

COMMISSION REGULATION (EC) No 721/2008

of 25 July 2008

concerning the authorisation of a preparation of red carotenoid-rich bacterium *Paracoccus carotinifaciens* as a feed additive

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

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 the preparation set out in the Annex to this Regulation. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) The application concerns authorisation of preparation of dried killed cells of red carotenoid-rich bacterium *Paracoccus carotinifaciens* (NITE SD 00017) as a feed additive for salmon and trout, to be classified in the additive category 'sensory additives'.

(4) The European Food Safety Authority (the Authority) concluded in its opinion of 18 September 2007 that that preparation of dried killed cells of red carotenoid-

rich bacterium *Paracoccus carotinifaciens* (NITE SD 00017) does not have an adverse effect on animal health, human health or the environment and that it favourably affects the characteristics of animal products⁽²⁾. It further concluded that that preparation does not present any other risk which would, in accordance with Article 5(2) of Regulation (EC) No 1831/2003, exclude authorisation. The Authority made a recommendation concerning maximum residue limits. 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 Community Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of that preparation shows that the conditions for authorisation, provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that preparation should be authorised, as specified in the Annex to this Regulation.

(6) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

The preparation specified in the Annex, belonging to the additive category 'sensory additives' and to the functional group 'a (ii). Colourants; substances which when fed to animals add colours to food of animal origin', is authorised as an additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

This Regulation shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29. Regulation as amended by Commission Regulation (EC) No 378/2005 (OJ L 59, 5.3.2005, p. 8).

⁽²⁾ Scientific Opinion of the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on a request from the European Commission on safety and efficacy of Panaferd-AX (red carotenoid-rich bacterium *Paracoccus carotinifaciens*) as feed additive for salmon and trout. The EFSA Journal (2007) 546, p. 1-30.

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

Done at Brussels, 25 July 2008.

For the Commission
Androulla VASSILIOU
Member of the Commission

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	Maximum Residue Limits (MRLs) in the relevant foodstuffs of animal origin	End of period of authorisation
					mg/kg of complete feedingstuff with a moisture content of 12 %	mg/kg of complete feedingstuff with a moisture content of 12 %				
Category of sensory additives. Functional group: colourants; substances which when fed to animals add colours to food of animal origin										
2a(ii)167	Red carotenoid-rich <i>Paracoccus carotinifaciens</i>	<p>Active substances:</p> <p>Astaxanthin (C₄₀H₅₂O₄, CAS: 472-61-7)</p> <p>Adonirubin (C₄₀H₅₂O₃, 3-Hydroxy-beta, beta-carotene-4,4'-dione CAS: 511-23801)</p> <p>Canthaxanthin (C₄₀H₅₂O₂, CAS: 514-78-3)</p> <p>Additive composition:</p> <p>Preparation of dried killed cells of <i>Paracoccus carotinifaciens</i> (NITE SD 00017) containing:</p> <ul style="list-style-type: none"> — 20-23 g/kg astaxanthin — 10-15 g/kg adonirubin — 3-5 g/kg canthaxanthin <p>Analytical methods</p> <p>Normal phase High Performance Liquid Chromatography (HPLC) coupled to UV/visible detection for determination of astaxanthin, adonirubin and canthaxanthin in feedingstuffs and fish tissue (1)</p>	Salmon, trout	—	—	100	<p>1. The maximum content is expressed as the sum of astaxanthin, adonirubin and canthaxanthin.</p> <p>2. Use permitted from the age of 6 months onwards or weight of 50 g.</p> <p>3. The mixture of the additive with astaxanthin or canthaxanthin is allowed provided that the total concentration of the sum of astaxanthin, adonirubin and canthaxanthin from other sources does not exceed 100 mg/kg in complete feedingstuff.</p>	<p>For salmon: 10 mg/kg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue)</p> <p>For trout: 8 mg/kg for the sum of adonirubin and canthaxanthin/kg muscle (wet tissue)</p>	15.8.2018	

(1) Further details of the analytical methods are available at the following address of the Community Reference Laboratory: www.irmm.jrc.be/crl-feed-additives