# COMMISSION IMPLEMENTING REGULATION (EU) 2020/157

## of 5 February 2020

## concerning the authorisation of tartrazine as a feed additive for dogs, cats, 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 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) Tartrazine 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'. It was also authorised without a time limit as a feed additive for dogs and cats belonging to the group 'colourants, including pigments', under the heading 'colouring agents authorised for colouring foodstuffs by Community rules'. The additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003. It was also further authorised without a time limit by Commission Regulation (EC) No 358/2005 ([3]) as a feed additive for grain-eating ornamental birds and small rodents belonging to the group 'colourants, including pigments', under the heading 'other colourants'.

(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 tartrazine as a feed additive for ornamental fish, dogs and cats, grain-eating ornamental birds and small rodents. The applicant requested the additive to be classified in the additive category 'sensory additives' 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 18 October 2016 ([4]) that, under the proposed conditions of use, tartrazine does not have an adverse effect on animal health. It also concluded that the inhalation exposure to tartrazine is regarded as hazardous for the user of the additive, it is considered as a skin sensitiser and that no conclusion could be drawn on the irritancy to skin or eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human health, in particular as regards the users of the additive. In accordance with Commission Regulation (EC) No 429/2008 ([5]), phase I of the environmental risk assessment has determined that tartrazine, 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 the Authority in its above-mentioned opinion. The Authority further concluded that tartrazine is effective in adding colour to feedingstuffs and in favourably affecting the colour of ornamental fish and grain-eating ornamental birds. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the Reference Laboratory set up by Regulation (EC) No 1831/2003.

([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* 2016; 14(11):4613.
([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).

(5) The assessment of tartrazine 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.

(6) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of the substance concerned, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from 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 26 August 2020 in accordance with the rules applicable before 26 February 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2. Feed materials and compound feed containing the substance specified in the Annex which are produced and labelled before 26 February 2022 in accordance with the rules applicable before 26 February 2020 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, 5 February 2020.

*For the Commission*
*The President*
Ursula VON DER LEYEN

ANNEX

| Identification number of the additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | mg of active substance of kg of complete feedingstuff with a moisture content of 12 % | | | |
| **Category: Sensory additives. Functional group: Colourants.** (i) substances that add or restore colour in feedingstuffs | | | | | | | | |
| 2a102 | Tartrazine | *Additive composition*<br><br>Tartrazine is described as the sodium salt as the principal component<br>Solid form<br><br>*Characterisation of the active substance as the sodium salt*<br><br>Tartrazine consists essentially of trisodium 5- hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole- 3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>The calcium and the potassium salts are also permitted<br>Chemical formula: $C_{16}H_9N_4Na_3O_9S_2$<br>Solid form produced by chemical synthesis<br>CAS number 1934-21-0<br><br>Purity criteria:<br>Colouring matter calculated as the sodium salt: ≥ 85 % (assay)<br>Subsidiary colouring matter: ≤ 1 %<br>Organic compounds other than colouring matters ≤ 0,5 %:<br>— 4-hydrazinobenzene sulfonic acid,<br>— 4-aminobenzene-1-sulfonic acid,<br>— 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid,<br>— 4,4′-diazoaminodi(benzene sulfonic acid), | Cats | - | - | 433 | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye, skin and breathing protection. | 26.2.2030 |
| | | | Dogs | - | - | 520 | | |
| | | | Small rodents | - | - | 2 000 | | |
| | | | Grain-eating ornamental birds | - | - | 63 | | |

| Identification number of the additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | mg of active substance of kg of complete feedingstuff with a moisture content of 12 % | | | |
| | | — Tetrahydroxysuccinic acid<br>Unsulfonated primary aromatic amines: ≤ 0,01 %<br>Ether extractable matter ≤ 0,2 % under neutral conditions<br><br>*Analytical method* (1)<br>For the quantification of total colouring matters content of tartrazine in the feed additive:<br>— Spectrophotometry at 426 nm (FAO JECFA monographs No 1, Vol. 4 and Commission Regulation (EU) No 231/2012).<br>For the quantification of tartrazine in feedingstuffs:<br>— high performance liquid chromatography coupled to tandem mass spectrometry (LC-MS/MS) | | | | | | |
| **Category: Sensory additives. Functional group: Colourants.** (iii) substances which favourably affect the colour of ornamental fish or birds | | | | | | | | |
| 2a102 | Tartrazine | *Additive composition*<br><br>Tartrazine described as the sodium salt as the principal component.<br>Solid form<br><br>*Characterisation of the active substance as the sodium salt*<br><br>Tartrazine consists essentially of trisodium 5- hydroxy-1-(4-sulfonatophenyl)-4-(4-sulfonatophenylazo)-H-pyrazole- 3-carboxylate and subsidiary colouring matters together with sodium chloride and/or sodium sulphate as the principal uncoloured components.<br>The calcium and the potassium salts are also permitted. | Ornamental fish | - | - | 1 924 | 1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.<br>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 or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye, skin and breathing protection. | 26.2.2030 |

| Identification number of the additive | Additive | Composition, chemical formula, description, analytical method | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | mg of active substance of kg of complete feedingstuff with a moisture content of 12 % | | | |
| | | Chemical formula: $C_{16}H_9N_4Na_3O_9S_2$<br>Solid form produced by chemical synthesis<br>CAS number 1934-21-0<br><br>Purity criteria:<br>Colouring matter calculated as the sodium salt: ≥ 85 % (assay)<br>Subsidiary colouring matter: < 1 %<br>Organic compounds other than colouring matters ≤ 0,5 %:<br>— 4-hydrazinobenzene sulfonic acid,<br>— 4-aminobenzene-1-sulfonic acid,<br>— 5-oxo-1-(4-sulfophenyl)-2-pyrazoline-3-carboxylic acid,<br>— 4,4′-diazoaminodi(benzene sulfonic acid),<br>— Tetrahydroxysuccinic acid<br>Unsulfonated primary aromatic amines: ≤ 0,01 %<br>Ether extractable matter ≤ 0,2 % under neutral conditions<br><br>*Analytical method* (1)<br>For the quantification of total colouring matters content of tartrazine in the feed additive:<br>— Spectrophotometry at 426 nm (FAO JECFA monographs No 1, Vol. 4 and Commission Regulation (EU) No 231/2012).<br>For the quantification of tartrazine in feedingstuffs:<br>— 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://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports