Commission Implementing Regulation (EU) 2020/1418 of 6 October 2020 concerning the authorisation of saponified paprika (Capsicum annuum) extract (capsanthin) as a feed additive for chickens for fattening, minor poultry species for fattening, laying hens and minor poultry species for laying (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1418

of 6 October 2020

concerning the authorisation of saponified paprika *(Capsicum annuum)* extract (capsanthin) as a feed additive for chickens for fattening, minor poultry species for fattening, laying hens and minor poultry species for laying

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

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

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

Whereas:

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

(2) Saponified paprika (*Capsicum annuum*) extract (capsanthin) was authorised without a time limit in accordance with Directive 70/524/EEC as feed additive for poultry belonging to the group ‘colourants, including pigments’, under the heading ‘carotenoids and xanthophylls’. 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.

(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 saponified paprika (*Capsicum annuum*) extract (capsanthin) as a feed additive for chickens for fattening, minor poultry species for fattening, laying hens and minor poultry species for laying. The applicant requested the additive to be classified in the additive category ‘sensory additives’ and in the functional group ‘colourants: (ii) substances which, when fed to animals, add colours to food of animal origin’. The application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 29 January 2020[(3)] that, under the proposed conditions of use, saponified paprika

(*Capsicum annuum)* extract does not have an adverse effect on animal health, consumer safety or the environment. It stated that, the conclusion on the safety of saponified paprika (*Capsicum annuum*) extract (capsanthin) for chickens for fattening and for laying hens, can be extrapolated to minor poultry for fattening and for laying. It also concluded that the active substance is a viscous paste, so operators will not be exposed by inhalation to the active substance. The applicant recognises that the active substance may be irritant to skin and eyes. Therefore, the Commission considers that appropriate protective measures should be taken to prevent adverse effects on human heath, in particular as regards the users of the additive, including the use of the additives in the form a preparation, where toxicity by inhalation, skin/eye irritation or skin sensitisation cannot be excluded. The Authority further concluded that the additive is efficacious as it has the potential to pigment broiler skin and egg yolk. This conclusion is extrapolated to minor poultry species for fattening and laying. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the report on the method of analysis of the feed additive in feed submitted by the European Union Reference Laboratory set up by Regulation (EC) No 1831/2003.

(5) The assessment of saponified paprika (*Capsicum annuum*) extract (capsanthin) 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 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.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

The substance specified in the Annex, belonging to the additive category ‘sensory additives’ and to the functional group ‘colourants: (ii) substances which, when fed to animals, add colours to food of animal origin’, is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

1 The substance specified in the Annex and premixtures containing this substance, which are produced and labelled before 27 April 2021 in accordance with the rules applicable before 27 October 2020 may continue to be placed on the market and used until the existing stocks are exhausted.

2 Compound feed and feed materials containing the substance as specified in the Annex which are produced and labelled before 27 October 2021 in accordance with the rules applicable before 27 October 2020 may continue to be placed on the market and used until the existing stocks are exhausted if they are intended for food-producing animals.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1418. (See end of Document for details)*

Article 3

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

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

Done at Brussels, 6 October 2020.

For the Commission

The President

Ursula VON DER LEYEN

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1418. (See end of Document for details)*

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 total carotenoids of the active substance/ kg of complete feedingstuff with a moisture content of 12 %			
Category: Sensory additives. Functional group: Colourants. (ii) substances which, when fed to animals, add colours to food of animal origin								
2a160c	Saponified paprika extract (capsanthin)	**Additive composition:** Saponified extract from dried fruits of *Capsicum annuum L.* rich in capsanthin. Benzene ≤ 2 mg/kg Hexane ≤ 130 mg/kg Capsaicin ≤ 250 mg/kg	Chickens for fattening			40	1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. The total carotenoids content of the additive shall be indicated on the label of the additive	27.10.2030
			Minor poultry for fattening			40		
			Laying hens			40		
		Characterisation of the active substance: Saponified extract of the dried fruits of *C. annuum* L. Total carotenoids content:	Minor poultry for laying.			40		

a 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