

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.
- (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.

⁽¹⁾ OJ L 268, 18.10.2003, p. 29.⁽²⁾ Commission Implementing Regulation (EU) No 1263/2011 of 5 December 2011 concerning the authorisation of *Lactobacillus buchneri* (DSM 16774), *Lactobacillus buchneri* (DSM 12856), *Lactobacillus paracasei* (DSM 16245), *Lactobacillus paracasei* (DSM 16773), *Lactobacillus plantarum* (DSM 12836), *Lactobacillus plantarum* (DSM 12837), *Lactobacillus brevis* (DSM 12835), *Lactobacillus rhamnosus* (NCIMB 30121), *Lactococcus lactis* (DSM 11037), *Lactococcus lactis* (NCIMB 30160), *Pediococcus acidilactici* (DSM 16243) and *Pediococcus pentosaceus* (DSM 12834) as feed additives for all animal species (OJ L 322, 6.12.2011, p. 3).⁽³⁾ EFSA Journal 2018; 16(3):5218.⁽⁴⁾ EFSA Journal 2019; 17(11):5890.

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

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	<i>Lactococcus lactis</i> (NCIMB 30160)	<p><i>Additive composition:</i></p> <p>Preparation of <i>Lactococcus lactis</i> (NCIMB 30160) containing a minimum of 4×10^{11} CFU/g additive</p> <p>One of the following cryoprotectants: ascorbic acid, lactose, mannitol, monosodium glutamate, sodium citrate, whey powder or polyethylene glycol (PEG 4000)</p> <p><i>Characterisation of the active substance:</i></p> <p><i>Lactococcus lactis</i> (NCIMB 30160)</p> <p><i>Analytical method</i> ⁽¹⁾:</p> <p>Enumeration: pour plate method using MSR agar (ISO 15214)</p> <p>Identification: Pulsed-Field Gel Electrophoresis (PFGE)</p>	All animal species	-	-	-	<ol style="list-style-type: none"> 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 fresh material. 3. If used as a cryoprotectant, polyethylene glycol (PEG 4000) shall be used up to a maximum concentration of 0,025 mg/kg silage. 4. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from its use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including breathing protection. 	16.8.2030
---------	---	--	--------------------	---	---	---	---	-----------

⁽¹⁾ 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>