

COMMISSION IMPLEMENTING DECISION**of 24 June 2014****authorising the placing on the market of UV-treated baker's yeast (*Saccharomyces cerevisiae*) as a novel food ingredient under Regulation (EC) No 258/97 of the European Parliament and of the Council***(notified under document C(2014) 4114)***(Only the French text is authentic)**

(2014/396/EU)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients ⁽¹⁾, and in particular Article 7 thereof,

Whereas:

- (1) On 4 May 2012, the company Lallemand SAS made a request to the competent authorities of the United Kingdom to place UV-treated baker's yeast (*Saccharomyces cerevisiae*) on the market as a novel food ingredient. UV-treated baker's yeast is intended to be used during the production of yeast-leavened bread, rolls and fine bakery wares and in food supplements.
- (2) On 31 August 2012, the competent food assessment body of the United Kingdom issued its initial assessment report. In that report it came to the conclusion that UV-treated baker's yeast meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 11 September 2012, the Commission forwarded the initial assessment report to the other Member States.
- (4) Reasoned objections were raised within the 60-day period laid down in the first subparagraph of Article 6(4) of Regulation (EC) No 258/97.
- (5) On 14 April 2013, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for UV-treated baker's yeast as novel food ingredient in accordance with Regulation (EC) No 258/97.
- (6) On 12 December 2013, in its 'Scientific Opinion on the safety of vitamin D-enriched UV-treated baker's yeast' ⁽²⁾, EFSA concluded that UV-treated baker's yeast exhibiting an enhanced content of vitamin D₂ is safe under the intended conditions of use.
- (7) Therefore, the opinion gives sufficient grounds to establish that UV-treated baker's yeast as a novel food ingredient complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ and Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽⁴⁾ lay down specific provisions for the use of vitamins and minerals when added to food and in food supplements. The use of UV-treated baker's yeast should be authorised without prejudice to those specific provisions.
- (9) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.⁽²⁾ EFSA Journal 2014; 12(1):3520.⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).⁽⁴⁾ Regulation (EC) No 1925/2006 of the European Parliament and of the Council of 20 December 2006 on the addition of vitamins and minerals and of certain other substances to foods (OJ L 404, 30.12.2006, p. 26).

HAS ADOPTED THIS DECISION:

Article 1

UV-treated baker's yeast as specified in Annex I may be placed on the market in the Union as a novel food ingredient for the uses defined and at the maximum levels established in Annex II without prejudice to Directive 2002/46/EC and Regulation (EC) No 1925/2006.

Article 2

The designation of UV-treated baker's yeast authorised by this Decision on the labelling of the foodstuffs containing it shall be 'vitamin D yeast' or 'vitamin D₂ yeast'.

Article 3

This Decision is addressed to Lallemand SAS, 19 Rue des Briquetiers BP59, 31702 Blagnac Cedex, France.

Done at Brussels, 24 June 2014.

For the Commission
Tonio BORG
Member of the Commission

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ANNEX I

SPECIFICATION OF UV-TREATED BAKER'S YEAST

Definition:

Baker's yeast (*Saccharomyces cerevisiae*) is treated with ultraviolet light to induce the conversion of ergosterol to vitamin D₂ (ergocalciferol). Vitamin D₂ content in the yeast concentrate varies between 1 800 000-3 500 000 IU vitamin D/100 g (450-875 µg/g).

Description: Tan-coloured, free-flowing granules

Vitamin D₂:

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|------------------|--|
| Chemical name | (5Z,7E,22E)-3S-9,10-secoergosta-5,7,10(19),22-tetraen-3-ol |
| Synonym | Ergocalciferol |
| CAS No | 50-14-6 |
| Molecular weight | 396,65 g/mol |

Microbiological criteria of the yeast concentrate:

| | |
|-------------------------|-----------------------|
| Coliforms | Not more than 1 000/g |
| <i>Escherichia coli</i> | Not more than 10/g |
| <i>Salmonella</i> spp. | Absent in 25 g |

ANNEX II

AUTHORISED USES OF UV-TREATED BAKER'S YEAST

| Food category | Maximum use level |
|----------------------------------|---|
| Yeast-leavened breads and rolls | 5 µg of vitamin D ₂ /100 g final product |
| Yeast-leavened fine bakery wares | 5 µg of vitamin D ₂ /100 g final product |
| Food supplements | 5 µg of vitamin D ₂ /day |