Commission Implementing Regulation (EU) No 131/2012 of 15 February 2012 concerning the authorisation of a preparation of caraway oil, lemon oil with certain dried herbs and spices as a feed additive for weaned piglets (holder of authorisation Delacon Biotechnik GmbH) (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 131/2012

of 15 February 2012

concerning the authorisation of a preparation of caraway oil, lemon oil with certain dried herbs and spices as a feed additive for weaned piglets (holder of authorisation Delacon Biotechnik GmbH)

(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 caraway oil, lemon oil with certain dried herbs and spices. 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 caraway oil, lemon oil with certain dried herbs with spices, as specified in the Annex, as a feed additive for weaned piglets, to be classified in the additive category ‘zootechnical additives’.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 7 April 2011[(2)] that, under the proposed conditions of use, the preparation of caraway oil, lemon oil with certain dried herbs and spices, as specified in the Annex, does not have an adverse effect on animal health, human health or the environment, and that its use can improve the growth rate of weaned piglets. 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.

(5) In order to ensure efficacy and safety and accordance with the characterisation provided by the applicant for the active substances, the maximum levels of natural substances laid down in Annex III, Part B to Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food

ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC[3] should be respected as regards dried herbs and spices used in the preparation, as specified in the Annex, and the product characterisations laid down in the European Pharmacopoeia should apply to caraway oil and lemon oil, respectively.

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

(7) 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 ‘zootechnical additives’ and to the functional group ‘other zootechnical additives’, 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*.

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

Done at Brussels, 15 February 2012.

For the Commission

The President

José Manuel BARROSO

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 131/2012. (See end of Document for details)*

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 (improvement of performance parameters)									
4d6	Delacon Biotechnik GmbH	Preparation of caraway oil, lemon oil with dried herbs and spices	*Additive composition* Preparation of essential oil > 1,5 % (caraway oil ≥ 0,75 % and lemon oil ≥ 0,75 %) — — *Characterisation of the active substances and other ingredients* —	Piglets (weaned)	—	250	400	1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life, and stability to pelleting. 2. For use in weaned piglets up to approximately 35 kg. 3. For safety: breathing protection and gloves shall be used	7 March 2022

a European Pharmacopoeia of the Council of Europe.

b Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

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				—	3,5-6,0 mg/g, as defined by the European Pharmacopoeia[a] lemon oil: limonene 2,3-9,0 mg/g, as defined by the European Pharmacopoeia			during handling. 4. The additive shall be incorporated in compound feedingstuff in form of a premixture.	
				Dried herbs and spices: Clove powder 1,5 %, cinnamon powder 10 %, nutmeg powder 1,5 %, onion powder 5 %, pimento powder 2 %, orange peel powder 5 %, peppermint power 12,5 % and chamomile powder 12,5 %.					

a European Pharmacopoeia of the Council of Europe.

b Details of the analytical methods are available at the following address of the Reference Laboratory: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx