Commission Regulation (EC) No 521/2005 of 1 April 2005 concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 521/2005

of 1 April 2005

concerning the permanent authorisation of an additive and the provisional authorisation of new uses of certain additives already authorised in feedingstuffs

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 70/524/EEC of 23 November 1970 concerning additives in feedingstuffs[(1)], and in particular Articles 3, 9d(1) and 9e(1) thereof,

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[(2)], and in particular Article 25 thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition.

(2) Article 25 of Regulation (EC) No 1831/2003 lays down transitional measures for applications for the authorisation of feed additives submitted in accordance with Directive 70/524/EEC before the date of application of Regulation (EC) No 1831/2003.

(3) The applications for authorisation of the additives listed in the Annexes to this Regulation were submitted before the date of application of Regulation (EC) No 1831/2003.

(4) Initial comments on those applications, as provided for in Article 4(4) of Directive 70/524/EEC, were forwarded to the Commission before the date of application of Regulation (EC) No 1831/2003. Those applications are therefore to continue to be treated in accordance with Article 4 of Directive 70/524/EEC.

(5) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106), endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (ATCC 2105) and subtilisin produced by *Bacillus subtilis* (ATCC 2107) was provisionally authorised for the first time for chickens for fattening, by Commission Regulation (EC) No 1636/1999[(3)]. New data were submitted in support of an application for authorisation without a time limit of that enzyme preparation. The assessment shows that the conditions laid down in Article 3a of

Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation as specified in Annex I, should be authorised without a time limit.

(6) The use of the enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 14223) was authorised without a time limit for chickens for fattening, laying hens, turkeys for fattening, piglets, pigs for fattening and sows by Commission Regulation (EC) No 255/2005[(4)]. New data were submitted in support of an application to extend the authorisation of the use of that enzyme preparation to salmonids. The European Food Safety Authority (EFSA) has delivered an opinion on the use of that preparation which concludes that it does not present a risk to salmonids under the conditions set out in Annex II to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that enzyme preparation as specified in Annex II, should be provisionally authorised for four years.

(7) The use of the micro-organism preparation of *Enterococcus faecium* (DSM 7134) was provisionally authorised, for the first time, for piglets and pigs for fattening by Commission Regulation (EC) No 666/2003[(5)]. New data were submitted in support of an application to extend the authorisation of the use of that micro-organism preparation to chickens for fattening. The EFSA has delivered a favourable opinion on 28 October 2004 on the safety of that additive when used in the animal category chickens for fattening, under the conditions of use set out in Annex III to this Regulation. The assessment shows that the conditions laid down in Article 9e(1) of Directive 70/524/EEC for such authorisation are satisfied. Accordingly, the use of that micro-organism preparation as specified in Annex III, should be provisionally authorised for four years.

(8) The assessment of those applications shows that certain procedures should be required to protect workers from exposure to the additives set out in the Annexes. Such protection should be assured by the application of Council Directive 89/391/EEC of 12 June 1989 on the introduction of measures to encourage improvements in the safety and health of workers at work[(6)].

(9) 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:

[F1]Article 1

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Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2017/1145 of 8 June 2017 on the withdrawal from the market of certain feed additives authorised pursuant to Council Directives 70/524/EEC and 82/471/EEC and repealing the obsolete provisions authorising those feed additives (Text with EEA relevance).

[F2]Article 2

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Textual Amendments

F2 Deleted by Commission Regulation (EU) No 221/2011 of 4 March 2011 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by Aspergillus oryzae DSM 14223 as a feed additive for salmonids (holder of authorisation DSM Nutritional Products Ltd represented by DSM Nutritional products Sp. Z o.o) (Text with EEA relevance).

Article 3

The preparation belonging to the group ‘Micro-organisms’, as specified in Annex III, is authorised provisionally for four years as an additive in animal nutrition under the conditions laid down in that Annex.

Article 4

This Regulation shall enter into force on the third 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.