EUROPEAN
COMMISSION

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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Implementing Regulation (EU) No 338/2018 as regards the minimum content of a preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) as a feed additive for chickens for fattening or reared for laying (holder of authorisation BASF SE)

(Text with EEA relevance)

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(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 the preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) was authorised for ten years for chickens for fattening or reared for laying by Commission Implementing Regulation (EU) No 338/2018[2].

(3) In accordance with Article 13(3) of Regulation (EC) No 1831/2003, the holder of the authorisation has proposed changing the terms of the authorisation of that preparation by reducing its minimum content from 750 FTU/kg to 125 FTU/kg feed. The application was accompanied by the relevant supporting data. The Commission forwarded that application to the European Food Safety Authority ('the Authority').

(4) The Authority concluded in its opinion of 23 January 2019[3] that, under the new proposed conditions of use, the preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) has the potential to be efficacious at the requested minimum doses of 125 FGU/kg of feed on chickens for fattening and that this conclusion can be extended to chickens reared for laying/breeding. 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.

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1 OJ L 268, 18.10.2003, p. 29.

2 Commission Implementing Regulation (EU) 2018/338 of 7 March 2018 concerning the authorisation of a preparation of 6-phytase, produced by Aspergillus niger (DSM 25770) as feed additive for chickens for fattening, chickens reared for laying, pigs for fattening, sows, minor porcine species for fattening or for reproduction, turkeys for fattening, turkeys reared for breeding, all other avian species (excluding laying birds) and weaned piglets (holder of the authorisation BASF SE) (OJ L 65, 8.3.2018, p. 17).

3 EFSA Journal 2019; 17(2):5607.

(5) The assessment of the preparation of 6-phytase, produced by *Aspergillus niger* (DSM 25770) 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 338/2018 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 Regulation (EU) No 338/2018 is replaced by the Annex of this Regulation.

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