COMMISSION IMPLEMENTING REGULATION (EU) 2021/551

of 30 March 2021

concerning the authorisation of turmeric extract, turmeric oil, turmeric oleoresin from *Curcuma longa* L. rhizome as feed additives for all animal species and turmeric tincture from *Curcuma longa* L. rhizome as a feed additive for horses and dogs

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

Having regard to Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition ([1]), and in particular Article 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting such authorisation. Article 10(2) of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC ([2]).

(2) Turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome were authorised without a time limit in accordance with Directive 70/524/EEC as feed additives for all animal species. These additives were subsequently entered in the Register of feed additives as existing products, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 thereof, an application was submitted for the re-evaluation of turmeric extract, turmeric oil, turmeric oleoresin from *Curcuma longa* L. rhizome as a feed additives for all animal species and turmeric tincture from *Curcuma longa* L. rhizome for horses and dogs.

(4) The applicant requested turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome to be authorised for use also in water for drinking. However, Regulation (EC) No 1831/2003 does not allow the authorisation of 'flavouring compounds' for use in water for drinking. Therefore, the use of turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome in water for drinking should not be allowed.

(5) The applicant requested the additives to be classified in the additive category 'sensory additives' and in the functional group 'flavouring compounds'. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(6) The European Food Safety Authority ('the Authority') concluded in its opinion of 7 May 2020 ([3]) that, under the proposed conditions of use turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome do not have adverse effects on animal health, consumer health or the environment. The Authority also concluded that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome should be considered as irritants to skin and eyes and the respiratory tract and as skin sensitisers. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive.

([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* 2020;18(6):6146.

(7) The Authority concluded, that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome are recognised to flavour food and since their function in feed would be essentially the same as that in food, no further demonstration of efficacy is considered necessary. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the methods of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

(8) The assessment of turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of these substances should be authorised [as specified in the Annex to this Regulation].

(9) Restrictions and conditions should be provided for to allow better control. In particular, a recommended content should be indicated on the label of the feed additives. Where such content is exceeded, certain information should be indicated on the label of premixtures.

(10) The fact that turmeric extract, turmeric oil, turmeric oleoresin and turmeric tincture from *Curcuma longa* L. rhizome are not authorised for use as flavourings in water for drinking, does not preclude their use in compound feed which is administered via water.

(11) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substances concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(12) 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', are authorised as feed additives in animal nutrition, subject to the conditions laid down in that Annex.

Article 2

Use in water for drinking

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

Article 3

Transitional measures

1. The substances specified in the Annex and premixtures containing these substances, which are produced and labelled before 20 October 2021 in accordance with the rules applicable before 20 April 2021 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Compound feed and feed materials containing the substances as specified in the Annex which are produced and labelled before 20 April 2022 in accordance with the rules applicable before 20 April 2021 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 as specified in the Annex which are produced and labelled before 20 April 2023 in accordance with the rules applicable before 20 April 2021 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 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, 30 March 2021.

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 active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b163-eo	-	Turmeric essential oil	**Additive composition** Essential oil derived by steam distillation from the dried rhizomes of *Curcuma longa* L. **Characterisation of the active substance** Essential oil derived by steam distillation from the dried rhizomes of *Curcuma longa* L. as defined by the Council of Europe ([1]): — ar-Turmerone: 40-60 % — β-Turmerone (curlone): 5-15 % — ar-Curcumene: 3-6 % — β-Sesquiphellandrene: 3-6 % — α-Zingiberene: 1–5 % — (E)-Atlantone: 2–4 % CAS number 8024-37-1 ([2]) Einecs number 283-882-1 ([1]) FEMA number 3085 ([1]) CoE number 163 Liquid form	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 and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 % or milk replacers with a moisture content of 5,5 %: — all animal species except veal calves: 20 mg — veal calves: 80 mg (milk replacers)'. 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, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded.	20.4.2031

			Analytical method ([3]) For the quantification of the phytochemical markers: ar-turmerone and beta-turmerone in the feed additive (turmeric oil): — Gas chromatography coupled to mass spectrometry (GC-MS) (full scan mode) using Retention Time Locking (RTL) methodology (or standard substances of the phytochemical markers) with (or without) gas chromatography coupled to flame ionisation detection (GC-FID) based on the ISO 11024 standard method					5. The mixture of Turmeric essential oil with other authorised additives obtained from *Curcuma longa* L. shall be not be allowed in feedingstuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	
2b163-or		Turmeric oleoresin	**Additive composition** Oleoresin obtained by solvent extraction of dried rhizomes of *Curcuma longa* L. **Characterisation of the active substance** Oleoresin obtained by solvent extraction of dried rhizomes of *Curcuma longa* L. as defined by the Council of Europe ([4]).	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 and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg complete feedingstuff with a moisture content of 12 %:	20.4.2031

			Essential oil: 30-33 % (w/w) Total curcuminoids: 20-35 % (w/w) — Curcumin (I): 16-21 % (w/w) — Desmethoxycurcumin (II): 4-6 % (w/w) — Bis-desmethoxycurcumin (III): 3-5 % (w/w). Humidity: 12-30 % (w/w) **Analytical method** (5) For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric oleoresin): — Spectrophotometry – FAO JECFA Combined Compendium of Food Additive Specifications, 'Turmeric Oleoresin', monograph No 1 (2006)					— Chicken and laying hens: 30 mg — Other animal species: 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, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded. 5. The mixture of Turmeric oleoresin with other authorised additives obtained from *Curcuma longa* L. shall be not be allowed in feedingstuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	

2b163-ex		Turmeric extract	**Additive composition** Extract of dried rhizomes *Curcuma longa* L. using organic solvents. **Characterisation of the active substance** Extract of dried rhizomes *Curcuma longa* L. using organic solvents as defined by the Council of Europe ([6]). Total curcuminoids: ≥ 90 % (w/w) — Curcumin (I):74-79 %(w/w) — Desmethoxycurcumin (II) 15-19 % (w/w) — Bis-desmethoxycurcumin (III) 2-5 % (w/w) Water: 0,30-1,7 % (w/w) Einecs number: 283-882-1 ([4]) FEMA number: 3086 ([4]) CAS number 8024-37-1 ([4]) CoE number:163 Solid form (powder) **Analytical method** ([7]) For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric extract): — Spectrophotometry – FAO JECFA Combined Compendium of Food Additive Specifications, 'Curcumin', monograph No 1 (2006)	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 and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 % and milk replacers with a moisture content of 5,5 %: all species and veal calves (milk replacers): 15 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, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded. 5. The mixture of Turmeric extract with other authorised additives obtained from *Curcuma longa* L. shall be not be allowed in feedingstuffs.	20.4.2031

								6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	

(1) Natural sources of flavourings – Report No 2 (2007)
(2) The same identifier applies indiscriminately to different kinds of extracts and derivatives from Curcuma longa such as turmeric essential oil, turmeric extract and turmeric tincture.
(3) 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
(4) Natural sources of flavourings – Report No 2 (2007)
(5) 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
(6) Natural sources of flavourings – Report No.. 2 (2007)
(7) 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

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
						mL active substance/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b163-t		Turmeric tincture	**Additive composition** Tincture produced by extraction of ground-dried rhizomes of *Curcuma longa* L. using a water/ethanol mixture (55/45 % v/v). **Characterisation of the active substance** Tincture produced by extraction of ground-dried rhizomes of *Curcuma longa* L. using a water/ethanol mixture (55/45 % v/v), as defined by the Council of Europe ([1]). Phenols (as gallic acid equivalent): 1 100–1 500 µg/mL Total curcuminoids ([2]) (as curcumin): 0,04 to 0,09 % (w/v) Curcumin (I): 83–182 µg/mL Desmethoxycurcumin (II): 80–175 µg/mL Bis-desmethoxycurcumin (III): 139–224 µg/mL	— Horses — Dogs	-	-	-	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 and premixtures the following shall be indicated: 'Recommended maximum content of the active substance per kg of complete feedingstuff with a moisture content of 12 %: — horses: 0,75 mL; — dogs: 0,05 mL'. 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, if the content of the active substance in complete feedingstuff specified in point 3 is exceeded.	20.4.2031

			Essential oil: 1 176–1 537 µg/mL Dry matter: 2,62–3,18 % (w/w) Solvent (water/ethanol, 55/45):96-97,5 % (w/w) Liquid form CoE No 163 **Analytical method** (3) For the quantification of the phytochemical marker (total curcuminoids) in the feed additive (turmeric tincture): — Spectrophotometry (based on European Pharmacopeia monograph 'Turmeric Javanese' (01/2008:1441))					5. The mixture of Turmeric tincture with other authorised additives obtained from *Curcuma longa* L. shall be not be allowed in feedingstuffs. 6. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks by inhalation, dermal contact or eyes contact. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection, safety glasses and gloves.	

(1) Natural sources of flavourings – Report No 2 (2007)
(2) Determined by spectrophotometry as dicinnamoyl methane derivatives
(3) 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