Commission Implementing Regulation (EU) 2019/111 of 24 January 2019 concerning the authorisation of hop extract (Humulus lupulus L. flos) as a feed additive for weaned piglets, pigs for fattening and minor porcine species weaned and for fattening (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2019/111

of 24 January 2019

concerning the authorisation of hop extract (*Humulus lupulus* L. flos) as a feed additive for weaned piglets, pigs for fattening and minor porcine species weaned and for fattening

(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, and in particular Article 9(2) thereof[(1)],

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for the authorisation of hop extract (*Humulus lupulus* L. flos) as a feed additive for all animal species. The application was accompanied by the particulars and documents required under Article 7(3) of that Regulation. The applicant requested that the additive be classified in the additive category ‘sensory additives’.

(3) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 3 October 2018[(2)] that, under the proposed conditions of use, hop extract (*Humulus lupulus* L. flos) does not have adverse effects on animal health, human health or the environment. The Authority concluded that the tolerance study made with weaned piglets shows that the additive is safe for the proposed dose of 50 mg/kg of complete feed and can be extrapolated to pigs for fattening and to minor growing porcine species weaned and for fattening. It is therefore appropriate to authorise hop extract as a feed additive only for those species and categories. The Authority also concluded that since harvested hop and its extracts are universally recognised to flavour food and their function in feed would be essentially the same as that in food, no further demonstration of efficacy was necessary. Therefore, that conclusion can be extrapolated for feed.

(4) The Authority further noted that the additive is a potential respiratory and skin sensitiser for users and contains a variety of compounds known to cause allergic reactions in sensitive persons. Consequently, appropriate protective measures should be taken.

(5) The Authority did not consider that there was 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.

(6) The assessment of this additive 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 additive should be authorised as specified in the Annex to this Regulation.

(7) Having regard to the use level proposed by the applicant, the Authority considered that the maximum proposed use level is safe. For the purpose of official controls along the food chain, the recommended maximum content of the active substance should be indicated on the label of the feed additive and the incorporation into the feedingstuffs should be done via premixtures.

(8) The fact that the use of the substances concerned in water for drinking is not authorised should not preclude their use in compound feed, which is administered via water.

(9) 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 ‘flavouring compounds’, is authorised as a feed additive in animal nutrition subject to the conditions laid down in that Annex.

Article 2

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, 24 January 2019.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2019/111. (See end of Document for details)*

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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/kg of complete feed with a moisture content of 12 %			
Category: Sensory additives. Functional group: Flavouring compounds									
2b233	—	Hop extract (strobiles) rich in beta acids	*Additive composition* Preparation of supercritical carbon dioxide extract of *Humulus lupulus* L. flos extract treated with potassium hydroxide to form potassium salts of the beta acids and dissolved in propylene glycol. The specifications of the additive are: — Beta-acids: 40 ± 1,5 %	— — <