# Commission Regulation (EC) No 490/2004 of 16 March 2004 concerning the provisional authorization of a new use of an additive already authorized in feedingstuffs (Saccharomyces cerevisiae) (Text with EEA relevance)

## COMMISSION REGULATION (EC) No 490/2004

## of 16 March 2004

## concerning the provisional authorization of a new use of an additive already authorized in feedingstuffs (*Saccharomyces cerevisiae*)

## (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)], as last amended by Regulation (EC) No 1756/2002[(2)], and in particular Articles 3 and 9e(1) thereof,

Whereas:

(1) Directive 70/524/EEC provides that no additive may be put into circulation unless a Community authorisation has been granted.

(2) In the case of additives referred to in Part II of Annex C to Directive 70/524, which includes micro-organisms, provisional authorisation of a new use of an additive already authorised may be given if the conditions laid down in that Directive are satisfied, and if it is reasonable to assume, in view of the available results, that when used in animal nutrition it has one of the effects referred to in Article 2(a) of that Directive. Such provisional authorisation may be given for a period not exceeding four years in the case of additives referred to in Part II of Annex C to that Directive.

(3) The use of the micro-organism preparation of *Saccharomyces cerevisiae* (CBS 493.94) has been provisionally authorised, for the first time, for calves by Commission Regulation (EC) No 1436/1998[(3)], for cattle for fattening by Commission Regulation (EC) No 866/1999[(4)] and for dairy cows by Commission Regulation (EC) No 937/2001[(5)]. These authorisations have been last modified by Commission Regulation (EC) No 2200/2001[(6)].

(4) New data were submitted in support of an application to extend the authorisation of this additive to horses.

(5) The assessment of the application for authorisation submitted in respect of the new use of this additive, shows that the conditions provided for in Directive 70/524/EEC for provisional authorisation are satisfied.

(6) The European Food Safety Authority (Scientific Panel on Additives and Products or Substances Used in Animal Feed) delivered a favourable opinion on 13 November

**Changes to legislation:** *There are currently no known outstanding effects for the Commission Regulation (EC) No 490/2004. (See end of Document for details)*

2003 on the safety of the additive when used in the animal category horses, under the conditions of use set out in the annex to this Regulation.

(7) The use of this additive for horses should therefore be provisionally authorised for a period of four years.

(8) The assessment of the application 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[(7)], as amended by Regulation (EC) No 1882/2003 of the European Parliament and of the Council[(8)].

(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

*Article 1*

The preparation belonging to the group ‘Micro-organisms’ as set out in the Annex is provisionally authorised for use as 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.

***Changes to legislation:** There are currently no known outstanding effects for the Commission Regulation (EC) No 490/2004. (See end of Document for details)*

# [F1ANNEX

**Textual Amendments**

**F1** Substituted by Commission Regulation (EC) No 1812/2005 of 4 November 2005 amending Regulations (EC) Nos 490/2004, 1288/2004, 521/2005 and 833/2005 as regards the conditions for the authorisation of certain additives in feedingstuffs belonging to the groups of enzymes and micro-organisms (Text with EEA relevance).

| No (or EC No) | Additive | Chemical formula, description | Species or category of animal | Maximum age | Minimum content | Maximum content | Other provisions | End of period of authorisation |
|---|---|---|---|---|---|---|---|---|
| | | | | | CFU/kg of complete feedingstuff | | | |
| **Micro-organisms** | | | | | | | | |
| 5 | *Saccharomyces cerevisiae* CBS 493.94 | Preparation of *Saccharomyces cerevisiae* containing a minimum of $1 \times 10^9$ CFU/g additive | Horses | — | $4 \times 10^9$ | $2{,}5 \times 10^{10}$ | In the directions for use of the additive and premixture, indicate the storage temperature, storage life and stability to pelleting. The quantity of *Saccharomyces cerevisiae* in the daily ration must not exceed $4{,}17 \times 10^{10}$ CFU for 100 kg of body weight. Use permitted from two months | 20.3.2008] |