COMMISSION IMPLEMENTING DECISION (EU) 2016/398

of 16 March 2016

authorising the placing on the market of UV-treated bread as a novel food under Regulation (EC) No 258/97 of the European Parliament and of the Council

(notified under document C(2016) 1527)

(Only the Swedish text is authentic)

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 12 February 2014, the company Viasolde AB which makes the equipment for UV-treatment made a request to the competent authorities of Finland to place ultraviolet (UV) treated bread on the market as a novel food within the meaning of point (f) of Article 1(2) of Regulation (EC) No 258/97. The aim of the UV treatment is to enhance the vitamin D content of the bread, which means that the nutritional value of the bread would significantly differ from the nutritional value of traditionally baked bread.

(2) On 14 March 2014, the competent food assessment body of Finland issued its initial assessment report. In that report it came to the conclusion that UV-treated bread meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.

(3) On 19 March 2014, 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 13 November 2014, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for UV-treated bread as novel food in accordance with Regulation (EC) No 258/97.

(6) On 11 June 2015, EFSA concluded in its 'Scientific Opinion on the safety of UV-treated bread as a novel food' ([2]), that bread enriched with vitamin D_2 through UV treatment is safe under the proposed conditions of use.

(7) Therefore, the opinion gives sufficient grounds to establish that UV-treated bread as a novel food complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.

(8) Regulation (EC) No 1925/2006 of the European Parliament and of the Council ([3]) lays down requirements on the addition of vitamins and minerals and of certain other substances to foods. The use of UV-treated bread should be authorised without prejudice to the requirements of this legislation.

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

HAS ADOPTED THIS DECISION:

Article 1

UV-treated bread as specified in Annex I may be placed on the market as a novel food at the maximum level of 3 µg vitamin D_2 per 100 g without prejudice to the specific provisions of Regulation (EC) No 1925/2006.

([1]) OJ L 43, 14.2.1997, p. 1.
([2]) *EFSA Journal* 2015; 13(7):4148.
([3]) 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).

Article 2

The following shall be added to the designation for the labelling of the foodstuffs: 'contains vitamin D produced by UV-treatment'.

Article 3

This Decision is addressed to Viasolde AB, Dalstigen 4, 262 63, Ängelholm, Sweden.

Done at Brussels, 16 March 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

ANNEX

SPECIFICATION OF UV-TREATED BREAD

Definition:

UV-treated bread is yeast leavened bread and rolls (without toppings) to which a treatment with ultraviolet radiation is applied after baking in order to convert ergosterol to vitamin D_2 (ergocalciferol).

UV radiation: a process of radiation in ultraviolet light within the wavelength of 240-315 nm for maximum of 5 seconds with energy input of 10-50 mJ/cm^2.

Vitamin D_2:

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

Contents:

Vitamin D_2 (ergocalciferol) in the final product	0,75-3 µg/100 g [1]
Yeast in dough	1-5 g/100 g [2]

[1] EN 12821, 2009, European Standard.
[2] Recipe calculation.