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COMMISSION IMPLEMENTING REGULATION (EU) …/...

of XXX

amending Regulation (EC) No 429/2008 as regards the application form for authorisations of feed additives and the designation of target animal species and categories

(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 7(4), first subparagraph, and Article 7(5), first subparagraph, thereof,

After consulting the European Food Safety Authority,

Whereas:

(1) Regulation (EC) No 1831/2003 establishes the procedure for authorising the placing on the market and use of feed additives. It provides that any person seeking an authorisation for a feed additive, or a new use of a feed additive is to submit an application for authorisation to the Commission in accordance with that Regulation.

(2) Commission Regulation (EC) No 429/2008[2] sets out detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the preparation and the presentation of applications for the authorisation of feed additives and the assessment of such applications. Annex I to Regulation (EC) No 429/2008 sets out the form that must be used to submit an application for the authorisation of a feed additive, and Annex IV to that Regulation lays down target animals' categories and their respective definitions and indicates the minimum duration of the related efficacy studies.

(3) The application form set out in Annex I to Regulation (EC) No 429/2008 was established at a time when applications for the authorisation of feed additives were submitted as physical or scanned documents. Since 2021, all applications for feed additives must be submitted via the electronic submission system of the Commission. That evolution would allow the system to have an automatically generated application form, by extracting the necessary information from the electronic submission. In addition, the content of the application form should be simplified with a view to optimise the treatment of applications.

(4) The experience accumulated by the Commission, the European Food Safety Authority ('the Authority') and the Standing Committee on Plants, Animals, Food and Feed in

[1] OJ L 268, 18.10.2003, p. 29, ELI: http://data.europa.eu/eli/reg/2003/1831/oj.

[2] Commission Regulation (EC) No 429/2008 of 25 April 2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (OJ L 133, 22.5.2008, p. 1, ELI: http://data.europa.eu/eli/reg/2008/429/oj).

processing applications for authorisation of feed additives has shown the need to update the terminology used in Annex IV to Regulation (EC) No 429/2008 for designating the animal species and categories subject to a particular application, while also ensuring that Annex IV covers all possible animal species and categories which are bred or kept in the Union and not just the main food-producing animal species and categories. Such approach would give clarity as to the concrete scope of the applications and facilitate the authorisation process. Article 1(2), Article 3(2), last subparagraph, of Regulation (EC) No 429/2008 and Annexes II, III and IV thereto should therefore be amended accordingly.

(5) The minimum duration of long-term efficacy studies laid down in point 4.4, fourth subparagraph of Annex II to Regulation (EC) No 429/2008 and in the last column of Annex IV to that Regulation was set out in 2008. That minimum duration should be adjusted in accordance with the latest recommendations of the Authority[3], which reflect the recent technological progress and scientific developments and advise for a shorter minimum duration of long-term efficacy studies for some animal species and categories such as laying hens or salmon and trout.

(6) The definition of 'minor species' laid down in Article 1(2) of Regulation (EC) No 429/2008 should be complemented for more clarity by introducing a definition of 'major species'.

(7) A new Annex V should be added to that Regulation on definitions of the respective animal species and the differentiation between the major and minor species, comprised therein. In addition, it should be made clear in the new Annex V to that Regulation that rabbits and horses that are not used for human consumption do not belong to the group of pets and non-food producing animals but to the group of leporids (*Leporidae*) and equines (*Equidae*) respectively.

(8) A concordance table should be provided in Annex III to this Implementing Regulation, offering a correspondence between the terms commonly used for the designation of animal species and categories in the authorisations of feed additives granted before the date of application of this Implementing Regulation and the terms designating the same animal species and categories to be used as of the date of application of this Implementing Regulation. The objective of that concordance table is to assist applicants in designating the relevant scope of target animal species, when preparing applications in accordance with Article 13 and Article 14 of Regulation (EC) 1831/2003 for the modification or the renewal of existing authorisations, to be submitted as of the date of application of this Implementing Regulation.

(9) Regulation (EC) No 429/2008 should therefore be amended accordingly.

(10) In order to enable business operators to adapt to the new requirements set by this Implementing Regulation, it is necessary that this Regulation starts applying 6 months after its date of entry into force.

(11) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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[3] Guidance on the assessment of the efficacy of feed additives, *EFSA Journal.* 2024;22:e8856. https://doi.org/10.2903/j.efsa.2024.8856.

HAS ADOPTED THIS REGULATION:

Article 1

Amendments to Regulation (EC) No 429/2008

Regulation (EC) No 429/2008 is amended as follows:

(1) Article 1 is replaced by the following:

'*Article 1*

Definitions

The following definitions shall apply for the purpose of this Regulation:

(1) 'pets and other non-food producing animals' means animals belonging to species normally fed, bred or kept, but not consumed by humans, as detailed in point 8 of Annex V;

(2) 'major species' means animal species normally used for human consumption in the Union as detailed in points 1 to 4 of Annex V.

(3) 'minor species' means animal species normally used for human consumption in the Union as detailed in points 1 to 7 of Annex V.';

(2) Article 2(1), first subparagraph, is replaced by the following:

'1. An application for the authorisation of a feed additive, as provided for in Article 7 of Regulation (EC) No 1831/2003, shall be submitted to the Commission via the electronic submission system of the Commission. Once the application is submitted in the electronic system, the applicant, the Commission, the Authority and the Member States shall have access to the application form as set out in Annex I.';

(3) Article 3(2), third subparagraph, is replaced by the following:

'The terminology to be used for designating the target animal species and categories, as well as the minimum duration of long term efficacy studies shall be as set out in Annex IV.

The definitions of the respective animal species shall be set out in Annex V.';

(4) Annexes I, II, III and IV to Regulation (EC) No 429/2008 are amended in accordance with Annex I to this Implementing Regulation.

(5) A new Annex V is added to Regulation (EC) No 429/2008 in accordance with Annex II to this Implementing Regulation.

Article 2

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from [*6 months from the date of entry into force of this Regulation. To be completed by the Service responsible for the publication*].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the Commission
The President
Ursula VON DER LEYEN