COMMISSION IMPLEMENTING REGULATION (EU) 2019/899

of 29 May 2019


(Text with EEA relevance)

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 9(2) thereof,

Whereas:

(1) Regulation (EC) No 1831/2003 provides for the authorisation of additives for use in animal nutrition and for the grounds and procedures for granting and renewing such authorisation.


(3) In accordance with Article 14 of Regulation (EC) No 1831/2003, applications were submitted by the holder of those authorisations for the renewal of the authorisation of Saccharomyces cerevisiae CNCM I-4407 (formerly NCYC Sc 47) as a feed additive for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes, pigs for fattening and horses requesting that additive to be classified in the additive category ‘zootechnical additives’. Those applications were accompanied by the particulars and documents required under Article 14(2) of Regulation (EC) No 1831/2003.

(4) The European Food Safety Authority (‘the Authority’) concluded in its opinion of 13 June 2018 (7) that the applicant has provided data demonstrating that the additive complies with the conditions of authorisation.

(5) The assessment of Saccharomyces cerevisiae CNCM I-4407 shows that the conditions for authorisation, as provided for in Article 5 of Regulation (EC) No 1831/2003, are satisfied. Accordingly, the authorisation of that additive should be renewed as specified in the Annex to this Regulation.


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

(7) EFSA Journal 2018;16(7):5339.
HAS ADOPTED THIS REGULATION:

Article 1

The authorisation of the additive specified in the Annex, belonging to the additive category ‘zootechnical additives’ and to the functional group ‘gut flora stabilisers’ when it is used for lambs for fattening, dairy goats, dairy sheep, dairy buffaloes and pigs for fattening; and to the functional group ‘digestibility enhancers’ when it is used for horses, is renewed subject to the conditions laid down in that Annex.

Article 2

Saccharomyces cerevisiae NCYC Sc47 as feed additive under the conditions laid down in the Annex to this Regulation, Regulations (EC) No 1447/2006, (EC) No 186/2007, (EC) No 188/2007, (EC) No 209/2008 and (EC) No 232/2009, and premixtures and compound feed containing it, labelled in accordance with those Regulations before the entry into force of this Regulation, may be continued to be placed on the market until the existing stocks are exhausted.

Article 3


Article 4

This Regulation shall enter into force on the twentieth 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.

Done at Brussels, 29 May 2019.

For the Commission
The President
Jean-Claude JUNCKER
## ANNEX

<table>
<thead>
<tr>
<th>Identification number of the additive</th>
<th>Name of the holder of authorisation</th>
<th>Additive</th>
<th>Composition, chemical formula, description, analytical method</th>
<th>Species or category of animal</th>
<th>Maximum age</th>
<th>Minimum content</th>
<th>Maximum content</th>
<th>Other provisions</th>
<th>End of period of authorisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>4b1702</td>
<td>S.I. Lesaffre</td>
<td><em>Saccharomyces cerevisiae</em> CNCM I-4407</td>
<td>Additive composition: Preparation of <em>Saccharomyces cerevisiae</em> CNCM I-4407 with a minimum concentration of $5 \times 10^9$ CFU/g. Solid form</td>
<td>Lambs for fattening</td>
<td>—</td>
<td>$1.4 \times 10^9$</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated.</td>
<td>23 June 2029</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Characterisation of the active substance: Viable dried cells of <em>Saccharomyces cerevisiae</em> CNCM I-4407</td>
<td>Dairy goats and dairy sheep</td>
<td>—</td>
<td>$7 \times 10^8$</td>
<td>—</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Dairy buffaloes</td>
<td>—</td>
<td>$5 \times 10^8$</td>
<td>—</td>
<td>3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.</td>
<td></td>
</tr>
</tbody>
</table>

(1) Details of the analytical methods are available at the following address of the European Union Reference Laboratory for Feed Additives: https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports
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<td>Additive composition: Preparation of <em>Saccharomyces cerevisiae</em> CNCM I-4407 with a minimum concentration of $5 \times 10^9$ CFU/g. Solid form. Characterisation of the active substance: Viable dried cells of <em>Saccharomyces cerevisiae</em> CNCM I-4407. Analytical method (1) Enumeration: pour plate method using chloramphenicol dextrose yeast extract agar (EN 15789:2009). Identification: polymerase chain reaction (PCR) method CEN/TS 15790:2008.</td>
<td>Horses</td>
<td>—</td>
<td>$8 \times 10^8$</td>
<td>—</td>
<td>1. In the directions for use of the additive and premixture, the storage conditions and stability to heat treatment shall be indicated. 2. Recommended doses (CFU/head/day) for: — horses: $1.25 \times 10^{10} - 6 \times 10^{10}$ 3. For users of the additive and premixtures, feed business operators shall establish operational procedures and organisational measures to address potential risks resulting from their use. Where those risks cannot be eliminated or reduced to a minimum by such procedures and measures, the additive and premixtures shall be used with personal protective equipment, including eye and breathing protection.</td>
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