EUROPEAN
COMMISSION

Brussels, XXX
SANTE/10700/2017 CIS
(POOL/E5/2017/10700/10700-EN
CIS.doc)
[…](2017) XXX draft

COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

concerning the authorisation of a new use of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) as a feed additive for fish (holder of authorisation Huvepharma EOOD)

(Text with EEA relevance)

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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.

(2) In accordance with Article 7 of Regulation (EC) No 1831/2003 an application was submitted for the authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) as a feed additive for fish. That application was accompanied by the particulars and documents required under Article 7(3) of Regulation (EC) No 1831/2003.

(3) That application concerns the authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) as a feed additive for fish to be classified in the additive category "zootechnical additives".

(4) The use of that preparation was authorised for ten years for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows by Commission Implementing Regulation (EU) 98/2012[2].

(5) The European Food Safety Authority ('the Authority') concluded in its opinion of 21 March 2017[3] that, under the proposed conditions of use, preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) does not have an adverse effect on animal health, human health or the environment. It concluded that the additive has the potential to be efficacious in rainbow trout and salmon and this conclusion can be extrapolated to all finfish. The Authority does not consider that there is a need for specific requirements of post-market monitoring. It also verified the

[1] OJ L 268, 18.10.2003, p. 29.

[2] Commission Implementing Regulation (EU) No 98/2012 of 7 February 2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by Pichia pastoris (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows (holder of authorisation Huvepharma AD) OJ L 35, 8.2.2012, p. 6.

[3] *EFSA Journal 2017;15(4):4763*.

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.

(6) The assessment of preparation of 6-phytase (EC 3.1.3.26) produced by *Komagataella pastoris* (DSM 23036) 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 preparation should be authorised as specified in the Annex to this Regulation.

(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 preparation specified in the Annex, belonging to the additive category 'zootechnical additives' and to the functional group 'digestibility enhancers', is authorised as an additive 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