

Official Journal of the European Union

L 221



English edition

Legislation

Volume 66

8 September 2023

Contents

II Non-legislative acts

REGULATIONS

- ★ **Commission Implementing Regulation (EU) 2023/1702 of 1 September 2023 entering a name in the register of protected designations of origin and protected geographical indications ('Milas Yağlı Zeytini' (PDO))** 1
- ★ **Commission Implementing Regulation (EU) 2023/1703 of 7 September 2023 concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), the authorisation of that preparation for suckling piglets and minor porcine species (suckling piglets) (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) and repealing Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 ⁽¹⁾** 3
- ★ **Commission Implementing Regulation (EU) 2023/1704 of 7 September 2023 concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1119/2012 ⁽¹⁾** 8
- ★ **Commission Implementing Regulation (EU) 2023/1705 of 7 September 2023 concerning the authorisation of a preparation of riboflavin (vitamin B₂) produced by *Bacillus subtilis* CGMCC 13326 as a feed additive for all animal species ⁽¹⁾** 11
- ★ **Commission Implementing Regulation (EU) 2023/1706 of 7 September 2023 amending Implementing Regulation (EU) 2020/1201 as regards the lists of plants known to be susceptible to *Xylella fastidiosa*** 14
- ★ **Commission Implementing Regulation (EU) 2023/1707 of 7 September 2023 concerning the authorisation of 2-acetylfuran and 2-pentylfuran as feed additives for all animal species ⁽¹⁾** 27

⁽¹⁾ Text with EEA relevance.

EN

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

The titles of all other acts are printed in bold type and preceded by an asterisk.

★ Commission Implementing Regulation (EU) 2023/1708 of 7 September 2023 concerning the renewal of the authorisation of urea as a feed additive for ruminants with a functional rumen and repealing Implementing Regulation (EU) No 839/2012 ⁽¹⁾	31
★ Commission Implementing Regulation (EU) 2023/1709 of 7 September 2023 concerning the authorisation of a preparation of <i>Lentilactobacillus diolivorans</i> DSM 33625 as a feed additive for all animal species ⁽¹⁾	34
★ Commission Implementing Regulation (EU) 2023/1710 of 7 September 2023 concerning the renewal of the authorisation of a preparation of ammonium chloride as a feed additive for all ruminants and cats and dogs, an authorisation of a preparation of ammonium chloride as a feed additive for sows (holder of the authorisation: Latochema Co. Ltd) and repealing Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007 ⁽¹⁾	37
★ Commission Implementing Regulation (EU) 2023/1711 of 7 September 2023 concerning the renewal of the authorisation of a preparation of the fermentation product of <i>Aspergillus oryzae</i> NRRL 458 as a feed additive for dairy cows and repealing Regulation (EC) No 537/2007 (holder of authorisation: Biozyme Incorporated) ⁽¹⁾	42
★ Commission Implementing Regulation (EU) 2023/1712 of 7 September 2023 concerning the authorisation of Sunset Yellow FCF as a feed additive for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents ⁽¹⁾	46
★ Commission Implementing Regulation (EU) 2023/1713 of 7 September 2023 concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> ATCC PTA-5588, protease produced by <i>Bacillus subtilis</i> CBS 148232 and alpha-amylase produced by <i>Bacillus licheniformis</i> ATCC SD-6525 for chickens for fattening, chickens reared for laying and minor poultry species (holder of authorisation: Danisco (UK) Ltd represented in the Union by Genencor international B.V.) ⁽¹⁾	51

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

★ UN Regulation No 92 – Uniform provisions concerning the approval of non-original replacement exhaust silencing systems (NORESS) for vehicles of categories L ₁ , L ₂ , L ₃ , L ₄ and L ₅ with regard to sound emission [2023/1714]	55
---	----

⁽¹⁾ Text with EEA relevance.

II

(Non-legislative acts)

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1702

of 1 September 2023

entering a name in the register of protected designations of origin and protected geographical indications ('Milas Yağlı Zeytini' (PDO))

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs ⁽¹⁾, and in particular Article 52(2) thereof,

Whereas:

- (1) Pursuant to Article 50(2)(a) of Regulation (EU) No 1151/2012, Turkey's application to register the name 'Milas Yağlı Zeytini' was published in the *Official Journal of the European Union* ⁽²⁾.
- (2) As no statement of opposition under Article 51 of Regulation (EU) No 1151/2012 has been received by the Commission, the name 'Milas Yağlı Zeytini' should therefore be entered in the register,

HAS ADOPTED THIS REGULATION:

Article 1

The name 'Milas Yağlı Zeytini' (PDO) is hereby entered in the register.

The name specified in the first paragraph denotes a product in Class 1.6. 'Fruit, vegetables and cereals fresh or processed' of Annex XI to Commission Implementing Regulation (EU) No 668/2014 ⁽³⁾.*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*.

⁽¹⁾ OJ L 343, 14.12.2012, p. 1.⁽²⁾ OJ C 174, 16.5.2023, p. 30.⁽³⁾ Commission Implementing Regulation (EU) No 668/2014 of 13 June 2014 laying down rules for the application of Regulation (EU) No 1151/2012 of the European Parliament and of the Council on quality schemes for agricultural products and foodstuffs (OJ L 179, 19.6.2014, p. 36).

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

Done at Brussels, 1 September 2023.

*For the Commission,
On behalf of the President,
Janusz WOJCIECHOWSKI
Member of the Commission*

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1703

of 7 September 2023

concerning the renewal of the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), the authorisation of that preparation for suckling piglets and minor porcine species (suckling piglets) (holder of authorisation: Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) and repealing Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997

(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 endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 (previously taxonomically identified as ATCC PTA-5588) and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 (previously taxonomically identified as ATCC SD-2106) was authorised for 10 years as a feed additive for poultry, weaned piglets and pigs for fattening by Commission Regulation (EU) No 337/2011 ⁽²⁾, and for lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows) by Commission Implementing Regulation (EU) 2016/997 ⁽³⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), requesting the additive to be classified in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application included a proposal for amending the conditions of the original authorisation, consisting of a reduction of the minimum recommended level for turkeys. The application also included a request in accordance with Article 7 of Regulation (EC) No 1831/2003 for the authorisation of the same preparation as a feed additive for suckling piglets and minor porcine species (suckling piglets). The application was accompanied by the particulars and documents required respectively under Article 14(2) and 7(3) of that Regulation.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EU) No 337/2011 of 7 April 2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase and endo-1,3(4)-beta-glucanase as feed additive for poultry, weaned piglets and pigs for fattening (holder of the authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 94, 8.4.2011, p. 19).

⁽³⁾ Commission Implementing Regulation (EU) 2016/997 of 21 June 2016 concerning the authorisation of endo-1,4-beta-xylanase EC 3.2.1.8 produced by *Trichoderma reesei* (ATCC PTA 5588) and endo-1,3(4)-beta-glucanase EC 3.2.1.6 produced by *Trichoderma reesei* (ATCC SD 2106) as a feed additive for lactating sows and minor porcine species (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.) (OJ L 164, 22.6.2016, p. 4).

- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 27 September 2022 ⁽⁴⁾ that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 remains safe for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), consumers and the environment under the conditions of use currently authorised. It added that those conclusions on safety apply also to the use of that preparation for suckling piglets and minor porcine species (suckling piglets). It further stated that the preparation should be considered a potential eye irritant and a respiratory sensitiser, while no conclusions could be drawn on the skin irritancy and sensitisation potential of the preparation. The Authority also concluded that there was no need for an assessment of the efficacy of the preparation for poultry species other than turkeys, for weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), and that the preparation was considered efficacious in turkeys, suckling piglets and minor porcine species (suckling piglets) at the newly proposed intended level of 610 Units of activity of endo-1,4-beta-xylanase per kilogramme of complete feedingstuff and 76 Units of activity of endo-1,3(4)-beta-glucanase per kilogramme of complete feedingstuff. However, the Authority also highlighted that the actual effective level used in the studies supporting the conclusions on efficacy for all target species, except lactating sows and minor porcine species (lactating sows), was approximately 50 % higher than the newly proposed intended level. Finally, the Authority concluded that there was no need for specific requirements of post-market monitoring.
- (5) In accordance with Article 5(4), first subparagraph, points (a) and (c), of Commission Regulation (EC) No 378/2005 ⁽⁵⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment of 28 June 2010 ⁽⁶⁾ are valid and applicable to the current application.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 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 preparation should be renewed for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows) and the use of that preparation should be authorised for suckling piglets and minor porcine species (suckling piglets). However, it is appropriate to set the minimum content applicable to poultry species, suckling piglets, weaned piglets, pigs for fattening and minor porcine species (suckling piglets, weaned piglets and pigs for fattening) 50 % higher than the intended level in order to ensure the efficacy of that preparation when fed to those target species and categories.
- (7) The Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (8) As a consequence of the renewal of the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 as a feed additive, Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 should be repealed.
- (9) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* CBS 143953 and endo-1,3(4)-beta-glucanase produced by *Trichoderma reesei* CBS 143945 for use for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening), it is appropriate to provide for a transitional period for interested parties to prepare themselves to meet the new requirements.

⁽⁴⁾ EFSA Journal 2022;20(11):7615.

⁽⁵⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

⁽⁶⁾ Report of the European Union Reference Laboratory available at <https://joint-research-centre.ec.europa.eu/system/files/2013-02/FinRep-FAD-2010-0007.pdf>.

- (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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is renewed for poultry species, weaned piglets, pigs for fattening, lactating sows and minor porcine species (weaned piglets, pigs for fattening and lactating sows), subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised for suckling piglets and minor porcine species (suckling piglets) as an additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 3

Repeals

Regulation (EU) No 337/2011 and Implementing Regulation (EU) 2016/997 are repealed.

Article 4

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are intended for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening) and are produced and labelled before 28 March 2024 in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are intended for poultry species, weaned piglets, pigs for fattening and minor porcine species (weaned piglets and pigs for fattening) and are produced and labelled before 28 September 2024 in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 5

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, 7 September 2023.

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
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers.									
4a15	Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.	Endo-1,4-beta-xylanase (EC 3.2.1.8) Endo-1,3(4)-beta-glucanase (EC 3.2.1.6)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> CBS 143953 and endo-1,3(4)-beta-glucanase produced by <i>Trichoderma reesei</i> CBS 143945 having a minimum activity of: — 12 200 U ⁽¹⁾ /g endo-1,4-beta-xylanase — 1 520 U ⁽²⁾ /g endo-1,3(4)-beta-glucanase Solid and liquid form	Laying hens	—	Endo-1,4-beta-xylanase 1 830 U Endo-1,3(4)-beta-glucanase 228 U	—	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 the potential risks resulting from their use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, skin and eye protective equipment.	28 September 2033
				Lactating sows Minor porcine species (lactating sows)	—	Endo-1,4-beta-xylanase 1 220 U Endo-1,3(4)-beta-glucanase 152 U	—		
				Other poultry Suckling piglets Weaned piglets Pigs for fattening Minor porcine species (suckling piglets, weaned piglets and pigs for fattening)	—	Endo-1,4-beta-xylanase 915 U Endo-1,3(4)-beta-glucanase 114 U	—		
<i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> CBS 143953 and endo-1,3(4)-beta-glucanase (EC 3.2.1.6) produced by <i>Trichoderma reesei</i> CBS 143945 <i>Analytical method</i> ⁽³⁾ For quantification of the active substances in the additive, premixtures and compound feeds: — colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabinoxylan substrates; — colorimetric method measuring water soluble dye released by action of endo-1,3(4)-beta-glucanase from azurine cross-linked barley beta-glucan substrates.									

⁽¹⁾ One U of endo-1,4-beta-xylanase is the amount of enzyme that liberates 0,48 µmol of reducing sugar (xylose equivalents) per minute from a wheat arabinoxylan at pH 4,2 and 50 °C.

⁽²⁾ One U of endo-1,4-beta-glucanase is the amount of enzyme that liberates 2,4 µmol of reducing sugar (glucose equivalents) per minute from a barley glucan at pH 5,0 and 50 °C.

⁽³⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1704**of 7 September 2023****concerning the renewal of the authorisation of a preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive for all animal species and amending Implementing Regulation (EU) No 1119/2012****(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 *Pediococcus pentosaceus* DSM 23376 was authorised for a period of 10 years as a feed additive for all animal species by Commission Implementing Regulation (EU) No 1119/2012 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive for all animal species, requesting the additive to be classified in the additive category 'technological additives' and in the functional group 'silage additives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 February 2023 ⁽³⁾ that the preparation of *Pediococcus pentosaceus* DSM 23376 remains safe for all animal species, the consumers and the environment under the conditions of use currently authorised. It also concluded that the additive is not irritant to skin or eyes but that, owing to its proteinaceous nature, it should be considered a respiratory sensitiser. The Authority could not conclude, in the absence of data, on the skin sensitisation potential of the additive. It also indicated that there is no need for assessing the efficacy of the additive in the context of the renewal of the authorisation.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c) of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 1119/2012 of 29 November 2012 concerning the authorisation of preparations of *Pediococcus acidilactici* CNCM MA 18/5M DSM 11673, *Pediococcus pentosaceus* DSM 23376, NCIMB 12455 and NCIMB 30168, *Lactobacillus plantarum* DSM 3676 and DSM 3677 and *Lactobacillus buchneri* DSM 13573 as feed additives for all animal species (OJ L 330, 30.11.2012, p. 14).

⁽³⁾ EFSA Journal 2023;21(3):7872.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (6) In view of the above, the Commission considers that the preparation of *Pediococcus pentosaceus* DSM 23376 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the authorisation of that additive should be renewed. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the preparation of *Pediococcus pentosaceus* DSM 23376 as a feed additive, Implementing Regulation (EU) No 1119/2012 should be amended accordingly.
- (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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', is renewed subject to the conditions laid down in that Annex.

Article 2

Amendment to Implementing Regulation (EU) No 1119/2012

In the Annex to Implementing Regulation (EU) No 1119/2012, entry 1k2105 on '*Pediococcus pentosaceus* DSM 23376' is deleted.

Article 3

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, 7 September 2023.

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
					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k2105	<i>Pediococcus pentosaceus</i> DSM 23376	<i>Additive composition</i> Preparation of <i>Pediococcus pentosaceus</i> DSM 23376 containing a minimum of 1 × 10 ¹¹ CFU/g additive Solid form <i>Characterisation of the active substance</i> Viable cells of <i>Pediococcus pentosaceus</i> DSM 23376 <i>Analytical method</i> ⁽¹⁾ Enumeration in the feed additive of <i>Pediococcus pentosaceus</i> DSM 23376: — Spread plate method using MRS Agar (EN 15786) Identification of <i>Pediococcus pentosaceus</i> DSM 23376: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1 × 10⁸ CFU/kg fresh material. 3. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	28 September 2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1705**of 7 September 2023****concerning the authorisation of a preparation of riboflavin (vitamin B₂) produced by *Bacillus subtilis* CGMCC 13326 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 a preparation of riboflavin (vitamin B₂) produced by *Bacillus subtilis* CGMCC 13326. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of a preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 as a feed additive for all animal species, to be classified in the additive category 'nutritional additives' and in the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 February 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 is safe for all animal species consumers and the environment. The Authority further concluded that riboflavin is a known photosensitiser which may elicit skin and eye photoallergic reactions and that the preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 has a risk for users of exposure by inhalation and that in the absence of data, it cannot conclude on the potential of skin and eye irritation or dermal sensitisation of the additive. The Authority concluded that the additive is efficacious in covering the animal's nutritional requirements. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (5) In view of the above, the Commission considers that the preparation of riboflavin produced by *Bacillus subtilis* CGMCC 13326 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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 2023;21(2):7874.

HAS ADOPTED THIS REGULATION:

Article 1

Authorisation

The preparation specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'vitamins, pro-vitamins and chemically well-defined substances having similar effect', is authorised as a feed additive in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Entry into force

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

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

Done at Brussels, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

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/kg of complete feedingstuff with a moisture content of 12 %			
Category of nutritional additives. Functional group: vitamins, pro-vitamins and chemically well-defined substances having similar effect								
3a825V	'Riboflavin' or 'Vitamin B ₂ '	<i>Additive composition</i> Preparation with ≥ 80 % of Riboflavin. Maximum 3 % water Solid form <i>Characterisation of active substance</i> Riboflavin Chemical formula: C₁₇H₂₀N₄O₆ CAS number: 83-88-5 Purity: minimum 98 % Produced by fermentation with <i>Bacillus subtilis</i> CGMCC 13326 <i>Analytical method</i> ⁽¹⁾ For the determination of riboflavin in the feed additive preparation and premixtures: — High Performance Liquid Chromatography with UV detection, HPLC-UV (VDLUFA Bd. III, 13.9.1) For the determination of riboflavin (as total vitamin B₂) in compound feed: — High Performance Liquid Chromatography with Fluorescence detection, HPLC-FLD (EN 14152)	All animal species	—	—	—	1. In the directions for use of the additive and premixtures, the storage conditions, the 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	28 September 2033

⁽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) 2023/1706

of 7 September 2023

amending Implementing Regulation (EU) 2020/1201 as regards the lists of plants known to be susceptible to *Xylella fastidiosa*

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EU) 2016/2031 of the European Parliament and of the Council of 26 October 2016 on protective measures against pests of plants, amending Regulations (EU) No 228/2013, (EU) No 652/2014 and (EU) No 1143/2014 of the European Parliament and of the Council and repealing Council Directives 69/464/EEC, 74/647/EEC, 93/85/EEC, 98/57/EC, 2000/29/EC, 2006/91/EC and 2007/33/EC ⁽¹⁾, and in particular Article 28(1) thereof,

Whereas:

- (1) Annexes I and II to Commission Implementing Regulation (EU) 2020/1201 ⁽²⁾ list the plants for planting, other than seeds, known to be susceptible to one or more subspecies, and to specific subspecies, of *Xylella fastidiosa* (Wells *et al.*) ('the specified pest').
- (2) Since the adoption of Implementing Regulation (EU) 2020/1201, the European Food Safety Authority ('the Authority') has updated its database of plants for planting, other than seeds, known to be susceptible to the specified pest by including *Anthyllis barbajovis* L., *Arbutus unedo* L., *Argyranthemum frutescens* (L.) Sch.Bip., *Berberis thunbergii* DC., *Calocephalus brownii* (Cass.) F.Muell., *Cortaderia selloana* (Schult. & Schult.f.) Asch. & Graebn., *Citrus limon* (L.) Osbeck, *Citrus paradisi* Macfad., *Citrus reticulata* Blanco, *Clematis vitalba* L., *Cortaderia selloana* (Schult. & Schult.f.) Asch. & Graebn., *Dittrichia viscosa* (L.) Greuter, *Elaeagnus angustifolia* L., *Elaeagnus x submacrophylla* Servett., *Erica cinerea* L., *Eriocephalus africanus* L., *Ficus carica* L., *Gazania rigens* (L.) Gaertn., *Genista hirsuta* Vahl., *Hypericum androsaemum* L., *Hypericum perforatum* L., *Jacobaea maritima* (L.) Pelsér & Meijden, *Magnolia x soulangeana* Soul.-Bod., *Myoporum laetum* G. Forst., *Myrtus communis* L., *Olea europaea* subsp. *sylvestris* (Mill.) Rouy, *Pelargonium graveolens* L'Hér., *Phlomis italica* L., *Retama monosperma* (L.) Boiss., *Ruta graveolens* L., *Salvia apiana* Jeps., *Scabiosa atropurpurea* var. *maritima* L., *Strelitzia reginae* Aiton, *Syringa vulgaris* L., *Thymus vulgaris* L., *Ulex europaeus* L., *Viburnum tinus* L. and *Vitex agnus-castus* L. as hosts of certain subspecies of the specified pest ⁽³⁾. Annexes I and II to Implementing Regulation (EU) 2020/1201 should therefore reflect that update.
- (3) In the case of the genus *Phoenix*, it is appropriate to list the species *Phoenix reclinata* Jacquin and *Phoenix roebelenii* O'Brien in Annex I to Implementing Regulation (EU) 2020/1201, as only those two species have been found to be susceptible to the specified pest according to the latest update by the Authority of the database of plants for planting, other than seeds, known to be susceptible to the specified pest.
- (4) In the case of the genus *Lonicera*, it is appropriate to list the species *Lonicera implexa* Soland. and *Lonicera japonica* Thunb. in Annexes I and II to Implementing Regulation (EU) 2020/1201, as only those two species have been found to be susceptible to the *Xylella fastidiosa* subspecies *multiplex* according to the latest update by the Authority of the database of plants for planting, other than seeds, known to be susceptible to the specified pest.
- (5) *Phillyrea latifolia* L. should be removed from the list of specified plants susceptible to the *Xylella fastidiosa* subspecies *multiplex* in Annex II to Implementing Regulation (EU) 2020/1201 because it was mistakenly reported by Member States as a specified plant.

⁽¹⁾ OJ L 317, 23.11.2016, p. 4.

⁽²⁾ Commission Implementing Regulation (EU) 2020/1201 of 14 August 2020 as regards measures to prevent the introduction into and the spread within the Union of *Xylella fastidiosa* (Wells *et al.*) (OJ L 269, 17.8.2020, p. 2).

⁽³⁾ Update of the *Xylella* spp. host plant database – systematic literature search up to 30 June 2022 (EFSA Journal 2023;21(1):7726).

- (6) *Fortunella* should be removed from Annex I to Implementing Regulation (EU) 2020/1201 because it has never been reported by Member States and neither is it included in the Authority's database of plants for planting, other than seeds, known to be susceptible to the specified pest.
- (7) The names of certain plants in Annexes I and II to Implementing Regulation (EU) 2020/1201 should be updated to reflect the latest developments of the international nomenclature. In this respect, the denominations of the species *Osteospermum ecklonis* DC./*Osteospermum ecklonis* DC. Norl. and *Osteospermum fruticosum* (L.) Norl., which are listed in Annexes I and II to Implementing Regulation (EU) 2020/1201, should be replaced by the denominations *Dimorphotheca ecklonis* (DC.) Norl. and *Dimorphotheca fruticosa* (L.) Norl.
- (8) For purposes of clarity and accuracy, the authors should be added in the names of certain genera and species in Annexes I and II to Implementing Regulation (EU) 2020/1201, where those indications were missing.
- (9) Implementing Regulation (EU) 2020/1201 should therefore be amended accordingly.
- (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

Amendments to Implementing Regulation (EU) 2020/1201

Implementing Regulation (EU) 2020/1201 is amended as follows:

- (1) Annex I is replaced by the text set out in Annex I to this Regulation;
- (2) Annex II is replaced by the text set out in Annex II to this Regulation.

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, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

'ANNEX I

List of plants known to be susceptible to one or more subspecies of the specified pest ("host plants")

Acacia Mill.
Acer L.
Adenocarpus lainzii (Castrov.) Castrov.
Albizia julibrissin Durazz.
Alnus rhombifolia Nutt.
Amaranthus retroflexus L.
Ambrosia L.
Ampelopsis arborea (L.) Koehne
Ampelopsis brevipedunculata (Maxim.) Trautv.
Ampelopsis cordata Michx.
Anthyllis barba-jovis L.
Anthyllis hermanniae L.
Arbutus unedo L.
Argyranthemum frutescens (L.) Sch.Bip.
Artemisia L.
Asparagus acutifolius L.
Athyrium filix-femina (L.) Roth
Baccharis L.
Berberis thunbergii DC.
Brassica L.
Calicotome spinosa (L.) Link
Calicotome villosa (Poir.) Link
Callicarpa americana L.
Callistemon citrinus (Curtis) Skeels
Calluna vulgaris (L.) Hull
Calocephalus brownii (Cass.) F.Muell.
Carya Nutt.
Catharanthus roseus (L.) G.Don
Celtis occidentalis L.
Cercis canadensis L.
Cercis occidentalis Torr.
Cercis siliquastrum L.
Chamaecrista fasciculata (Michx.) Greene
Chenopodium album L.
Chionanthus L.
x *Chitalpa tashkentensis* T. S. Elias & Wisura
Cistus L.
Citrus L.

Clematis cirrhosa L.
Clematis vitalba L.
Coelorachis cylindrica (Michx.) Nash
Coffea L.
Conium maculatum L.
Convolvulus cneorum L.
Coprosma repens A.Rich.
Coronilla L.
Cortaderia selloana (Schult. & Schult.f.) Asch. & Graebn.
Cyperus eragrostis Lam.
Cytisus Desf.
Digitaria Haller
Dimorphotheca ecklonis (DC.) Norl.
Dimorphotheca fruticosa (L.) Norl.
Diospyros kaki L.f.
Diplocyclos palmatus (L.) C.Jeffrey
Dittrichia viscosa (L.) Greuter
Dodonaea viscosa (L.) Jacq.
Echium plantagineum L.
Elaeagnus angustifolia L.
Elaeagnus x submacrophylla Servett.
Encelia farinosa A.Gray ex Torr.
Eremophila maculata (Ker Gawler) F. von Müller.
Erica cinerea L.
Erigeron L.
Ericephalus africanus L.
Erodium moschatum (L.) L'Hérit.
Erysimum L.
Euphorbia chamaesyce L.
Euphorbia terracina L.
Euryops chrysanthemoides (DC.) B.Nord.
Euryops pectinatus (L.) Cass.
Fagus crenata Blume
Fallopia japonica (Houtt.) Ronse Decr.
Fatsia japonica (Thunb.) Decne. & Planch.
Ficus carica L.
Frangula alnus Mill.
Fraxinus L.
Gazania rigens (L.) Gaertn.
Genista L.

Ginkgo biloba L.
Gleditsia triacanthos L.
Grevillea juniperina Br.
Hebe Comm. ex Juss.
Helianthus L.
Helichrysum Mill.
Heliotropium europaeum L.
Hemerocallis L.
Hevea brasiliensis (Willd. ex A.Juss.) Müll.Arg.
Hibiscus L.
Humulus scandens (Lour.) Merr.
Hypericum androsaemum L.
Hypericum perforatum L.
Ilex aquifolium L.
Ilex vomitoria Sol. ex Aiton
Iva annua L.
Jacaranda mimosifolia D. Don
Jacobaea maritima (L.) Pelser & Meijden
Juglans L.
Juniperus ashei J. Buchholz
Koelreuteria bipinnata Franch.
Lagerstroemia L.
Laurus nobilis L.
Lavandula L.
Lavatera cretica L.
Ligustrum lucidum W.T.Aiton.
Liquidambar styraciflua L.
Lonicera implexa Soland.
Lonicera japonica Thunb.
Lupinus aridorum McFarlin ex Beckner
Lupinus villosus Willd.
Magnolia grandiflora L.
Magnolia x soulangeana Soul.-Bod.
Mallotus paniculatus (Lam.) Müll.Arg.
Medicago arborea L.
Medicago sativa L.
Metrosideros Banks ex Gaertn.
Mimosa L.
Modiola caroliniana (L.) G. Don
Morus L.
Myoporum insulare R.Br.

Myoporum laetum G. Forst.
Myrtus communis L.
Nandina domestica Murray
Neptunia lutea (Leavenw.) Benth.
Nerium oleander L.
Olea L.
Parthenocissus quinquefolia (L.) Planch.
Paspalum dilatatum Poir.
Pelargonium L'Hér. ex Aiton
Perovskia abrotanoides Kar.
Persea americana Mill.
Phagnalon saxatile (L.) Cass.
Phillyrea angustifolia L.
Phillyrea latifolia L.
Phlomis fruticosa L.
Phlomis italica L.
Phoenix reclinata Jacquin
Phoenix roebelenii O'Brien
Pinus taeda L.
Pistacia vera L.
Plantago lanceolata L.
Platanus L.
Pluchea odorata (L.) Cass.
Polygala grandiflora Wight
Polygala myrtifolia L.
Prunus L.
Psidium L.
Pteridium aquilinum (L.) Kuhn
Pyrus L.
Quercus L.
Ratibida columnifera (Nutt.) Wooton & Standl.
Retama monosperma (L.) Boiss.
Rhamnus L.
Rhus L.
Robinia pseudoacacia L.
Rosa L.
Rubus L.
Ruta chalepensis L.
Ruta graveolens L.
Salvia apiana Jeps.
Salvia mellifera Greene

Salvia officinalis L.
Salvia rosmarinus Spenn.
Sambucus L.
Santolina chamaecyparissus L.
Santolina magonica (O.Bolòs, Molin. & P.Monts.) Romo
Sapindus saponaria L.
Sassafras L. ex Nees
Scabiosa atropurpurea var. *maritima* L.
Setaria magna Griseb.
Solidago fistulosa Mill.
Solidago virgaurea L.
Sorghum halepense (L.) Pers.
Spartium L.
Stewartia pseudocamellia Maxim.
Strelitzia reginae Aiton
Streptocarpus Lindl.
Symphytotrichum divaricatum (Nutt.) G.L.Nesom
Syringa vulgaris L.
Teucrium capitatum L.
Thymus vulgaris L.
Trifolium repens L.
Ulex L.
Ulmus L.
Vaccinium L.
Viburnum tinus L.
Vinca L.
Vitex agnus-castus L.
Vitis L.
Westringia fruticosa (Willd.) Druce
Westringia glabra R.Br.
Xanthium strumarium L.'

ANNEX II

‘ANNEX II

List of plants known to be susceptible to specific subspecies of the specified pest (“specified plants”)**Specified plants susceptible to *Xylella fastidiosa* subspecies *fastidiosa***

Acer L.

Ambrosia artemisiifolia L.

Calicotome spinosa (L.) Link

Cercis occidentalis Torr.

Cistus monspeliensis L.

Citrus limon (L.) Osbeck

Citrus paradisi Macfad.

Citrus reticulata Blanco

Citrus sinensis (L.) Osbeck

Coffea L.

Elaeagnus angustifolia L.

Erysimum L.

Ficus carica L.

Genista lucida L.

Juglans regia L.

Lupinus aridorum McFarlin ex Beckner

Magnolia grandiflora L.

Medicago sativa L.

Metrosideros Banks ex Gaertn.

Morus L.

Myrtus communis L.

Nerium oleander L.

Pelargonium graveolens L'Hér.

Pluchea odorata (L.) Cass.

Polygala myrtifolia L.

Prunus L.

Psidium L.

Rhamnus alaternus L.

Rubus rigidus Sm.

Rubus ursinus Cham. & Schldl.

Ruta chalepensis L.

Salvia rosmarinus Spenn.

Sambucus L.

Spartium junceum L.

Strelitzia reginae Aiton

Streptocarpus Lindl.

Teucrium capitatum L.

Ulex europaeus L.

Ulmus americana L.

Vaccinium corymbosum L.

Vinca L.

Vitis L.

Specified plants susceptible to *Xylella fastidiosa* subspecies *multiplex*

Acacia Mill.

Acer griseum (Franch.) Pax

Acer pseudoplatanus L.

Acer rubrum L.

Adenocarpus lainzii (Castrov.) Castrov.

Alnus rhombifolia Nutt.

Ambrosia L.

Ampelopsis cordata Michx.

Anthyllis barba-jovis L.

Anthyllis hermanniae L.

Arbutus unedo L.

Argyranthemum frutescens (L.) Sch.Bip.

Artemisia L.

Asparagus acutifolius L.

Athyrium filix-femina (L.) Roth

Baccharis halimifolia L.

Berberis thunbergii DC.

Calicotome spinosa (L.) Link

Calicotome villosa (Poir.) Link

Callistemon citrinus (Curtis) Skeels

Calluna vulgaris (L.) Hull

Calocephalus brownii (Cass.) F.Muell

Carya Nutt.

Celtis occidentalis L.

Cercis canadensis L.

Cercis occidentalis Torr.

Cercis siliquastrum L.

Chionanthus L.

Cistus L.

Clematis cirrhosa L.
Clematis vitalba L.
Convolvulus cneorum L.
Coprosma repens A.Rich.
Coronilla L.
Cytisus Desf.
Dimorphotheca ecklonis (DC.) Norl.
Dimorphotheca fruticosa (L.) Norl.
Dittrichia viscosa (L.) Greuter
Dodonaea viscosa (L.) Jacq.
Echium plantagineum L.
Elaeagnus angustifolia L.
Elaeagnus x submacrophylla Servett.
Encelia farinosa A.Gray ex Torr.
Erica cinerea L.
Erigeron L.
Ericephalus africanus L.
Erodium moschatum (L.) L'Hérit.
Euryops chrysanthemoides (DC.) B.Nord.
Euryops pectinatus (L.) Cass.
Fallopia japonica (Houtt.) Ronse Decr.
Ficus carica L.
Frangula alnus Mill.
Fraxinus L.
Gazania rigens (L.) Gaertn.
Genista L.
Ginkgo biloba L.
Gleditsia triacanthos L.
Grevillea juniperina Br.
Hebe Comm. ex Juss.
Helianthus L.
Helichrysum Mill.
Hibiscus syriacus L.
Hypericum androsaemum L.
Hypericum perforatum L.
Ilex aquifolium L.
Iva annua L.
Jacobaea maritima (L.) Pelser & Meijden
Koeleruteria bipinnata Franch.
Lagerstroemia L.

Laurus nobilis L.
Lavandula L.
Lavatera cretica L.
Liquidambar styraciflua L.
Lonicera implexa Soland.
Lonicera japonica Thunb.
Lupinus aridorum McFarlin ex Beckner
Lupinus villosus Willd.
Magnolia grandiflora L.
Magnolia x soulangeana Soul.-Bod.
Medicago arborea L.
Medicago sativa L.
Metrosideros Banks ex Gaertn.
Myoporum laetum G.Forst.
Myrtus communis L.
Nerium oleander L.
Olea L.
Pelargonium L'Hér. ex Aiton
Perovskia abrotanoides Kar.
Phagnalon saxatile (L.) Cass.
Phillyrea angustifolia L.
Phlomis fruticosa L.
Phlomis italica L.
Pistacia vera L.
Plantago lanceolata L.
Platanus L.
Polygala grandiflora Wight
Polygala myrtifolia L.
Prunus L.
Pteridium aquilinum (L.) Kuhn
Quercus L.
Ratibida columnifera (Nutt.) Wooton & Standl.
Retama monosperma (L.) Boiss.
Rhamnus L.
Robinia pseudoacacia L.
Rosa L.
Rubus L.
Ruta graveolens L.
Salvia apiana Jeps.
Salvia mellifera Greene

Salvia officinalis L.
Salvia rosmarinus Spenn.
Sambucus L.
Santolina chamaecyparissus L.
Santolina magonica (O.Bolòs, Molin. & P.Monts.) Romo
Sapindus saponaria L.
Scabiosa atropurpurea var. *maritima* L.
Solidago virgaurea L.
Spartium L.
Strelitzia reginae Aiton
Syringa vulgaris L.
Ulex L.
Ulmus L.
Vaccinium L.
Viburnum tinus L.
Vinca L.
Vitex agnus-castus L.
Westringia fruticosa (Willd.) Druce
Xanthium strumarium L.

Specified plants susceptible to *Xylella fastidiosa* subspecies *pauca*

Acacia Mill.
Amaranthus retroflexus L.
Asparagus acutifolius L.
Catharanthus roseus (L.) G.Don
Chenopodium album L.
Cistus albidus L.
Cistus creticus L.
Citrus L.
Coffea L.
Dimorphotheca fruticosa (L.) Norl.
Dodonaea viscosa (L.) Jacq.
Elaeagnus angustifolia L.
Eremophila maculata (Ker Gawler) F. von Müller.
Erigeron L.
Euphorbia chamaesyce L.
Euphorbia terracina L.
Genista hirsuta Vahl.
Grevillea juniperina Br.
Hebe Comm. ex Juss.
Heliotropium europaeum L.

Hibiscus L.
Laurus nobilis L.
Lavandula L.
Myoporum insulare R.Br.
Myrtus communis L.
Nerium oleander L.
Olea europaea subsp. *europaea* L.
Olea europaea subsp. *sylvestris* (Mill.) Rouy
Pelargonium L'Hér. ex Aiton
Phillyrea latifolia L.
Pistacia vera L.
Polygala myrtifolia L.
Prunus L.
Rhamnus alaternus L.
Salvia rosmarinus Spenn.
Spartium junceum L.
Thymus vulgaris L.
Ulex parviflorus Pourr.
Vinca minor L.
Westringia fruticosa (Willd.) Druce
Westringia glabra R.Br.'

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1707**of 7 September 2023****concerning the authorisation of 2-acetylfuran and 2-pentylfuran as feed additives 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 an authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ⁽²⁾.
- (2) The substances 2-acetylfuran and 2-pentylfuran were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. Those substances 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 Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of 2-acetylfuran and 2-pentylfuran for all animal species. The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. The applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (4) The applicant requested the additives to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the applicant withdrew the application for water for drinking for all the substances concerned.
- (5) That application concerns the authorisation of 2-acetylfuran and 2-pentylfuran as feed additives for all animal species, to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'.
- (6) The European Food Safety Authority ('the Authority') concluded in its opinion of 1 February 2023 ⁽³⁾ that, under the proposed conditions of use 2-acetylfuran and 2-pentylfuran are safe for all animals, consumers and the environment. It also concluded that 2-acetylfuran and 2-pentylfuran should be considered as irritant to skin and eyes and the respiratory tract, and as dermal and respiratory sensitisers. The Authority further concluded that the additives are efficacious to flavour feed. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additives in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.
- (7) In view of the above, the Commission considers that 2-acetylfuran and 2-pentylfuran, satisfy the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that substance should be authorised as specified in the Annex to this Regulation. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additives.

⁽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 2023;21(3):7868.

- (8) Certain conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.
- (9) 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 provide for a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

Authorisation

The substances 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

Transitional measures

1. The substances specified in the Annex and premixtures containing those substances, which are produced and labelled before 28 March 2024 in accordance with the rules applicable before 28 September 2023 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 specified in the Annex, which are produced and labelled before 28 September 2024 in accordance with the rules applicable before 28 September 2023 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 substances specified in the Annex, which are produced and labelled before 28 September 2025 in accordance with the rules applicable before 28 September 2023 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

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, 7 September 2023.

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

Category: Sensory additives. Functional group: Flavouring compounds

2b13054	2-Acetylfuran	<i>Additive composition</i> 2-Acetylfuran Liquid form <i>Characterisation of active substance</i> 2-Acetylfuran Produced by chemical synthesis Purity: min. 97 % Chemical formula: C₆H₆O₂ CAS number: 1192-62-7 FLAVIS: 13.054 <i>Analytical method ⁽¹⁾</i> For the identification of 2-acetylfuran in the feed additives and flavouring premixtures: — Gas chromatography-mass spectrometry with retention time locking (GC-MS-RTL)	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 per kg of complete feedingstuff with a moisture content of 12 %: 0,5 mg.' 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 premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3. 5. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	28 September 2033
---------	---------------	---	--------------------	---	---	---	---	-------------------

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

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

Category: Sensory additives. Functional group: Flavouring compounds

2b13059	2-Pentylfuran	<i>Additive composition</i> 2-Pentylfuran Liquid form <i>Characterisation of active substance</i> 2-Pentylfuran Produced by chemical synthesis Purity: min. 99 % Chemical formula: C₉H₁₄O CAS number: 3777-69-3 FLAVIS: 13.059 <i>Analytical method ⁽¹⁾</i> For the identification of 2-pentylfuran in the feed additives and flavouring premixtures: — Gas chromatography-mass spectrometry with retention time locking (GC-MS-RTL)	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 per kg of complete feedingstuff with a moisture content of 12 %: 0,5 mg." 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 premixture where the use level on the label of the premixture would result in exceeding the level referred to in point 3. 5. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	28 September 2033
---------	---------------	--	--------------------	---	---	---	---	-------------------

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1708**of 7 September 2023****concerning the renewal of the authorisation of urea as a feed additive for ruminants with a functional rumen and repealing Implementing Regulation (EU) No 839/2012****(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) Urea was authorised for a period of 10 years as a feed additive for ruminants with a functional rumen by Commission Implementing Regulation (EU) No 839/2012 ⁽²⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of urea as a feed additive for ruminants with a functional rumen, requesting the additive to be classified in the additive category 'nutritional additives' and in the functional group 'urea and its derivatives'. That application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 11 January 2023 ⁽³⁾ that the applicant provided evidence that the additive remains safe for the target species, the consumers and the environment under the existing conditions of authorisation. In the absence of new information providing evidence for the safety of the additive for the user, the Authority could not conclude on the users' safety. The Authority also indicated that the conclusion made previously on the efficacy remains valid. It did not consider that there is a need for specific requirements of post-market monitoring.
- (5) The Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the assessment carried out regarding the method of analysis of urea as a feed additive in the context of the previous authorisation are valid and applicable for the current application. In accordance with Article 5(4), point (c), of Commission Regulation (EC) No 378/2005 ⁽⁴⁾, an evaluation report of the Reference Laboratory is therefore not required.
- (6) In view of the above, the Commission considers 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. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of urea as a feed additive, Implementing Regulation (EU) No 839/2012 should be repealed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 839/2012 of 18 September 2012 concerning the authorisation of urea as a feed additive for ruminants (OJ L 252, 19.9.2012, p. 11).

⁽³⁾ EFSA Journal 2023;21(2):7821.

⁽⁴⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

- (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

Renewal of authorisation

The authorisation of the substance specified in the Annex, belonging to the additive category 'nutritional additives' and to the functional group 'urea and its derivatives', is renewed subject to the conditions laid down in that Annex.

Article 2

Repeal of Implementing Regulation (EU) No 839/2012

Implementing Regulation (EU) No 839/2012 is repealed.

Article 3

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, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identifica- tion 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 the additive/kg of complete feed with a moisture content of 12 %			
Category: nutritional additives. Functional group: Urea and its derivatives								
3d1	Urea	<i>Additive composition</i> Urea content: minimum 97 % Nitrogen content: 46 % Solid form <i>Characterisation of the active substance</i> Diaminomethanone, CAS number 57-13-6, chemical formula: (NH ₂) ₂ CO <i>Analytical method ⁽¹⁾</i> For the determination of the total nitrogen in the additive: Titrimetry (EN 15478) For the determination of the biuret contribution to the total nitrogen in the additive: Spectrophotometry (EN 15479) For the determination of urea in premixtures, compound feed and feed materials: Spectrophotometry (Annex III.D to Regulation (EC) No 152/2009)	Ruminants with a functional rumen			8 800	1. In the directions for use of the additive and feed containing it, the following shall be indicated: 'Urea shall only be fed to animals with a functional rumen. Feeding urea to the maximum level dose should be done gradually. The maximum content of urea should be fed only as part of diets rich in easily digestible carbohydrates and low in soluble nitrogen. A maximum 30 % of total nitrogen in the daily ration should come from urea-N.' 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 by such procedures and measures, the additive and premixtures shall be used with personal skin, eye and breathing protective equipment.	28 September 2033

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1709

of 7 September 2023

concerning the authorisation of a preparation of *Lentilactobacillus diolivorans* DSM 33625 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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of *Lentilactobacillus diolivorans* DSM 33625 (previously taxonomically identified as *Lactobacillus diolivorans* DSM 33625). That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) The application concerns the authorisation of the preparation of *Lentilactobacillus diolivorans* DSM 33625 as a feed additive for all animal species, requesting that additive to be classified in the category 'technological additives' and in the functional group 'silage additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 17 January 2023 ⁽²⁾ that, under the proposed conditions of use, the preparation of *Lentilactobacillus diolivorans* DSM 33625 is safe for the target species, consumers and the environment. It also concluded that the preparation is not a skin or an eye irritant, that in the absence of data, no conclusion can be drawn on the skin sensitisation of the additive and that, given the proteinaceous nature of the active agent, the additive should be considered a respiratory sensitiser. The Authority further concluded that *Lentilactobacillus diolivorans* DSM 33625 at a minimum concentration of 1×10^8 CFU/kg forage may extend the aerobic stability of silage prepared from easy and moderately difficult to ensile forage material with a dry matter range of 32–65 %. The Authority 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) In view of the above, the Commission considers that the preparation of *Lentilactobacillus diolivorans* DSM 33625 satisfies the conditions provided for in Article 5 of Regulation (EC) No 1831/2003. Accordingly, the use of that preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

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

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ EFSA Journal 2023;21(2):7820.

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, 7 September 2023.

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
					CFU/kg of fresh material			
Category: technological additives. Functional group: silage additives								
1k21901	<i>Lentilactobacillus diolivorans</i> DSM 33625	Additive composition Preparation of <i>Lentilactobacillus diolivorans</i> DSM 33625 containing a minimum of 2 × 10 ¹¹ CFU/g additive Solid form	All animal species	-		-	1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum dose of the additive when used without combination with other micro-organisms as silage additives: 1 × 10 ⁸ CFU/kg of easy and moderately difficult to ensile fresh material ⁽²⁾ . 3. 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 by such procedures and measures, the additive and premixtures shall be used with personal skin and breathing protective equipment.	28 September 2033
		Characterisation of the active substance Viable cells of <i>Lentilactobacillus diolivorans</i> DSM 33625						
		Analytical method ⁽¹⁾ Enumeration in the feed additive of <i>Lentilactobacillus diolivorans</i> DSM 33625: — Spread plate method on MRS agar (EN 15787) Identification of <i>Lentilactobacillus diolivorans</i> DSM 33625: — Pulsed Field Gel Electrophoresis (PFGE) or DNA sequencing methods						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1,5–3,0 % soluble carbohydrates in the fresh material in accordance with Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1710**of 7 September 2023**

concerning the renewal of the authorisation of a preparation of ammonium chloride as a feed additive for all ruminants and cats and dogs, an authorisation of a preparation of ammonium chloride as a feed additive for sows (holder of the authorisation: Latochema Co. Ltd) and repealing Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007

(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 Articles 9(2),

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 an authorisation.
- (2) A preparation of ammonium chloride was authorised for a period of 10 years as a feed additive for lambs for fattening by Commission Implementing Regulation (EU) No 832/2012 ⁽²⁾ and for ruminants other than lambs for fattening, cats and dogs by Commission Implementing Regulation (EU) 2016/1007 ⁽³⁾.
- (3) In accordance with Article 14(1) of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of the preparation of ammonium chloride for all ruminants, cats and dogs. In accordance with Article 7 of Regulation (EC) No 1831/2003, another application was submitted for a new use of that preparation for sows. Those applications requested that additive to be classified in the category 'zootechnical additives' and in the functional group 'other zootechnical additives' and were accompanied by the particulars and documents required respectively under Article 7(3) and Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 22 November 2022 ⁽⁴⁾, that the preparation of ammonium chloride remains safe for lambs for fattening, ruminants other than lambs for fattening, cats and dogs, as well as for the consumers and the environment under the conditions of use currently authorised. The Authority also concluded that this preparation is safe and efficacious in reducing the urinary pH for sows at the inclusion level of 5 000 mg/kg feedingstuffs from week 9th to 11th of gestation and from week 15th of gestation to 1st of lactation and that is safe for the consumers and the environment when used as a feed additive for sows. The Authority further concluded that the preparation should be considered a potential respiratory sensitiser but not a skin sensitiser nor irritant to the skin. It could not conclude on its eye irritation potential. The Authority did not consider that there is a need for specific requirements of post-market monitoring.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Implementing Regulation (EU) No 832/2012 of 17 September 2012 concerning the authorisation of a preparation of ammonium chloride as a feed additive for lambs for fattening (holder of authorisation Latochema Co. Ltd) (OJ L 251, 18.9.2012, p. 27).

⁽³⁾ Commission Implementing Regulation (EU) 2016/1007 of 22 June 2016 concerning the authorisation of ammonium chloride as a feed additive for ruminants other than lambs for fattening, cats and dogs (holder of authorisation Latochema Co. Ltd) (OJ L 165, 23.6.2016, p. 10).

⁽⁴⁾ EFSA Journal 2023;21(1):7696.

- (5) In accordance with Article 5(4), points (a) and (c) of Commission Regulation (EC) No 378/2005 ⁽ⁱ⁾, the Reference Laboratory set up by Regulation (EC) No 1831/2003 considered that the conclusions and recommendations reached in the previous assessment regarding the methods used for the control of the preparation of ammonium chloride in feed are valid and applicable for the current applications.
- (6) The assessment of the preparation of ammonium chloride 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 for all ruminants, cats and dogs and the use of that additive should be authorised for sows. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (7) As a consequence of the renewal of the authorisation of the preparation of ammonium chloride for all ruminants, cats and dogs as a feed additive, Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007 should be repealed.
- (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

Renewal of the authorisation

The authorisation of the preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is renewed for ruminants, cats and dogs, subject to the conditions laid down in that Annex.

Article 2

Authorisation

The preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'other zootechnical additives', is authorised for sows, subject to the conditions laid down in that Annex.

Article 3

Repeal

Implementing Regulations (EU) No 832/2012 and (EU) 2016/1007 are repealed.

Article 4

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*.

⁽ⁱ⁾ Commission Regulation (EC) No 378/2005 of 4 March 2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives (OJ L 59, 5.3.2005, p. 8).

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

Done at Brussels, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

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

Category of zootechnical additives. Functional group: other zootechnical additives (reduction of urinary pH).

4d7	Latochema Co Ltd	Ammonium chloride	<i>Additive composition</i> Preparation of ammonium chloride ≥ 99,5 % Solid form	Lambs for fattening	—	—	10 000	- In the directions for use of the additive and premixtures, the storage conditions and stability to heat treatment shall be indicated. - The additive shall be incorporated into the feed in the form of a premixture. - For lambs for fattening, the additive shall be used for a feeding period which does not exceed three months. - For ruminants other than lambs for fattening the additive shall be used under the following conditions: — maximum content of 5 000 mg additive/kg complete feed for a feeding period exceeding three months or — maximum content of 10 000 mg additive/kg complete feed for a feeding period not exceeding three months. - For sows the additive shall only be used from 9th to 11th week of gestation and from 15th week of gestation to 1st week of lactation.	28 September 2033
			<i>Characterisation of the active substance</i> Ammonium chloride ≥ 99,5 % Chemical formula: NH ₄ Cl CAS No: 12125-02-9 Sodium chloride ≤ 0,5 % Produced by chemical synthesis	Ruminants other than lambs for fattening	—	—	5 000/10 000		
			<i>Analytical method</i> ⁽¹⁾ Quantification of ammonium chloride in feed additive: titration with sodium hydroxide (European Pharmacopoeia, monograph 0007) or titration with silver nitrate (JECFA monograph 'ammonium chloride')	Cats and dogs	—	—	5 000		
				Sows	—	—	5 000		

								6. 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 by such procedures and measures, the additive and premixtures shall be used with personal eye and breathing protective equipment. 7. The mixture of different sources of ammonium chloride shall not exceed the permitted maximum levels in complete feedingstuffs for ruminants, including lambs for fattening, for cats, dogs and sows.	
--	--	--	--	--	--	--	--	--	--

(¹) Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1711**of 7 September 2023****concerning the renewal of the authorisation of a preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive for dairy cows and repealing Regulation (EC) No 537/2007 (holder of authorisation: Biozyme Incorporated)****(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) A preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 was authorised for 10 years as a feed additive for dairy cows by Commission Regulation (EC) No 537/2007 ⁽²⁾.
- (3) In accordance with Article 14 of Regulation (EC) No 1831/2003, an application was submitted for the renewal of the authorisation of that preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive for dairy cows in the additive category 'zootechnical additives' and in the functional group 'digestibility enhancers'. The application was accompanied by the particulars and documents required under Article 14(2) of that Regulation.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 10 November 2021 ⁽³⁾, with reference to its opinion of 28 January 2020 ⁽⁴⁾, that the applicant had provided evidence that the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 remains safe for the target species, the consumers and the environment under the conditions of use currently authorised. The Authority stated that the preparation should be considered a potential respiratory sensitiser, and indicated that there was no need for assessing its efficacy in the context of the renewal of the authorisation. It also verified the report on the methods of analysis used for the control of the active substances of the preparation submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003, including a modified method for the quantification of endo-1,4-beta-glucanase activity in the feed additive. The Reference Laboratory recommended to change the specification and description of the endo-1,4-beta-glucanase enzyme accordingly in the authorisation act.
- (5) The assessment of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 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 preparation should be renewed.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.

⁽²⁾ Commission Regulation (EC) No 537/2007 of 15 May 2007 concerning the authorisation of the fermentation product of *Aspergillus oryzae* (NRRL 458) (Amaferm) as a feed additive (OJ L 128, 16.5.2007, p. 13).

⁽³⁾ EFSA Journal 2022;20(2):6983.

⁽⁴⁾ EFSA Journal 2020;18(2):6011.

- (6) 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. Those protective measures should be without prejudice to other worker safety requirements under Union law.
- (7) As a consequence of the renewal of the authorisation of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458 as a feed additive, Regulation (EC) No 537/2007 should be repealed.
- (8) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the preparation concerned, it is appropriate to provide for a transitional period for the interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (9) 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

Renewal of the authorisation

The authorisation of the preparation of the fermentation product of *Aspergillus oryzae* NRRL 458, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers' is renewed subject to the conditions laid down in the Annex.

Article 2

Repeal of Regulation (EC) No 537/2007

Regulation (EC) No 537/2007 is repealed.

Article 3

Transitional measures

1. The preparation specified in the Annex and premixtures containing that preparation, which are produced and labelled before 28 March 2024 in accordance with the rules applicable before 28 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted.
2. Compound feed and feed materials containing the preparation specified in the Annex, which are produced and labelled before 28 September 2024 in accordance with the rules applicable before 28 September 2023 may continue to be placed on the market and used until the existing stocks are exhausted.

Article 4

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, 7 September 2023.

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 of additive/kg of complete feedingstuff with a moisture content of 12 %			

Category of zootechnical additives. Functional group: digestibility enhancers

4a2i	Biozyme Incorporated	Fermentation product of <i>Aspergillus oryzae</i> NRRL 458	<i>Additive composition</i> Preparation of: Fermentation product of <i>Aspergillus oryzae</i> NRRL 458: 4 to 5 % Wheat bran: 94 to 95 % Solid form. <i>Characterisation of the active substance</i> Endo-1,4-beta-glucanase (EC 3.2.1.4) and alpha-amylase (EC 3.2.1.1) having respectively a minimum activity of 14,5 mU ⁽¹⁾/g and 20 mIU ⁽²⁾/g. <i>Analytical method ⁽³⁾</i> For the quantification of endo-1,4-beta-glucanase in the feed additive: colorimetric method based on the enzymatic reaction by endo-1,4-beta-glucanase on a CellG5 substrate. For the quantification of alpha-amylase in the feed additive: colorimetric (DNS) method based on the enzymatic reaction by alpha-amylase on a potato starch substrate.	Dairy cows	—	85	300	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended dose: the quantity of the additive in daily ration should be 3 to 5 g/cow/day. 3. 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 by such procedures and measures, the additive and premixtures shall be used with personal breathing protective equipment.	28 September 2033
------	----------------------	--	--	------------	---	----	-----	--	-------------------

⁽¹⁾ One CellG5 Unit (U) is the amount of enzyme in the presence of excess thermostable beta-glucosidase, required to release one micromole of 4-nitrophenol from CellG5 in one minute under the defined assay conditions.

⁽²⁾ One unit of alpha-amylase activity (IU) refers to the amylase that liberates 1 micromole of glucose per minute from potato starch at pH 6,9 and at 38 °C.

⁽³⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1712**of 7 September 2023****concerning the authorisation of Sunset Yellow FCF as a feed additive for cats, dogs, ornamental fish, grain-eating ornamental birds and small rodents****(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 an 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) Sunset Yellow FCF was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive for ornamental fish belonging to the group 'colourants, including pigments' under the heading 'other colourants' and for dogs and cats under the heading 'other colourants – colouring agents authorised for colouring foodstuffs by Community rules'. Under the same Directive, it was authorised without a time limit for all species or categories of animals, with the exception of cats and dogs, in animal feedingstuffs only in products processed from: (i) waste products of foodstuffs; (ii) other base substances, with the exception of cereals and manioc flour, denaturated by means of these agents or coloured during technical preparation to ensure the necessary identification during manufacture. It was also authorised without a time limit for grain-eating ornamental birds and small rodents by Commission Regulation (EC) No 358/2005 ⁽³⁾. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1), point (b), 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 Sunset Yellow FCF as a feed additive for dogs, cats, ornamental fish, grain-eating ornamental birds and small rodents. The applicant requested the additive to be classified in the additive category 'sensory additive' and in the functional group 'colourants'. 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 23 March 2022 ⁽⁴⁾ that, under the proposed conditions of use, Sunset Yellow FCF does not have adverse effects on animal health. However, in the absence of adequate information, it could not conclude on the eyes and skin irritation potential, and on its skin sensitisation potential. Users are likely to be exposed by inhalation. In accordance with Commission Regulation (EC) No 429/2008 ⁽⁵⁾, phase I of the environmental risk assessment has determined that Sunset Yellow FCF, as an additive intended for non-food producing animals, is exempted from further assessment due to the unlikelihood of a significant environmental effect, there being no scientifically-based evidence for concern having been identified by

⁽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⁾ Commission Regulation (EC) No 358/2005 of 2 March 2005 concerning the authorisations without a time limit of certain additives and the authorisation of new uses of additives already authorised in feedingstuffs (OJ L 57, 3.3.2005, p. 3).

⁽⁴⁾ EFSA Journal 2022;20(5):7266.

⁽⁵⁾ Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1).

the Authority in its abovementioned opinion. The Authority could not conclude on the efficacy of Sunset Yellow FCF, considering the wide variety of feedingstuffs used in complete and complementary feed for the target species, and the uncertainty of which concentration of Sunset Yellow FCF would result in a visible effect. However, the Authority also stated that for this additive, which is authorised in food and, where the function for feed is the same as that for food, no further demonstration of efficacy might be necessary. The applicant also provided further information and the Commission considered that there is sufficient evidence of the efficacy of Sunset Yellow FCF. The Authority also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

- (5) The assessment of Sunset Yellow FCF 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. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the additive, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.
- (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

Authorisation

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

Article 2

Transitional measures

1. The substance specified in the Annex and premixtures containing that substance, which are produced and labelled before 28 March 2024, in accordance with the rules applicable before 28 September 2023, 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 28 September 2025, in accordance with the rules applicable before 28 September 2023, may continue to be placed on the market and used until the existing stocks are exhausted.

Article 3

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, 7 September 2023.

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (i) substances that add or restore colour in feedingstuffs								
2a110	Sunset Yellow FCF	Additive composition	Cats	-	-	165	1. In the directions for use of the additive and premixtures, the storage conditions 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 its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal eyes, skin and breathing protective equipment.	28 September 2033
		Sunset Yellow FCF	Dogs	-	-	198		
		Solid form (powder or granules)						
		Characterisation of the active substance	Ornamental fish	-	-	733		
		Sunset Yellow FCF, described as the sodium salt, consists essentially of disodium 2-hydroxy-1-(4-sulfonatophenylazo)naphthalene-6-sulfonate and subsidiary colouring matters together with sodium chloride and/or sodium sulfate as the principal uncoloured components. Calcium and potassium salts are also allowed with the same characterisation as sodium salt.	Grain-eating ornamental birds	-	-	24		
		Produced by chemical synthesis	Small rodents	-	-	750		
		Purity criteria: content not less than 90 % total colouring matters, calculated as the sodium salt (assay)						
		Water insoluble matter: ≤ 0,2 %						
		Subsidiary colouring matters: ≤ 5 %						
		1-(Phenylazo)-2-naphthalenol (Sudan I): ≤ 0,5 mg/kg)						
		Organic compounds other than colouring matters: ≤ 0,5 %						

		Unsulphonated primary aromatic amines: $\leq 0,01$ % (calculated as aniline) Ether extractable matter: $\leq 0,2$ % from a solution of pH 7 Chemical formula: $C_{16}H_{10}N_2Na_2O_7S_2$ CAS number: 2783-94-0						
		<i>Analytical method</i> ⁽¹⁾ For the determination of the total colouring matters content of Sunset Yellow FCF in the feed additive: — spectrophotometry at 485 nm and titration with titan chloride as specified and described in Commission Regulation (EU) No 231/2012 ⁽²⁾ which refers to FAO JECFA Combined Compendium for Food Additive Specifications (Analytical methods Vol. 4) and the Monograph No 11 (2011) 'Sunset Yellow FCF' For the determination of Sunset Yellow FCF in compound feed: — high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS)						

⁽¹⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

⁽²⁾ Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1713

of 7 September 2023

concerning the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 for chickens for fattening, chickens reared for laying and minor poultry species (holder of authorisation: Danisco (UK) Ltd represented in the Union by Genencor international B.V.)

(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 an authorisation.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease (also known as 'subtilisin') produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) That application concerns the authorisation of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 as a feed additive for chickens for fattening, chickens reared for laying, laying hens and minor poultry species, to be classified in the category 'zootechnical additives' and in the functional group 'digestibility enhancers'.
- (4) The European Food Safety Authority ('the Authority') could not conclude, in its opinion of 25 May 2020 ⁽²⁾, on the safety of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* ATCC SD-2107 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 for the target species, consumers, users and the environment. However, in its subsequent opinion of 6 January 2023 ⁽³⁾, the Authority reported that the applicant submitted new information to address some of the limitations identified in the opinion of 25 May 2020 and declared a change in the production strain of the protease, substituting *Bacillus subtilis* ATCC SD-2107 for *Bacillus subtilis* CBS 148232, and concluded that, under the proposed conditions of use, the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 does not have adverse effects on animal health, consumer safety or the environment. It also concluded that that preparation is considered a respiratory sensitiser and, in the absence of data, could not conclude on its irritancy potential to skin and eyes nor on its skin sensitising properties. The Authority also concluded in its opinion of 6 January 2023 with reference to its opinion of 25 May 2020 that the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 is efficacious in chickens for fattening, chickens reared for laying and minor poultry species up to the point of lay, but could not conclude on its efficacy for laying hens. It did 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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ EFSA Journal 2020;18(6):6165.⁽³⁾ EFSA Journal 2023;21(2):7816.

- (5) The applicant withdrew the application, on 14 April 2023, for the authorisation of the preparation for laying hens.
- (6) The assessment of the preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* ATCC PTA-5588, protease produced by *Bacillus subtilis* CBS 148232 and alpha-amylase produced by *Bacillus licheniformis* ATCC SD-6525 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised. In addition, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on the health of the users of the additive.
- (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

Authorisation

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

Article 2

Entry into force

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

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

Done at Brussels, 7 September 2023.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Identification number of the additive	Name of the holder of authorisation	Additive	Composition, chemical formula, description, analytical method	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
						Units of activity/kg of complete feedingstuff with a moisture content of 12 %			
Category of zootechnical additives. Functional group: digestibility enhancers									
4a40	Danisco (UK) Ltd represented in the Union by Genencor International B.V.	Endo- 1,4-beta-xylanase (EC 3.2.1.8), protease (EC 3.4.21.62) and alpha-amylase (EC 3.2.1.1)	<i>Additive composition</i> Preparation of endo-1,4-beta-xylanase produced by <i>Trichoderma reesei</i> ATCC PTA-5588, protease produced by <i>Bacillus subtilis</i> CBS 148232 and alpha-amylase produced by <i>Bacillus licheniformis</i> ATCC SD-6525 with a minimum activity of: Endo-1,4-beta-xylanase: 20 000 U _X ⁽¹⁾ /g Protease: 40 000 U _P ⁽²⁾ /g Alpha-amylase: 2 000 U _A ⁽³⁾ /g Solid form <i>Characterisation of the active substance</i> Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by <i>Trichoderma reesei</i> ATCC PTA-5588, protease (EC 3.4.21.62, also known as 'subtilisin') produced by <i>Bacillus subtilis</i> CBS 148232 and alpha-amylase (EC 3.2.1.1) produced by <i>Bacillus licheniformis</i> ATCC SD-6525	Chickens for fattening Chickens reared for laying Minor poultry species for fattening and reared for laying	—	Endo-1,4-beta-xylanase 2 000 U _X Protease 4 000 U _P Alpha-amylase 200 U _A	—	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 its use. Where those risks cannot be eliminated by such procedures and measures, the additive and premixtures shall be used with personal breathing, eye and skin protective equipment.	28 September 2033

			<i>Analytical method ⁽⁴⁾</i> For the quantification of endo-1,4-beta-xylanase in the feed additive, premixtures and compound feeds: colorimetric method, based on the enzymatic hydrolysis by xylanase of an azurine cross-linked wheat arabinoxylan substrate at pH 4,2 and 50 °C; For the quantification of protease in feed additive and premixtures and compound feeds: colorimetric method based on the enzymatic hydrolysis by protease of a dyed cross-linked casein substrate at pH 10,0 and 50 °C; For the quantification of alpha-amylase in feed additive, premixtures and compound feeds: colorimetric method based on the enzymatic hydrolysis by amylase of an azurine cross-linked starch polymer substrate at pH 8,0 and 40 °C.						
--	--	--	--	--	--	--	--	--	--

- ⁽¹⁾ One unit of endo-1,4-beta-xylanase activity (U_X) is the amount of enzyme, which liberates 0,48 micromoles per minute of reducing sugars, expressed as xylose equivalents, from a wheat arabinoxylan substrate at pH 4,2 and 50 °C.
- ⁽²⁾ One unit of protease activity (U_P) is defined as the amount of enzyme which liberates 2,3 micrograms per minute of phenolic compounds, expressed as tyrosine equivalents from a casein substrate at pH 10,0 and 50 °C.
- ⁽³⁾ One unit of alpha-amylase activity (U_A) is the amount of enzyme required to release, in the presence of an excess of alpha-glucosidase, 0,20 micromoles per minute of glucosidic linkages, expressed as p-nitrophenol equivalents, from a maltoheptasoide substrate at pH 8,0 and 40 °C.
- ⁽⁴⁾ Details of the analytical methods are available at the following address of the Reference Laboratory: https://joint-research-centre.ec.europa.eu/eurl-fa-eurl-feed-additives/eurl-fa-authorisation/eurl-fa-evaluation-reports_en.

ACTS ADOPTED BY BODIES CREATED BY INTERNATIONAL AGREEMENTS

Only the original UN/ECE texts have legal effect under international public law. The status and date of entry into force of this Regulation should be checked in the latest version of the UN/ECE status document TRANS/WP.29/343, available at: <https://unece.org/status-1958-agreement-and-annexed-regulations>

UN Regulation No 92 – Uniform provisions concerning the approval of non-original replacement exhaust silencing systems (NORESS) for vehicles of categories L₁, L₂, L₃, L₄ and L₅ with regard to sound emission [2023/1714]

Incorporating all valid text up to:

02 series of amendments – Date of entry into force: 15 October 2019

This document is meant purely as documentation tool. The authentic and legally binding text is: ECE/TRANS/WP.29/2019/7.

CONTENTS

Regulation

1. Scope
2. Definitions
3. Application for approval
4. Markings
5. Approval
6. Specifications
7. Modification and extension of the approval of NORESS and extension of approval
8. Conformity of production
9. Penalties for non-conformity of production
10. Production definitively discontinued
11. Names and addresses of Technical Services responsible for conducting approval tests, and of Type Approval Authorities
12. Transitional provisions

Annexes

1. Communication
2. Example of the approval marks
3. Requirements for fibrous absorbent materials used in NORESS
4. Statement of Compliance with the Additional Sound Emission Provisions

1. Scope

This UN Regulation applies to non-original replacement exhaust silencing systems for vehicles of categories L₁, L₂, L₃, L₄ and L₅ ⁽¹⁾.

2. Definitions

For the purpose of this UN Regulation

- 2.1. '*Non-original replacement exhaust silencing system or components of this system*' means a system of a type different from that fitted to the vehicle on approval or extension of approval. It may be used only as a replacement exhaust or silencing system.

The acronym NORESS denotes the non-original replacement exhaust silencing system.

- 2.2. '*Non-original replacement exhaust silencing system component*' means one of the various components which together form the exhaust silencing system. ⁽²⁾

- 2.3. '*Non-original replacement exhaust silencing systems of different types*' means silencing systems which differ significantly in such respects as:

- (a) Their components bear different trade names or marks,
- (b) The characteristics of the materials constituting a component are different or the components differ in shape or size; a modification in respect to coating (zinc coating, aluminium coating, etc.) is not considered a change of type,
- (c) The operating principles of at least one component are different,
- (d) Their components are combined differently.

- 2.4. '*Non-original replacement exhaust silencing system (NORESS) or component thereof*' means any part of the exhaust silencing system defined in paragraph 2.1. intended for use on a vehicle other than a part of the type fitted to the vehicle when submitted for type approval pursuant to UN Regulation No 9, UN Regulation No 41 or UN Regulation No 63;

- 2.5. '*Approval of a NORESS or component(s) thereof*' means the approval of the whole or a part of a silencing system adaptable to one or several specified types of vehicle, falling under the scope of this UN Regulation, as regards the limitation of their sound level;

- 2.6. '*Vehicle type*' means vehicles, falling under the scope of this UN Regulation, which do not differ in such essential respects as:

- (a) The type of engine (two-stroke or four-stroke with reciprocating or rotary pistons; number and capacity of cylinders; number and type of carburettors or injection systems; arrangement of valves; maximum net power and corresponding engine speed). For rotary piston engines, the cubic capacity should be taken to be double of the volume of the chamber;
- (b) Drive train, in particular the number and ratios of the gears of the transmission and the final ratio;
- (c) Number, type and arrangement of exhaust silencing systems.

- 2.7. '*Rated engine speed*' means the engine speed at which the engine develops its rated maximum net power as stated by the manufacturer. ⁽³⁾

The symbol n_{rated} denotes the numerical value of the rated engine speed expressed in revolutions per minute.

⁽¹⁾ As defined in the Consolidated Resolution on the Construction of Vehicles (R.E.3.) (ECE/TRANS/WP.29/78/Rev.6, para. 2).

⁽²⁾ Those components are, in particular, the exhaust manifold, the silencer proper, the expansion chamber and the resonator.

⁽³⁾ If the rated maximum net power is reached at several engine speeds, the rated engine speed is used in this Regulation as the highest engine speed at which the rated maximum net power is reached.

3. Application for approval

3.1. The application for approval of a NORESS or components thereof shall be submitted by its manufacturer or by his duly accredited representative.

3.2. It shall be accompanied by the under mentioned documents in triplicate and the following particulars:

- (a) A description of the vehicle type(s) on which the NORESS or components are intended to be fitted, with regard to the items referred to in paragraph 2.6 above. The numbers and/or symbols identifying the engine type and the vehicle type shall be specified and the ~~motor cycle~~ vehicle type approval number, if necessary;
- (b) A description of the complete NORESS showing the relative position of each of its components, together with instructions for their assembly;
- (c) Detailed drawings of each NORESS component to enable it to be easily located and identified, and specification of the materials used. These drawings shall also indicate the location for the mandatory affixing of the approval number.

3.3. At the request of the Technical Service conducting the tests for approval, the manufacturer of the NORESS shall submit:

- (a) Two samples of the NORESS or its components submitted for approval;
- (b) A sample of the original exhaust silencing system with which the vehicle was equipped when submitted for type approval;
- (c) A test vehicle representative of the type to which the NORESS is to be fitted; this vehicle, when measured for sound emission according to the methods described in Annex 3 (including all relevant amendments) to UN Regulation No 9, UN Regulation No 41 or UN Regulation No 63 shall satisfy the following conditions:
 - (i) If the vehicle is of a type for which approval has been issued pursuant to the requirements of each of UN Regulations Nos 9, 41 or 63:
 - (a) The sound level, during the test in motion shall not exceed the limit specified in the appropriate UN Regulation by more than 1 dB(A);
 - (b) The sound level during the stationary test shall not exceed by more than 3 dB(A), the level determined during the approval and indicated on the manufacturer's plate.
 - (ii) If the vehicle is not of the type for which approval has been issued pursuant to the requirements of the appropriate UN Regulation, the sound level shall not exceed by more than 1 dB(A) the limit applicable at the time when it was first put on the road.

4. Markings

4.1. Each component of the NORESS, excluding pipes and fitting accessories, shall bear:

- (a) The trade name or mark of the manufacturer of the NORESS or its components;
- (b) The commercial designation given by the manufacturer.

4.2. These markings shall be clearly legible and indelible and also visible in the position at which the NORESS is fitted.

4.3. The NORESS shall be labelled by its manufacturer; indicating the type(s) of vehicle(s) for which it has been granted the approval.

4.4. A component may carry several approval numbers if it has been approved as a component of several replacement exhaust systems.

4.5. The replacement exhaust system shall be supplied in a packaging or carry a label both providing the following particulars:

- (a) The trade name or mark of the manufacturer of the replacement silencing system and its components,

- (b) The address of the manufacturer or his representative,
 - (c) A list of vehicle models for which the replacement silencing system is intended.
- 4.6. The manufacturer shall provide:
 - (a) Instructions explaining in detail the correct method of mounting on the vehicle;
 - (b) Instructions for handling the silencing system;
 - (c) A list of components with the numbers of the corresponding parts, excluding retainers.
- 4.7. The approval mark.
- 5. Approval
 - 5.1. If the NORESS or component thereof submitted for approval under this UN Regulation meets the requirements of paragraph 6. below, approval for that type shall be granted.
 - 5.2. An approval number shall be assigned to each NORESS type approved. Its first two digits (at present 01 corresponding to the 01 series of amendments to the UN Regulation) shall indicate the series of amendments incorporating the most recent major technical amendments made to the UN Regulation at the time of issue of the approval. The same Contracting Party may not assign the same number to another type of NORESS or component designed for, the same type(s) of vehicle.
 - 5.3. Notice of approval or extension or refusal of approval of a NORESS or component thereof under this UN Regulation shall be communicated to the Parties to the Agreement which apply this UN Regulation, by means of a form conforming to the model in Annex 1 to this UN Regulation.
 - 5.4. There shall be affixed to every NORESS and component thereof conforming to a type approved under this UN Regulation an international approval mark consisting of:
 - (a) A circle surrounding the letter 'E' followed by the distinguishing number of the country which has granted approval; (*)
 - (b) The number of this UN Regulation, followed by the letter 'R', a dash and the approval number to the right of the circle prescribed in (a) above;
 - (c) The approval number shall be indicated in the approval form, together with the method used for the approval tests.
 - 5.5. The approval mark shall be easily legible when the NORESS is fitted to the vehicle, and shall be indelible.
 - 5.6. A component may be marked with more than one approval number if it has been approved as a part of more than one NORESS; in this case the circle need not to be repeated. Annex 2 to this UN Regulation gives an example of the approval mark.
- 6. Specifications
 - 6.1. General specifications

The silencer shall be designed, constructed and capable of being mounted so that:

 - (a) The vehicle complies with the requirements of this UN Regulation under normal conditions of use, and in particular regardless of any vibrations to which it may be subjected;

(*) The distinguishing numbers of the Contracting Parties to the 1958 Agreement are reproduced in Annex 3 to the Consolidated Resolution on the Construction of Vehicles (R.E.3) (ECE/TRANS/WP.29/78/Rev.6).

- (b) It displays reasonable resistance to the corrosion phenomena to which it is exposed, with due regard to the normal conditions of use of the vehicle;
- (c) The ground clearance provided by the silencer originally fitted, and the possible inclined position of the vehicle, are not reduced;
- (d) Unduly high temperatures do not exist at the surface;
- (e) Its edges are not sharp or jagged and there is sufficient space for shock absorbers and springs;
- (f) Adequate clearance of spring parts is provided;
- (g) Adequate safety clearance of pipes is provided;
- (h) It is tamper-resistant in a way that is compatible with clearly-defined maintenance and installation requirements.

6.2. Specifications regarding sound levels

The acoustic efficiency of the NORESS or components thereof shall be verified by means of the methods described in UN Regulations Nos 9, 41 or 63. In particular, for the application of this paragraph reference shall be made to the series of amendments to UN Regulation No 92 which was in force at the time of type approval of the new vehicle. When the NORESS or its components is fitted to the vehicle described in paragraph 3.3. (c), the sound level values obtained using the two methods (stationary and vehicle in motion) shall satisfy the following condition:

They shall not exceed the values measured in conformity with the requirements of paragraph 3.3.(c), for the same vehicle when fitted with the original silencing system during the test with the vehicle in motion and ~~or~~ the stationary test.

6.3. Additional requirements

6.3.1. Tampering protection provisions

The NORESS or its components shall be constructed in a way that does not permit removal of baffles, exit-cones and other parts whose primary function is as part of the silencing/expansion chambers. Where incorporation of such a part is unavoidable, its method of attachment shall be such that removal is not facilitated (e.g. with conventional threaded fixings) and shall also be attached such that removal causes permanent/irrecoverable damage to the assembly.

6.3.2. Multi-mode NORESS

NORESS with multiple, manually or electronically adjustable, rider selectable operating modes shall meet all requirements in all operating modes. The reported sound levels shall be those resulting from the mode with the highest sound levels.

6.3.3. Prohibition of defeat devices

The NORESS manufacturer shall not intentionally alter, adjust or introduce any device or procedure solely for the purpose of fulfilling the sound emission requirements of this UN Regulation, which will not be operational during typical on-road operation.

6.3.4. Additional sound emission provisions (ASEP)

6.3.4.1. The ASEP requirements shall also be fulfilled for the NORESS, if it is designed to be used on vehicles that are type approved according to a series of amendments to UN Regulation No 41, where ASEP was part of the issued type approval of the vehicle.

If ASEP has to be tested, these tests and necessary pre-tests have to be done in accordance with the series of amendments of UN Regulation No 41, which was the basis for the issued type approval of the vehicle.

- 6.3.4.2. If NORESS has different modes or variable geometries, it has to perform the ASEP tests of UN Regulation No 41 also, if it is designed to be used on vehicles that are type approved according to a series of amendments to UN Regulation No 41, where ASEP was not a part of the issued type approval of these vehicles.

These ASEP tests and necessary pre-tests have to be done in accordance with the actual series of amendments of the UN Regulation No 41, which is the actual base for issuing type approvals of these vehicles.

The sound emission of the NORESS equipped vehicle under typical on-road driving conditions, which are different from those under which the type-approval test set out in Annex 3 and Annex 7 of UN Regulation No 41 were carried out, shall not deviate from the test result in a significant manner.

- 6.3.4.3. The ASEP tests regarding 6.3.4.2. has to be done in comparison on a vehicle, which is equipped with the original exhaust silencer and the NORESS (back-to-back-test). The ASEP tests, of the vehicle equipped with the original exhaust silencer, have to be done in normal operation mode for road use of the based sound emission approval of the vehicle. These test results build only the base of comparison with the ASEP test results of the NORESS equipped vehicle.

During these tests, the sound-pressure level of the NORESS for each test condition can have in its maximum the same sound-pressure level as the measurement of the vehicle equipped with the original exhaust silencer in its approved mode.

- 6.3.4.4. If tests regarding 6.3.4.1. or 6.3.4.2. are to be performed for NORESS without multiple, manually or electronically adjustable, rider selectable operating modes or without variable geometries, the vehicle as described in paragraph 3.3. (c) shall be used.

- 6.3.4.5. If ASEP tests regarding 6.3.4.1. or 6.3.4.2. are to be performed for NORESS, which are equipped with multiple, manually or electronically adjustable, rider selectable operating modes or with variable geometries, each vehicle type of the range of approval application of the NORESS has to be tested in each selectable mode of the vehicle and the NORESS.

- 6.3.4.6. ASEP tests regarding 6.3.4.4. can be done by the manufacturer of the NORESS.

ASEP tests regarding 6.3.4.5. have to be performed by the Technical Service. The test results of these measurements of the original and the NORESS equipped vehicle, and all relevant data of these tests have to be mentioned into the test report of the Technical Service.

- 6.3.4.7. The Type Approval Authority may require any relevant test to verify the compliance of the NORESS to the above-mentioned requirements of paragraph 6.3.4.1. to 6.3.4.6. During these tests the type approval authority can also check the software of the steering units of the NORESS, which are equipped with multiple, electronically adjustable, rider selectable operating modes or with variable geometries.

- 6.3.4.8. The manufacturer shall provide in addition to the test report of the Technical Service a statement in conformity with Annex 4 of this UN Regulation that the NORESS or components to be approved comply with the additional sound emission provision requirements of the series of amendments to UN Regulation No 41.

In the case of NORESS which are equipped with multiple, manually or electronically adjustable, rider selectable operating modes or with variable geometries the manufacturer of the NORESS has to send the approval authority an additional document with detailed principle(s) and control of the NORESS in accordance to paragraph 6.3.4.9.

- 6.3.4.9. Additional documentation for NORESS equipped with multiple, manually or electronically adjustable, rider selectable operating modes or with variable geometries

- 6.3.4.9.1. The additional documentation package required by paragraph 6.3.4.8 enabling the approval authority to evaluate the sound emission control strategy or strategies to ensure the correct operation of the NORESS.

It shall be made available in the two following parts:

- (a) the 'formal additional documentation package' that may be made available to interested parties upon request;
- (b) the 'extended additional documentation package' that shall remain strictly confidential.

6.3.4.9.2. The formal additional documentation package may be brief, provided that it exhibits evidence that all parameters to control the NORESS have been identified. The additional documentation shall describe the functional operation of the NORESS. This material shall be retained by the approval authority.

6.3.4.9.3. The extended additional documentation package shall include information on the operation of all Additional Sound Emission Strategies (ASES) and Base Sound Emission Strategy (BSES), including a description of the parameters that are modified by any ASES and the boundary conditions under which the ASES operate, and indication of which ASES and BSES are likely to be active under the conditions of the test procedures set out in the applicable ASEP requirement of UN Regulation No 41. The extended documentation package shall include all modes of operation.

The extended documentation package shall remain strictly confidential. This material shall be retained by the Type Approval Authority.

6.4. Measurement of vehicle performance

6.4.1. The NORESS or its components shall be such as to ensure that the vehicle's performance is comparable with that achieved with the original exhaust silencing system or components thereof.

6.4.2. The NORESS or, at the manufacturer's choice, the components thereof shall be compared with an original silencing system or components, also in new condition, successively fitted to the vehicle referred to in paragraph 3.3. (c).

6.4.3. The verification shall be carried out by measuring the output curve in accordance with paragraph 6.4.1. or 6.4.2. The maximum power and the engine speed at maximum power measured with the NORESS shall not exceed the net power and the engine speed measured under the conditions set out below with the original equipment exhaust system by more than ± 5 per cent.

6.4.4. Test method

6.4.4.1. Engine test method

The measurements shall be carried out on the engine of the vehicle referred to in paragraph 3.3. (c), the engine being mounted on a dynamometer.

6.4.4.2. Vehicle test method

The measurements shall be carried out on the vehicle referred to in paragraph 3.3. (c). The values obtained with the original silencing system shall be compared with those obtained with the NORESS. The test shall be conducted on a roller dynamometer.

6.5. Additional provisions regarding the NORESS or its components filled with fibrous materials

The use of fibrous absorbent material shall be permitted in the construction of the NORESS only if the requirements in Annex 3 are met.

6.6. Evaluation of the emission of pollutants of vehicles equipped with replacement silencer system

The vehicle referred to in paragraph 3.3. (c) with the non-original replacement exhaust silencing system (NORESS) of the type for which approval is requested, shall fulfil the pollution requirements according to the type approval of the vehicle. The evidence shall be documented in the test report.

7. Modification and extension of the approval of NORESS and extension of approval

7.1. Every modification of the type of NORESS or its components shall be notified to the Type Approval Authority which approved the type of NORESS. The said Authority may then either:

- (a) Consider that the modifications made are unlikely to have an appreciable adverse effect; or
- (b) Require a further test report from the Technical Service responsible for conducting the tests.

7.2. The manufacturer of the NORESS or component thereof or his duly accredited representative may ask the Type Approval Authority which has granted the approval of the NORESS for one or several types of vehicle for an extension of the approval to other types of vehicle. The procedure shall be as described in paragraph 3. above.

7.3. Confirmation or refusal of approval, specifying the modifications, shall be communicated in accordance with the procedure specified in paragraph 5.3. above to the Contracting Parties to the Agreement applying this UN Regulation.

7.4. The competent authority issuing the extension of approval shall assign a series number to each communication form drawn up for such an extension.

8. Conformity of production

The conformity of production procedures shall comply with those set out in the Agreement, Appendix 2 (E/ECE/324-E/ECE/TRANS/505/Rev.2), with the following requirements:

- (a) The NORESS approved to this UN Regulation shall be so manufactured as to conform to the type approved by meeting the requirements set out in paragraph 6. Above;
- (b) The holder of the approval shall ensure that for each type of NORESS at least the tests prescribed in paragraph 6. of this UN Regulation are carried out;
- (c) The authority which has granted type approval may at any time verify the conformity control methods applied in each production facility. The normal frequency of these verifications shall be once every two years;
- (d) The production is considered to conform to the requirements of this UN Regulation, if the provisions of UN Regulations Nos 9, 41 and 63, corresponding to the type of vehicle, are complied with and if the sound level measured by the method described in the given UN Regulations during the test in motion does not exceed by more than 3 dB(A) the sound level measured during the type approval and does not exceed by more than 1 dB(A) the limits prescribed in UN Regulations Nos 9, 41 and 63 as applicable.

9. Penalties for non-conformity of production

9.1. The approval granted in respect of a type of NORESS or its components under this UN Regulation may be withdrawn if the requirements laid down in paragraph 8. above are not complied with, or if the NORESS or its components fail to pass the tests provided for in paragraph 8. (b) above.

9.2. If a Contracting Party to the Agreement applying this UN Regulation withdraws an approval it has previously granted, it shall forthwith so notify the other Contracting Parties to the 1958 Agreement applying this UN Regulation, by means of a communication form conforming to the model contained in Annex 1 to this UN Regulation.

10. Production definitively discontinued

If the holder of the approval completely ceases to manufacture a type of replacement silencing system or components thereof in accordance with this UN Regulation, he shall so inform the authority which granted the approval which shall in turn inform thereof the other Contracting Parties to the 1958 Agreement applying this UN Regulation, by means of a copy of the communication form conforming to the model contained in Annex 1 to this UN Regulation.

11. Names and addresses of Technical Services responsible for conducting approval tests, and of Type Approval Authorities

The Contracting Parties to the 1958 Agreement which apply this UN Regulation shall communicate to the United Nations Secretariat the names and addresses of the Technical Services responsible for conducting approval tests and of the Type Approval Authorities which grant approval and to which forms certifying approval or extension or refusal or withdrawal of approval, or production definitively discontinued issued in other countries, are to be sent.

12. Transitional provisions

12.1. As from the official date of entry into force of the 02 series of amendments to this UN Regulation, no Contracting Party applying this UN Regulation shall refuse to grant or refuse to accept type approvals under the 02 series of amendments to this UN Regulation.

12.2. As from 12 months after the date of entry into force of the 02 series of amendments, Contracting Parties applying this UN Regulation shall grant approvals only if the type of component or separate technical unit to be approved meets the requirements of the 02 series of amendments to this UN Regulation.

12.3. As from 24 months after the date of entry into force, Contracting Parties applying this UN Regulation shall grant extensions to existing approvals only if the type of component or separate technical unit to be approved meets the requirements of the 02 series of amendments to this UN Regulation.

12.4. Even after the entry into force of the 02 series of amendments to this UN Regulation, approvals of the components and separate technical units to the preceding series of amendments to the UN Regulation shall remain valid and Contracting Parties applying this UN Regulation shall continue to accept them.

ANNEX 1

COMMUNICATION

PART A

NORESS for vehicle types approved according to the 04 series of amendments to UN Regulation No 41

(Maximum format: A4 (210 × 297 mm))



Issued by: Name of administration:

concerning ⁽²⁾:
 Approval granted
 Approval extended
 Approval refused
 Approval withdrawn
 Production definitively discontinued

of a vehicle type with regard to a type of NORESS or component there of pursuant to UN Regulation No 92.

Approval No Extension No.

1. Trade name or mark of the vehicle:
2. Vehicle type:
3. Manufacturer's name and address:
4. If applicable, name and address of manufacturer's representative:
5. Engine
 - 5.1. Manufacturer:
 - 5.2. Type:
 - 5.3. Model:
 - 5.4. Rated maximum net power: kW at min⁻¹
 - 5.5. Kind of engine (e.g. positive-ignition, compression ignition, etc.) ⁽³⁾:
 - 5.6. Cycles: two-stroke/four-stroke ²
 - 5.7. Cylinder capacity: cm³
6. Transmission

⁽¹⁾ Distinguishing number of the country which has granted/extended/refused/withdrawn an approval (see approval provisions in the Regulation).

⁽²⁾ Delete what does not apply.

⁽³⁾ If a non-conventional engine is used, this should be stated.

- 6.1. Type of transmission: non-automatic gearbox/automatic gearbox:
- 6.2. Number of gears:
7. Equipment
 - 7.1. Exhaust silencer
 - 7.1.1. Manufacturer or authorized representative (if any):
 - 7.1.2. Model:
 - 7.1.3. Type:in accordance with drawing No.....
 - 7.2. Intake silencer
 - 7.2.1. Manufacturer or authorized representative (if any):
 - 7.2.2. Model:
 - 7.2.3. Type: in accordance with drawing No.....
8. Gears used for test of motor cycle in motion:
9. Final drive ratio(s):
10. ECE type approval number of tyre(s):
If not available, the following information shall be provided:
 - 10.1. Tyre manufacturer:
 - 10.2. Commercial description(s) of the type of tyre (by axle), (e.g. trade name, speed index, load index):
 - 10.3. Tyre size (by axle):
 - 10.4. Other type approval number (if available):
11. Masses
 - 11.1. Maximum permissible gross weight: kg
 - 11.2. Test mass: kg
 - 11.3. Power to mass ratio index (PMR):
12. Vehicle length: m
 - 12.1. Reference length l_{ref} : m
13. Vehicle speeds of measurements in gear (i)
 - 13.1. Vehicle speed at the beginning of the period of acceleration (average of 3 runs) for gear (i): km/h
 - 13.2. Pre-acceleration length for gear (i): m
 - 13.3. Vehicle speed $v_{PP'}$ (average of 3 runs) for gear (i): km/h
 - 13.4. Vehicle speed $v_{BB'}$ (average of 3 runs) for gear (i): km/h
14. Vehicle speeds of measurements in gear (i+1) (if applicable)
 - 14.1. Vehicle speed at the beginning of the period of acceleration (average of 3 runs) for gear (i+1): km/h
 - 14.2. Pre-acceleration length for gear (i+1): m

- 14.3. Vehicle speed $v_{PP'}$ (average of 3 runs) for gear (i+1): km/h
- 14.4. Vehicle speed $v_{BB'}$ (average of 3 runs) for gear (i+1): km/h
15. Accelerations are calculated between lines AA' and BB'/PP' and BB'
- 15.1. Description of functionality of devices used to stabilize the acceleration (if applicable):
16. Sound levels of moving vehicle
- 16.1. Wide-open-throttle test result L_{wot} : db(A)
- 16.2. Constant speed test results L_{CRS} : db(A)
- 16.3. Partial power factor k_p : db(A)
- 16.4. Final test result L_{urban} : db(A)
17. Sound level of stationary vehicle
- 17.1. Position and orientation of microphone (according to Appendix 2 of Annex 3 of 04 series of UN Regulation No 41):
- 17.2. Test result for stationary test: db(A) at min^{-1}
18. Additional sound emission provisions:
See manufacturer's statement of compliance (attached)
19. In-use compliance reference data
- 19.1. Gear (i) or, for vehicles tested with non-locked gear ratios, the position of the gear selector chosen for the test:
- 19.2. Pre-acceleration length l_{PA} : m
- 19.3. Vehicle speed at the beginning of the period of acceleration (average of 3 runs) for gear (i): km/h
- 19.4. Sound pressure level $L_{wot(i)}$: dB(A)
20. Date of submission of vehicle for approval:
21. Technical Service performing the approval tests:
22. Date of report issued by that Service:
23. Number of report issued by that Service:
24. Approval granted/extended/refused/withdrawn²:
25. Position of approval mark on the motor cycle:
26. Place:
27. Date:
28. Signature:
29. The following documents, bearing the approval number shown above, are annexed to this communication:
Drawings, diagrams and plans of the engine and of the exhaust silencing system;
Photographs of the engine and of the exhaust or silencing system;
List of components, duly identified constituting the exhaust silencing system.

PART B

NORESS for vehicle types approved according to UN Regulations Nos 9 or 63

(Maximum format: A4 (210 × 297 mm))



Issued by: Name of administration:

concerning ⁽²⁾:
 Approval granted
 Approval extended
 Approval refused
 Approval withdrawn
 Production definitively discontinued

of a vehicle type with regard to a type of NORESS or component there of pursuant to UN Regulation No 92.

Approval No. | Extension No.

1. Trade name or mark of the vehicle:
2. Vehicle type:
3. Manufacturer's name and address:
4. If applicable, name and address of manufacturer's representative:
5. Engine
 - 5.1. Manufacturer:
 - 5.2. Type:
 - 5.3. Model:
 - 5.4. Rated maximum net power: kW at min⁻¹
 - 5.5. Kind of engine (e.g. positive-ignition, compression ignition, etc.) ⁽⁴⁾
 - 5.6. Cycles: two-stroke/four-stroke ²
 - 5.7. Cylinder capacity: cm³
6. Transmission
 - 6.1. Type of transmission: non-automatic gearbox/automatic gearbox:

⁽⁴⁾ Distinguishing number of the country which has granted/extended/refused/withdrawn an approval (see approval provisions in the Regulation).

⁽²⁾ Delete what does not apply.

⁽⁶⁾ If a non-conventional engine is used, this should be stated.

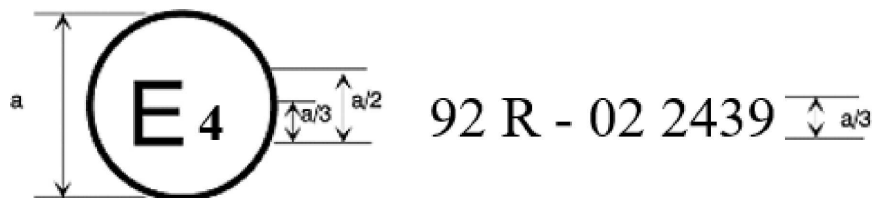
- 6.2. Number of gears:.....
7. Equipment
- 7.1. Exhaust silencer
- 7.1.1. Manufacturer or authorized representative (if any):
- 7.1.2. Model:.....
- 7.1.3. Type: in accordance with drawing No.....
- 7.2. Intake silencer
- 7.2.1. Manufacturer or authorized representative (if any):
- 7.2.2. Model:.....
- 7.2.3. Type: in accordance with drawing No
8. Gears used for test of motor cycle in motion:.....
9. Final drive ratio(s):
10. ECE type approval number of tyre(s):
- If not available, the following information shall be provided:
- 10.1. Tyre manufacturer:.....
- 10.2. Commercial description(s) of the type of tyre (by axle), (e.g. trade name, speed index, load index):.....
- 10.3. Tyre size (by axle):.....
- 10.4. Other type approval number (if available):.....
11. Masses
- 11.1. Maximum permissible gross weight: kg
- 11.2. Test mass: kg
- 11.3. Power to mass ratio index (PMR):
12. Vehicle length: m
13. Sound level of the vehicle in motion dB(A)
- 13.1. Gear (i) for the test of the vehicle in motion
- 13.2. Vehicle speed at the beginning of the period of acceleration (average of 3 runs) for gear (i):..... km/h
14. Sound level of the stationary vehicle dB(A)
- 14.1. at engine speed..... min⁻¹

- 14.2. Position and orientation of microphone:.....
15. In-use compliance reference data
- 15.1. Gear (i) or, for vehicles tested with non-locked gear ratios, the position of the gear selector chosen for the test:.....
- 15.2. Vehicle speed at the beginning of the period of acceleration (average of 3 runs) for gear (i):.....km/h
- 15.3. Sound pressure level $L_{(i)}$:dB(A)
16. Date of submission of vehicle for approval:.....
17. Technical Service performing the approval tests:.....
18. Date of report issued by that Service:
19. Number of report issued by that Service:
20. Approval granted/extended/refused/withdrawn²:
21. Position of approval mark on the motor cycle:.....
22. Place:.....
23. Date:
24. Signature:
25. The following documents, bearing the approval number shown above, are annexed to this communication:
Drawings, diagrams and plans of the engine and of the exhaust silencing system;
Photographs of the engine and of the exhaust or silencing system;
List of components, duly identified constituting the exhaust silencing system.
-

ANNEX 2

Example of the approval marks

(See paragraph 5.4. of this UN Regulation)

 $a = 8 \text{ mm min}$

The above approval mark affixed to a component of silencing systems shows that the replacement silencing system type concerned has been approved in the Netherlands (E4) pursuant to UN Regulation No 92 under approval No 022439. The approval number indicates that the approval was granted in accordance with the requirements of UN Regulation No 92 as amended by the 02 series of amendments.

ANNEX 3

Requirements for fibrous absorbent materials used in NORESS

(See paragraph 6.5. of this UN Regulation)

1. Fibrous absorbent material *shall be asbestos-free* and may be used in the construction of silencers only if suitable devices ensure that the fibrous absorbent material is kept in place for the whole time that the silencer is being used and it meets the requirements of any one of sections 2, 3, 4 or 5 according to the manufacturer's choice.
2. After removal of the fibrous material, the sound level shall comply with the requirements of paragraph 6.2. of this UN Regulation.
3. The fibrous absorbent material may not be placed in those parts of the silencer through which the exhaust gases pass and shall comply with the following requirements:
 - (a) The material shall be heated at a temperature of 650 ± 5 °C for four hours in a furnace without reduction in average length, diameter or bulk density of the fibre;
 - (b) After heating at 650 ± 5 °C for one hour in a furnace, at least 98 per cent of the material shall be retained in a sieve of nominal aperture size 250 µm complying with ISO 3310/1 when tested in accordance with ISO 2599;
 - (c) The loss in weight of the material shall not exceed 10,5 per cent after soaking for 24 hours at 90 ± 5 °C in a synthetic condensate of the following composition:
 - (i) 1 N hydrobromic acid (HBr), 10 ml
 - (ii) 1 N sulphuric acid (H₂SO₄), 10 ml
 - (iii) Distilled water to make up to 1 000 ml

Note: The material shall be washed in distilled water and dried for one hour at 105 °C before weighing.

4. Before the system is tested in accordance with paragraph 6.2. of this UN Regulation it shall be put into a normal state for road use by one of the conditioning methods in accordance with and as described in paragraph 5.1.4. of Annex 3 of UN Regulations Nos 9 or 63 or in paragraph 1.3. of Annex 5 of UN Regulation No 41, whatever is applicable.
 5. Exhaust gases are not in contact with fibrous materials and fibrous materials are not under the influence of pressure variations.
-

ANNEX 4

Statement of Compliance with the Additional Sound Emission Provisions

(Maximum format: A4 (210 × 297 mm))

This statement is required for non-original replacement exhaust silencing systems (NORESS):

- (a) with multiple, manually or electronically adjustable, rider selectable operating modes or variable geometries;
- (b) without multiple, manually or electronically adjustable, rider selectable operating modes or without variable geometries specified for the use on L₃ category vehicles that are type approved pursuant to the amendments to UN Regulation No 41 and are subject to the ASEP-requirements series of amendments to UN Regulation No 41. ⁽¹⁾

..... (Name of manufacturer) attests that the non-original replacement exhaust silencing systems of this type (type with regard to its sound emission pursuant to the ... ⁽²⁾ series of amendments to UN Regulation No 41) comply with the applicable ASEP requirements of UN Regulation No 41 during the type approval procedure and its production.

..... (Name of manufacturer) makes this statement in good faith, after having performed an appropriate evaluation of the sound emission performance of the non-original replacement exhaust silencing system in accordance with the requirements of UN Regulation No 92 during the type approval procedure and its production.

Date:

Name of authorized representative:

Signature of authorized representative:

⁽¹⁾ Delete the bullet point that does not apply.

⁽²⁾ Fill in the series of amendments to UN Regulation No 41, which the NORESS apply.

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office
of the European Union
L-2985 Luxembourg
LUXEMBOURG

EN