Commission Implementing Regulation (EU) 2020/1092 of 24 July 2020 amending Implementing Regulation (EU) No 1263/2011 as regards the authorisation of Lactococcus lactis (NCIMB 30160) as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1092

of 24 July 2020

amending Implementing Regulation (EU) No 1263/2011 as regards the authorisation of *Lactococcus lactis* (NCIMB 30160) as a feed additive for all animal species

(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 13(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 or modifying such authorisation.

(2) The use of *Lactococcus lactis* NCIMB 30160 as a feed additive was authorised for all animal species by Commission Implementing Regulation (EU) No 1263/2011[(2)].

(3) In accordance with Article 13(1) of Regulation (EC) No 1831/2003, the Commission requested the European Food Safety Authority ('the Authority') to issue an opinion on whether the authorisation of *Lactococcus lactis* (NCIMB 30160) as a feed additive would still meet the conditions laid down in Article 5 of Regulation (EC) No 1831/2003, considering a modification of the terms of that authorisation. The modification relates to the formulation of the additive, consisting of the inclusion of polyethylene glycol (PEG 4000) in the list of cryoprotectants that can be used for the manufacture of the additive. The request was accompanied by the relevant supporting data.

(4) The Authority concluded in its opinions of 6 March 2018[(3)] and 7 October 2019[(4)] that, under the proposed conditions of use, preparations of PEG 4000 as an excipient in formulations with *Lactococcus lactis* (NCIMB 30160) do not modify the previous conclusions that the additive does not have an adverse effect on animal health, human health or the environment and that it is efficacious as silage additive. Therefore, no safety concerns are expected when PEG 4000 is used as a cryoprotectant in the additive *Lactococcus lactis* NCIMB 30160 up to a maximum concentration of 0,025 mg PEG 4000/kg silage. The Authority does not consider that there is a need for specific requirements of post-market monitoring.

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) 2020/1092. (See end of Document for details)*

(5) The assessment of the proposed modification to the authorisation shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

(6) Implementing Regulation (EU) No 1263/2011 should therefore be amended accordingly.

(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 Annex to Implementing Regulation (EU) No 1263/2011 is amended in accordance with the Annex to this Regulation.

Article 2

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 July 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) 2020/1092. (See end of Document for details)*

ANNEX

In the Annex to Implementing Regulation (EU) No 1263/2011, the entry concerning the additive with the identification number 1k2082 is replaced by the following:

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**
					CFU of additive/ kg of fresh material			
Category of technological additives. Functional group: silage additives								
‘1k2082	*Lactococcus lactis* (NCIMB 30160)	*Additive composition* Preparation of *Lactococcus lactis* (NCIMB 30160) containing a minimum of 4×10^{11} CFU/g additive One of the following cryoprotectants: ascorbic acid, lactose, mannitol, monosodium glutamate, sodium citrate, whey powder or polyethylene glycol (PEG 4000) *Characterisation of the active substance:*	All animal species				1. In the directions for use of the additive and premixtures, the storage conditions shall be indicated. 2. Minimum content of the additive when used without combination with other micro-organisms as silage additives: 1×10^8 CFU/kg	16.8.2030

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’