementing Decisions (EU) 2019/313 ⁽⁸⁾ and (EU) 2019/314 ⁽⁹⁾.
- (8) Based on the experience gained from the assessment of the applications submitted by SEG Automotive Germany GmbH, together with the information provided with the present applications, it has been satisfactorily and conclusively demonstrated that a 48 Volt efficient motor-generator combined with a 48 Volt/12 Volt DC/DC converter meets the criteria referred to in Article 11(2) of Regulation (EU) 2019/631 and the eligibility criteria specified in Article 9(1)(a) of Implementing Regulations (EU) No 725/2011 and (EU) No 427/2014.
- (9) The innovative technology should be used in conventional ICE passenger cars or light commercial vehicles, or only in such NOVC-HEVs of those categories for which uncorrected measured fuel consumption and CO₂ emission values may be used in accordance with Annex 8 to Regulation No 101 of the Economic Commission for Europe of the United Nations ⁽¹⁰⁾.
- (10) Both applications propose a testing methodology that is based on the 'separate method' set out in point 3 of the Annex to the respective Implementing Decisions (EU) 2019/313 and (EU) 2019/314.
- (11) The methodology proposed in the first application differs from the 'separate method' set out in those Decisions with regard to the voltage level to be used for the efficiency measurement of the 48 Volt motor-generator, which is proposed to be set to 48 Volt instead of 52 Volt. In addition, in both applications it is proposed to modify the output current for the efficiency measurement of the 48 Volt/12 Volt DC/DC converter so that the output current is defined as half the nominal power of the DC/DC converter divided by 14,3 Volt, instead of the nominal power of the DC/DC converter divided by 14,3 V. Moreover, in both applications it is proposed to introduce a run-in procedure for the 48 Volt motor-generator.
- (12) With regard to the changes proposed to the 'separate method' set out in Implementing Decisions (EU) 2019/313 and (EU) 2019/314 regarding the voltage level of the efficiency measurement of the 48 Volt motor-generator and the output current of the efficiency measurement of the 48 Volt/12 Volt DC/DC converter, it is found that those changes may lead to less conservative results in terms of CO₂ savings. The applicants have claimed that the changes are justified as they would be more representative of real world driving conditions. The evidence provided in support

⁽⁸⁾ Commission Implementing Decision (EU) 2019/313 of 21 February 2019 approving the technology used in SEG Automotive Germany GmbH High efficient 48V motor generator (BRM) plus 48V/12V DC/DC converter for use in conventional combustion engine and certain hybrid powered light commercial vehicles as an innovative technology for reducing CO₂ emissions from light commercial vehicles pursuant to Regulation (EU) No 510/2011 of the European Parliament and of the Council (OJ L 51, 22.2.2019, p. 31).

⁽⁹⁾ Commission Implementing Decision (EU) 2019/314 of 21 February 2019 approving the technology used in SEG Automotive Germany GmbH High efficient 48V motor generator (BRM) plus 48V/12V DC/DC converter for use in conventional combustion engine and certain hybrid powered passenger cars as an innovative technology for reducing CO₂ emissions from passenger cars pursuant to Regulation (EC) No 443/2009 of the European Parliament and of the Council (OJ L 51, 22.2.2019, p. 42).

⁽¹⁰⁾ Regulation No 101 of the Economic Commission for Europe of the United Nations (UN/ECE) – Uniform provisions concerning the approval of passenger cars powered by an internal combustion engine only, or powered by a hybrid electric power train with regard to the measurement of the emission of carbon dioxide and fuel consumption and/or the measurement of electric energy consumption and electric range, and of categories M₁ and N₁ vehicles powered by an electric power train only with regard to the measurement of electric energy consumption and electric range (OJ L 138, 26.5.2012, p. 1).

of that claim can, however, not be considered sufficient, in particular due to the limited studies performed in support of the application and the absence of evidence supporting the change of the output current for the efficiency measurement of the 48 Volt/12 Volt DC/DC converter. Against that background, it is considered that these aspects of the 'separate method' set out in point 3 of the Annex to the respective Implementing Decisions (EU) 2019/313 and (EU) 2019/314 should not be changed based on the information provided in the applications.

- (13) With regard to the proposed addition to the testing methodology of a run-in procedure for the motor-generator, neither of the two applications set out with sufficient precision the details for how such run-in should be performed nor how the run-in effect should be taken into account. As the efficiency of the 48 Volt efficient motor-generator combined with a 48 Volt/12 Volt converter is determined on the basis of the average of the measurement results, any run-in effects, positive or negative, may be adequately taken into account in the final efficiency determination, where necessary by increasing the number of measurements. Against that background, it is not appropriate to complement the testing methodology with an additional specific run-in procedure such as the ones proposed in the applications.
- (14) Against that background, it is considered appropriate that the 'separate method' set out in point 3 of the Annex to the respective Implementing Decisions (EU) 2019/313 and (EU) 2019/314 should apply also for the purpose of this Decision.
- (15) Manufacturers should have the possibility to apply to a type-approval authority for the certification of CO₂ savings from the use of the innovative technology where the conditions laid down in this Decision are met. Manufacturers should for that purpose ensure that the application for certification is accompanied by a verification report from an independent and certified body confirming that the innovative technology complies with the conditions laid down in this Decision and that the savings have been determined in accordance with the testing methodology referred to in this Decision.
- (16) In order to facilitate a wider deployment of the innovative technology in new vehicles, a manufacturer should also have the possibility to submit a single application for the certification of the CO₂ savings from several 48 Volt efficient motor generators combined with a 48 Volt/12 Volt DC/DC converters. It is, however, appropriate to ensure that, where that possibility is used, a mechanism is applied that incentivises the deployment of only those eco-innovations that offer the highest CO₂ savings.
- (17) It is the responsibility of the type-approval authority to verify thoroughly that the conditions for certifying the CO₂ savings from the use of an innovative technology as specified in this Decision are met. Where the certification is issued, the responsible type-approval authority should ensure that all elements considered for the certification are recorded in a test report and kept together with the verification report and that this information is made available to the Commission on request.
- (18) For the purpose of determining the general eco-innovation code to be used in the relevant type-approval documents in accordance with Annexes I, VIII and IX to Directive 2007/46/EC of the European Parliament and of the Council ⁽¹¹⁾, it is necessary to attribute an individual code to the innovative technology.
- (19) From 2021, manufacturers' compliance with their specific CO₂ emission targets under Regulation (EU) 2019/631 is to be established on the basis of the CO₂ emissions determined in accordance with the Worldwide Harmonised Light Vehicle Test Procedure (WLTP) set out in Commission Regulation (EU) 2017/1151 ⁽¹²⁾. CO₂ savings from the innovative technology certified by reference to this Decision may therefore be taken into account for the calculation of manufacturers' average specific CO₂ emissions only for the calendar year 2020,

⁽¹¹⁾ Directive 2007/46/EC of the European Parliament and the Council of 5 September 2007 establishing a framework for the approval of motor vehicles and their trailers, and of systems, components and separate technical units intended for such vehicles (Framework Directive) (OJ L 263, 9.10.2007, p. 1).

⁽¹²⁾ Commission Regulation (EU) 2017/1151 of 1 June 2017 supplementing Regulation (EC) No 715/2007 of the European Parliament and of the Council on type-approval of motor vehicles with respect to emissions from light passenger and commercial vehicles (Euro 5 and Euro 6) and on access to vehicle repair and maintenance information, amending Directive 2007/46/EC of the European Parliament and of the Council, Commission Regulation (EC) No 692/2008 and Commission Regulation (EU) No 1230/2012 and repealing Commission Regulation (EC) No 692/2008 (OJ L 175, 7.7.2017, p. 1).

HAS ADOPTED THIS DECISION:

Article 1

Innovative technology

The technology used in 48 Volt efficient motor-generators combined with 48 Volt/12 Volt DC/DC converters is approved as an innovative technology within the meaning of Article 11 of Regulation (EU) 2019/631, taking into account that the CO₂ savings it delivers are only partially covered by the standard test procedure set out in Regulation (EC) No 692/2008, provided that the technology conforms to the following:

- (a) it is fitted in passenger cars (M₁) or light commercial vehicles (N₁) powered by internal combustion engines running on petrol or diesel (conventional ICE powered M₁ and N₁ vehicles) or in not-off-vehicle charging hybrid electric vehicles of category M₁ or N₁ for which uncorrected measured fuel consumption and CO₂ emission values may be used in accordance with Annex 8 to Regulation No 101 of the Economic Commission for Europe of the United Nations;
- (b) its efficiency, which is the product of the efficiency of the 48 Volt motor-generator and the efficiency of the 48 Volt/12 Volt DC/DC converter, determined in accordance with point 3.3 of the Annex to Implementing Decision (EU) 2019/313 or point 3.3 of the Annex to Implementing Decision (EU) 2019/314, is at least:
 - (i) 73,8 % for petrol-fuelled vehicles other than turbo-charged;
 - (ii) 73,4 % for turbo-charged petrol-fuelled vehicles;
 - (iii) 74,2 % for diesel-fuelled vehicles.

Article 2

Application for certification of CO₂ savings

1. A manufacturer may apply to a type-approval authority for certification of the CO₂ savings from the use of the technology approved in accordance with Article 1 ('the innovative technology') by reference to this Decision.
2. The manufacturer shall ensure that the application for the certification is accompanied by a verification report from an independent and certified body confirming that the technology conforms to points (a) and (b) of Article 1.
3. Where savings have been certified in accordance with Article 3, the manufacturer shall ensure that the certified CO₂ savings and the eco-innovation code referred to in Article 4(1) are recorded in the certificate of conformity of the vehicles concerned.

Article 3

Certification of CO₂ savings

1. The type-approval authority shall ensure that CO₂ savings from the use of the innovative technology have been determined using the methodology set out in points 3, 5, and 6 of the Annex to Implementing Decision (EU) 2019/313 in the case of light commercial vehicles or points 3, 5 and 6 of the Annex to Implementing Decision (EU) 2019/314 in the case of passenger cars.
2. Where a manufacturer applies for the certification of the CO₂ savings for more than one type of 48 Volt motor-generator combined with a 48 Volt/12 Volt DC/DC converter in relation to one vehicle version, the type-approval authority shall determine which of the 48 Volt motor-generators combined with a 48 Volt/12 Volt DC/DC converter tested delivers the lowest CO₂ savings. That value shall be used for the purpose of paragraph 4.
3. The type approval authority shall record the certified CO₂ savings determined in accordance with paragraphs 1 and 2, and the eco-innovation code referred to in Article 4(1) in the relevant type-approval documentation.
4. The type-approval authority shall record all the elements considered for the certification in a test report and keep that together with the verification report referred to in Article 2(2), and shall make that information available to the Commission on request.

5. The type-approval authority shall only certify CO₂ savings from the use of the innovative technology if it finds that the technology conforms with points (a) and (b) of Article 1, and if the CO₂ savings achieved are 1 g CO₂/km or higher, as specified in Article 9(1)(a) of Implementing Regulation (EU) No 725/2011 in the case of passenger cars, or in Article 9(1)(a) of Implementing Regulation (EU) No 427/2014 in the case of light commercial vehicles.

Article 4

Eco-innovation code

1. The innovative technology approved by this Decision is attributed with the eco-innovation code 31.
2. The certified CO₂ savings recorded by reference to that eco-innovation code may only be taken into account for the calculation of the average specific emissions of manufacturers for the calendar year 2020.

Article 5

Entry into force

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, 24 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

RULES OF PROCEDURE

AMENDMENT 1/2020 OF 23 JULY 2020 TO THE RULES OF PROCEDURE OF THE SUPERVISORY BOARD OF THE EUROPEAN CENTRAL BANK

THE SUPERVISORY BOARD OF THE EUROPEAN CENTRAL BANK,

Having regard to Council Regulation (EU) No 1024/2013 of 15 October 2013 conferring specific tasks on the European Central Bank concerning policies relating to the prudential supervision of credit institutions ⁽¹⁾, and in particular Article 26(12) thereof,

Having regard to Decision ECB/2004/2 of the European Central Bank of 19 February 2004 adopting the Rules of Procedure of the European Central Bank ⁽²⁾, and in particular Article 13d thereof,

Whereas:

- (1) The composition of the Steering Committee of the Supervisory Board follows a rotation system whereby representatives of the national competent authorities are appointed to one of the four groups, as set out in the Annex to the Rules of Procedure of the Supervisory Board of the European Central Bank ⁽³⁾ (hereinafter the 'Rules of Procedure'). Since the Governing Council of the European Central Bank (ECB) has adopted a decision to establish close cooperation between the European Central Bank and Hrvatska narodna banka ⁽⁴⁾ and Българска народна банка (Bulgarian National Bank) ⁽⁵⁾, respectively, the representatives of those national competent authorities should be included in the groups in accordance with the rules laid down in second and fifth sentences of Article 11.3 of the Rules of Procedure.
- (2) In addition, certain technical adjustments should be made to clarify the procedures for voting and for the submission of comments in written procedures, as well as for the submission of Steering Committee documents to Supervisory Board members.
- (3) Therefore, the Rules of Procedure should be amended accordingly,

HAS ADOPTED THIS AMENDMENT TO THE RULES OF PROCEDURE:

Article 1

Amendment

The Rules of Procedure are amended as follows:

- (1) Article 6 is amended as follows:

- (a) Article 6.3 is replaced by the following:

‘6.3. In order for the Supervisory Board to vote, there shall be a quorum of two-thirds of its members having a voting right at the time of the vote. If the quorum is not met, the Chair may convene an extraordinary meeting at which members of the Supervisory Board may vote without regard to the quorum.’;

⁽¹⁾ OJ L 287, 29.10.2013, p. 63.

⁽²⁾ OJ L 80, 18.3.2004, p. 33.

⁽³⁾ OJ L 182, 21.6.2014, p. 56.

⁽⁴⁾ Decision (EU) 2020/1016 of the European Central Bank of 24 June 2020 on the establishment of close cooperation between the European Central Bank and Hrvatska Narodna Banka (ECB/2020/31) (OJ L 224I, 13.7.2020, p. 4).

⁽⁵⁾ Decision (EU) 2020/1015 of the European Central Bank of 24 June 2020 on the establishment of close cooperation between the European Central Bank and Българска народна банка (Bulgarian National Bank) (ECB/2020/30) (OJ L 224I, 13.7.2020, p. 1).

(b) the following Article 6.8 is added:

‘6.8. For any written procedure, a member of the Supervisory Board may expressly authorise another person to sign their vote or comment on substance as approved by them in person.’;

(2) Article 12.3 is replaced by the following:

‘12.3. The agenda and the related documents of any meeting of the Steering Committee shall be made available before such meeting to all members of the Supervisory Board. The proceedings of any meeting of the Steering Committee shall be made available to all members of the Supervisory Board prior to the subsequent meeting of the Supervisory Board.’;

(3) the Annex to the Rules of Procedure is replaced by the Annex hereto.

Article 2

Entry into force

This amendment to the Rules of Procedure shall enter into force on 27 July 2020.

Done at Frankfurt am Main, 23 July 2020.

The Chair of the Supervisory Board
Andrea ENRIA

ANNEX

‘ANNEX

Rotation system

For the purposes of Article 11.3, the following rotation system applies, on the basis of the data as at 31 December 2019:

Group	Participating Member State	Number of seats on the Steering Committee
1	DE	1
	FR	
2	ES	1
	IT	
	NL	
3	BE	2
	IE	
	EL	
	LU	
	AT	
	PT	
	FI	
4	BG EE HR	1
	CY	
	LV	
	LT MT	
	SI	
	SK	

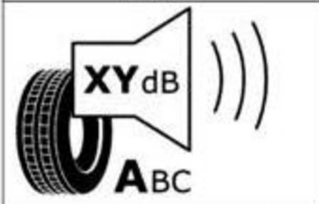
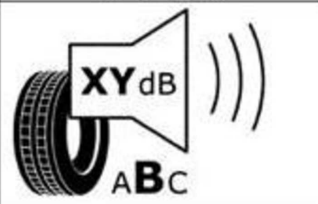
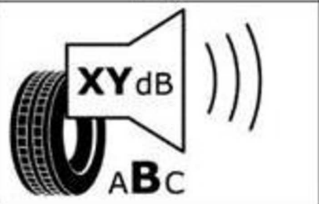
CORRIGENDA

Corrigendum to Regulation (EU) 2020/740 of the European Parliament and of the Council of 25 May 2020 on the labelling of tyres with respect to fuel efficiency and other parameters, amending Regulation (EU) 2017/1369 and repealing Regulation (EC) No 1222/2009

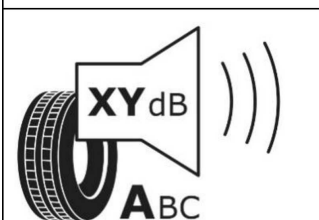
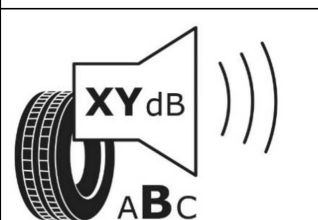
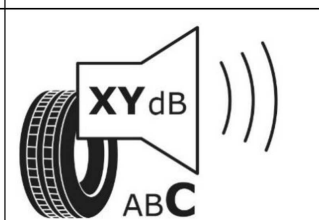
(Official Journal of the European Union L 177 of 5 June 2020)

On page 15, Annex I, part C:

for:

$N \leq LV - 3$	$LV - 3 < N \leq LV$	$N > LV$
		

read:

$N \leq LV - 3$	$LV - 3 < N \leq LV$	$N > LV$
		

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