COMMISSION IMPLEMENTING REGULATION (EU) 2018/1957

of 11 December 2018

amending Regulation (EC) No 885/2010 as regards the terms of authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd)

(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(3) 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) The use of preparation of narasin and nicarbazin as a feed additive was authorised for 10 years for chickens for fattening by Commission Regulation (EU) No 885/2010 ([2]).

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation proposed changing the terms of authorisation of the preparation by submitting an application to modify the content of micro tracer red from 11 g/kg to a range of 4-11g/kg. The application was accompanied by the relevant supporting data.

(4) The European Food Safety Authority ('the Authority') concluded in its opinion of 18 October 2016 ([3]) that the reduction of the content of micro tracer red from 11g/kg to a range of 4-11g/kg of additive has no effect on the physicochemical and biological properties of the additive. Therefore it came to the conclusion that the assessment of safety and efficacy made for the former formulation with 11g/kg micro tracer red is still valid for the new formulation. 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) On 10 July 2018 Eli Lilly and Company Ltd has also submitted an application under Article 13(3) of Regulation (EC) No 1831/2003 proposing to change the name of the holder of the authorisation. The applicant claimed that, with effect from 3 April 2018, Elanco GmbH, a division of Eli Lilly and Company Ltd, is to be considered holder of the marketing rights for the above mentioned additive. The application was accompanied by the relevant supporting data.

(6) The proposed change of the terms of the authorisation concerning the name of the holder of the authorisation is purely administrative in nature and does not entail a new assessment of the additive concerned. The Authority was informed of the application.

(7) The assessment of the preparation of narasin and nicarbazin with the new content of micro-tracer red shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied.

(8) Regulation (EU) No 885/2010 should therefore be amended accordingly.

(9) Since safety reasons do not require the immediate application of the amendments made by this Regulation, it is appropriate to provide for a transitional period during which the existing stocks of the feed additive narasin and nicarbazin, which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

([1]) OJ L 268, 18.10.2003, p. 29.
([2]) Commission Regulation (EU) No 885/2010 of 7 October 2010 concerning the authorisation of the preparation of narasin and nicarbazin as a feed additive for chickens for fattening (holder of authorisation Eli Lilly and Company Ltd) and amending Regulation (EC) No 2430/1999 (OJ L 265, 8.10.2010, p. 5).
([3]) *EFSA Journal 2016*; 14(11):4614.

(10) 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 Regulation (EC) No 885/2010 is amended as follows:

a) in column 2, the words 'Eli Lilly and Company Ltd' are replaced by 'Elanco GmbH';

b) in column 4 'Composition, chemical formula, description, analytical method', '*Additive composition*', in the content of Micro tracer red, the words '11 g/kg' are replaced by '4-11 g/kg'.

Article 2

Existing stocks of this additive which are in conformity with the provisions applying before the date of entry into force of this Regulation may continue to be placed on the market and used until they are exhausted.

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, 11 December 2018.

For the Commission

The President

Jean-Claude JUNCKER