Commission Regulation (EC) No 1453/2004 of 16 August 2004 concerning the permanent authorisation of certain additives in feedingstuffs (Text with EEA relevance)

COMMISSION REGULATION (EC) No 1453/2004

of 16 August 2004

concerning the permanent authorisation of certain additives 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 Article 3 and Article 9d(1) thereof,

Whereas:

(1) Directive 70/524/EEC provides for the authorisation of additives to be used in the Community. The additives referred to in Part II of Annex C to that Directive may be authorised without a time limit subject to certain conditions being satisfied.

(2) The use of the micro-organism preparation of *Bacillus licheniformis* (DSM 5749) and *Bacillus subtilis* (DSM 5750) was provisionally authorised, for the first time, for sows, by Commission Regulation (EC) No 2437/2000[(2)].

(3) New data were submitted in support of the application for authorisation without a time limit of that preparation. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(4) Accordingly, the use of that preparation for sows, as specified in the Annex I, should be authorised without a time limit.

(5) The use of the micro-organism preparation of *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I–1012) was provisionally authorised, for the first time, for pigs for fattening by Commission Directive 94/17/EC[(3)].

(6) The Scientific Committee on Animal Nutrition (SCAN), in its report on *Bacillus cereus* var. *toyoi* (NCIMB 40112/CNCM I–1012) adopted on 5 December 2001, confirmed that preparation, when used in the animal categories piglets, pigs for fattening and sows, satisfies the conditions of Article 3a(b) of Directive 70/524/EEC. The SCAN report also concluded favourably on the efficacy of that preparation when used in the animal categories piglets to two months and sows.

(7) New data were submitted in support of the application for authorisation without a time limit of that preparation.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1453/2004. (See end of Document for details)*

(8) The European Food Safety Authority (EFSA) was asked to issue on opinion on the efficacy of that preparation when used as feed additive for pigs for fattening. In its opinion adopted on 7 May 2004, the EFSA concluded favourably on the efficacy regarding that preparation and the whole assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(9) Accordingly, the use of that preparation for pigs for fattening, as specified in Annex I, should be authorised without a time limit.

(10) The use of the enzyme preparation of endo-1,4-beta-xylanase and endo-1,4-beta-glucanase produced by *Aspergillus niger* (CBS 600.94) set out in the first row of Annex II was provisionally authorised, for the first time, for chickens for fattening, turkeys for fattening and piglets by Commission Regulation (EC) No 654/2000[(4)].

(11) The use of the enzyme preparation of endo-1,4-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger* (CBS 600.94) set out in the second row of Annex II was provisionally authorised, for the first time, for chickens for fattening, by Commission Regulation (EC) No 654/2000.

(12) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase produced by *Trichoderma longibrachiatum* (ATCC 2106) and endo-1,4-beta-xylanase produced by *Trichoderma longibrachiatum* (IMI SD 135) and polygalacturonase produced by *Aspergillus aculeatus* (CBS 589.94) was provisionally authorised, for the first time, for pigs for fattening by Commission Regulation (EC) No 2690/1999[(5)].

(13) The use of the enzyme preparation of endo-1,3(4)-beta-glucanase and endo-1,4-beta-xylanase produced by *Aspergillus niger (phoenicis)* (NRRL 25541) and of alpha-amylase produced by *Aspergillus oryzae* (ATCC 66222) was provisionally authorised, for the first time, for piglets by Commission Regulation (EC) No 1636/1999[(6)].

(14) The use of the enzyme preparation of endo-1,4-beta-xylanase, produced from *Trichoderma longibrachiatum* (CNCM MA 6–10W) was provisionally authorised, for the first time, for chickens for fattening by Commission Regulation (EC) No 1436/98[(7)].

(15) New data were submitted in support of the application for authorisation without a time limit of those five enzyme preparations. The assessment shows that the conditions laid down in Directive 70/524/EEC for such authorisation are satisfied.

(16) Accordingly, the use of those five enzyme preparations as specified in Annex II, should be authorised without a time limit.

(17) The assessment of those seven 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[(8)].

(18) 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:

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 1453/2004. (See end of Document for details)*

Article 1

The preparations belonging to the groups ‘Micro-organisms’ and ‘Enzymes’, as set out in Annexes I and II are authorised for use without a time limit as additives in animal nutrition under the conditions laid down in those Annexes.

Article 2

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.

Changes to legislation: *There are currently no known outstanding effects for the Commission Regulation (EC) No 1453/2004. (See end of Document for details)*

[F1]ANNEX I

Textual Amendments

F1 Deleted by Commission Implementing Regulation (EU) 2017/447 of 14 March 2017 concerning the authorisation of the preparation of Bacillus subtilis (DSM 5750) and Bacillus licheniformis (DSM 5749) as a feed additive for sows, weaned piglets, pigs for fattening, calves for rearing and turkeys for fattening and amending Regulations (EC) No 1453/2004, (EC) No 2148/2004 and (EC) No 600/2005 (holder of authorisation Chr. Hansen A/S) (Text with EEA relevance).

[F1]

ANNEX II

EC No	Additive	Chemical formula, description	Species or category of animal	Maximum age	Minimum content	Maximum content	Other provisions	End of period of authorisation
					Units of activity/ kg of complete feedingstuff			
Enzymes								
[F2								
F2								
F2								
F2								
F2]								
[F2								
a	[F2]							
b	[F2]							
c	[F2]							
d	[F2]							
e	[F2]							
f	[F2]							
g	[F2]							
h	[F3]							
i	[F3]							
j	[F3]							
k	1 IFP is the quantity of enzyme which liberates 1 micromole of reducing sugars (measured as xylose equivalent) from oat xylan per minute at pH 4,8 and 50 °C.							