

**COMMISSION REGULATION (EC) No 1465/2004**  
**of 17 August 2004**  
**concerning the permanent authorisation of an additive 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<sup>(1)</sup>, and in particular Article 3 and Article 9d(1) thereof,

Whereas:

- (1) Directive 70/524/EEC provides that no additive may be put into circulation unless a Community authorisation has been granted. 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 enzyme preparation of 6-phytase produced by *Aspergillus oryzae* (DSM 11857) was provisionally authorised, for the first time, for chickens for fattening, laying hens, turkeys for fattening, piglets and pigs for fattening by Commission Regulation (EC) No 1353/2000<sup>(2)</sup>, and for sows by Commission Regulation (EC) No 261/2003<sup>(3)</sup>.
- (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 an authorisation have been satisfied.

- (4) Accordingly, the use of that preparation, under the conditions set out in the Annex, should be authorised without a time limit.
- (5) The assessment of that preparation shows that certain procedures should be required to protect workers from exposure to the additive set out in the Annex. 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<sup>(4)</sup>.
- (6) 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:

*Article 1*

The preparation belonging to the group 'Enzymes', as set out in the Annex, is authorised for use without a time limit as an additive in animal nutrition under the conditions laid down in that Annex.

*Article 2*

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

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

Done at Brussels, 17 August 2004.

For the Commission

David BYRNE

Member of the Commission

<sup>(1)</sup> OJ L 270, 14.12.1970, p. 1. Directive as last amended by Commission Regulation (EC) No 1289/2004 (OJ L 243, 15.7.2004, p. 15).

<sup>(2)</sup> OJ L 155, 28.6.2000, p. 15.

<sup>(3)</sup> OJ L 37, 13.2.2003, p. 12.

<sup>(4)</sup> OJ L 183, 29.6.1989, p. 1. Directive as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council (OJ L 284, 31.10.2003, p. 1).

## ANNEX

| 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 feedstuff | Units of activity/kg of complete feedstuff |  |                      |                                |
| <b>Enzymes</b> |                          |   |                               |             |  |  |  |                      |                                |
| E 1614         | 6-phytase<br>EC 3.1.3.26 | Preparation of 6-phytase produced by <i>Aspergillus oryzae</i> (DSM 11857) having a minimum activity of:<br>Solid form: 2 500 FYT (1)/g<br>Liquid form: 5 000 FYT/g | Chickens for fattening        | —           | 250 FYT                                    | —  | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedstuff: 500-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus.  | Without a time limit |                                |
|                |                          |   | Laying hens                   | —           | 300 FYT                                    | —  | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedstuff: 450-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus.  |                      | Without a time limit           |
|                |                          |   | Turkeys for fattening         | —           | 250 FYT                                    | —  | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedstuff: 500-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus.  | Without a time limit |                                |
|                |                          |   | Piglets                       | —           | 250 FYT                                    | —  | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedstuff: 500-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus.<br>4. For use in weaned piglets until approximately 35 kg. |                      | Without a time limit           |

| 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 |   |                 |  |                                |
|       |          |                               | Pigs for fattening            | —           | 250 FYT                                       | — |                 | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff: 500-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus. | Without a time limit           |
|       |          |                               | Sows                          | —           | 750 FYT                                       | — |                 | 1. In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting.<br>2. Recommended dose per kg of complete feedingstuff: 750-1 000 FYT.<br>3. For use in compound feed containing more than 0,25 % phytin-bound phosphorus. | Without a time limit           |

(1) 1 FYT is the amount of enzyme which liberates 1 micromole of inorganic phosphate per minute from sodium phytate at pH 5,5 and 37°C.