Commission Implementing Regulation (EU) No 1060/2013 of 29 October 2013 concerning the authorisation of bentonite as a feed additive for all animal species (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) No 1060/2013

of 29 October 2013

concerning the authorisation of bentonite 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 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. Article 10 of that Regulation provides for the re-evaluation of additives authorised pursuant to Council Directive 70/524/EEC[(2)].

(2) Bentonite was authorised without a time limit in accordance with Directive 70/524/EEC as a feed additive belonging to the group of binders, anticaking agents and coagulants, for use in all animal species, by Commission Directive 82/822/EEC[(3)]. That additive was subsequently entered in the Register of feed additives as an existing product, in accordance with Article 10(1)(b) of Regulation (EC) No 1831/2003.

(3) In accordance with Article 10(2) of Regulation (EC) No 1831/2003 in conjunction with Article 7 of that Regulation, an application was submitted for the re-evaluation of bentonite as a feed additive for all animal species as binders and anticaking agents and, in accordance with Article 7 of that Regulation, for a new authorisation as substance for control of radionuclide contamination, for all animal species. In addition, in accordance with Article 7 of Regulation (EC) No 1831/2003, an application was submitted for a new authorisation of bentonite as substance for reduction of the contamination of feed by mycotoxins for all animal species. Those applications request that additive to be classified in the additive category ‘technological additives’ and were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinions of 2 February 2011[(4)], 14 June 2011[(5)] and 14 June 2012[(6)] that, under the proposed conditions of use, bentonite does not have an adverse effect on animal health, human health or the environment, and that it has the potential to be efficacious as binder and anticaking

Changes to legislation: *There are currently no known outstanding effects for the Commission Implementing Regulation (EU) No 1060/2013. (See end of Document for details)*

agent and as substance for control of radionuclide contamination for all animal species. It was also recognised that bentonite has the potential to be efficacious as aflatoxin binder for dairy cows and that this conclusion can be extended to all ruminants. 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) Since the provided *in vitro* studies meet the conditions for the demonstration of the efficacy of the technological additives laid down by Commission Regulation (EC) No 429/2008[7], in particular under item 4 of Annex II and under item 1.4 of Annex III thereto, and they were recognised able to demonstrate the clear evidence to bind aflatoxin B1 (AfB) and moreover the binding capacity, restricted to aflatoxin B1, was defined as a characteristic of the bentonite, the conclusion on efficacy as a substance for reduction of the contamination of feed by mycotoxins can be considered sufficient to be extended to its use on poultry and pigs.

(6) The assessment of bentonite shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of that additive should be authorised as specified in the Annexes to this Regulation.

(7) Since safety reasons do not require the immediate application of the modifications to the conditions of authorisation of bentonite as binder and anticaking agent, it is appropriate to allow a transitional period for interested parties to prepare themselves to meet the new requirements resulting from the authorisation.

(8) 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

Bentonite specified in the Annexes, belonging to the additive category ‘technological additives’ and to the functional groups ‘substances for reduction of the contamination of feed by mycotoxins’, ‘binders’, ‘anticaking agents’ and ‘substances for control of radionuclide contamination’ is authorised as an additive in animal nutrition, subject to the conditions laid down in those Annexes.

Article 2

The additive specified in Annex II belonging to the functional groups ‘binders’ and ‘anticaking agents’ and feed containing that additive, which are produced and labelled before 19 November 2015 in accordance with the rules applicable before 19 November 2013 may continue to be placed on the market and used until the existing stocks 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, 29 October 2013.

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 1060/2013. (See end of Document for details)*

ANNEX I

Identification number of the additive	Additive	Chemical formula, description, methods of analysis	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					mg of active substance/kg of complete feedingstuff with a moisture content of 12 %			
Category of technological additives. Functional group: substances for reduction of the contamination of feed by mycotoxins: aflatoxin B1								
1m558	Bentonite	*Additive composition* Bentonite: ≥ 70 % smectite (dioctahedral montmorillonite) *Characterisation of active substance* Bentonite: ≥ 70 % smectite (dioctahedral montmorillonite) < 10 % opal and feldspar < 4 % quartz and calcite AfB_1-binding capacity (BC *AfB1*) above 90 % *Analytical method*[a] For the determination of bentonite	*Ruminants — Poultry*			20 000	1. In the instructions for use: — ‘The simultaneous oral use with macrolides shall be avoided’; — for poultry: ‘The simultaneous use with robenidine shall be avoided’. 2. For poultry: the simultaneous use with coccidiostats other than robenidine is contraindicated with	19 November 2023

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx

			in feed additive: X-ray diffraction (XRD) For the determination of BC *AfB1* of the additive: adsorption test carried out in a buffer solution at pH 5,0 with a concentration of 4 mg/l for AfB_1 and 0,02 % (w/v) for the feed additive.				3.	level of bentonite above 5 000 mg/kg of complete feed. The total amount of bentonite must not exceed the permitted maximum level in complete feedingstuff of 20 000 mg/kg of complete feedingstuff.
							4.	The use of the additive is allowed in feedingstuffs complying with the European Union legislation on undesirable substances in

a Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: http://irmm.jrc.ec.europa.eu/EURLs/EURL_feed_additives/Pages/index.aspx