

Brussels, XXX SANTE/11175/2015 CIS (POOL/E5/2015/11175/11175-EN CIS.doc) [...](2016) XXX draft

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

of XXX

concerning the authorisation of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species

(Text with EEA relevance)

EN EN

# COMMISSION IMPLEMENTING REGULATION (EU) .../...

#### of XXX

# concerning the authorisation of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives 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<sup>1</sup>, 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.
- (2) In accordance with Article 7 of Regulation (EC) No 1831/2003 applications were submitted for the authorisations of sodium benzoate, potassium sorbate, formic acid and sodium formate. Those applications were accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.
- (3) Those applications concern the authorisations of sodium benzoate, potassium sorbate, formic acid and sodium formate as feed additives for all animal species to be classified in the category 'technological additives'.
- (4) The European Food Safety Authority ('the Authority') concluded in its opinion of 13 June 2012<sup>2</sup> that, under the proposed conditions of use, sodium benzoate does not have an adverse effect on animal health, human health or the environment; however it was considered as a potential sensitizer and a risk for inhalation cannot be excluded. The Authority also concluded that the additive has a potential to improve the production of silage by reducing the pH and increasing the preservation of dry matter in easy, moderate difficult and difficult to ensile material.
- (5) The Authority concluded in its opinion of 18 June 2013<sup>3</sup> that, under the proposed conditions of use, potassium sorbate does not have an adverse effect on animal health, human health or the environment; however it was considered irritant for skin and eyes and potential irritant to respiratory tract. The Authority also concluded that the additive has a potential to improve the aerobic stability of silage in easy and moderate difficult to ensile material.
- (6) The Authority concluded in its opinion of 11 September 2014<sup>4</sup> that, under the proposed conditions of use, formic acid does not have an adverse effect on animal

OJ L 268, 18.10.2003, p. 29.

<sup>&</sup>lt;sup>2</sup> EFSA Journal 2012;10(7):2779.

<sup>&</sup>lt;sup>3</sup> EFSA Journal 2013;11(7):3283.

EFSA Journal 2014;1(10):3827.

health, human health or the environment; however it was considered corrosive for skin and eyes and respiratory tract. The Authority also concluded that the additive has a potential to improve the ensiling process and the quality of the silage in aerobic stability of silage in easy, in moderate difficult and difficult to ensile material.

- (7) The Authority concluded in its opinion of 11 March 2015<sup>5</sup> that, under the proposed conditions of use, sodium formate does not have an adverse effect on animal health, human health or the environment; however the liquid form was considered corrosive for skin and eyes and to respiratory tract. The Authority also concluded that the additive has a potential to improve the preservation of nutrients by reducing the dry matter loss in easy, moderate and difficult to ensile material.
- (8) For sodium benzoate, potassium sorbate, formic acid and sodium formate, 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
- (9) The assessments of sodium benzoate, potassium sorbate, formic acid and sodium formate show that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the use of those preparation ['substances' should be authorised as specified in the Annex to this Regulation.
- (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 additives specified in the Annex, belonging to the additive category 'technological additives' and to the functional group 'silage additives', are authorised as additives in animal nutrition, subject to the conditions laid down in that Annex.

### 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,

For the Commission
The President
Jean-Claude JUNCKER

<sup>&</sup>lt;sup>5</sup> EFSA Journal 2015;13(5):4056.