

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2016/1189

of 19 July 2016

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

(notified under document C(2016) 4565)

(Only the English 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 26 September 2012, the company Dairy Crest Ltd made a request to the competent authorities of Ireland to place UV-treated milk on the market as a novel food within the meaning of point (f) of Article 1(2) of Regulation (EC) No 258/97.
- (2) On 10 January 2013, the competent food assessment body of Ireland issued its initial assessment report. In that report it came to the conclusion that UV-treated milk meets the criteria for novel food set out in Article 3(1) of Regulation (EC) No 258/97.
- (3) On 16 January 2013, 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 9 February 2015, the Commission consulted the European Food Safety Authority (EFSA) asking it to carry out an additional assessment for UV-treated milk as novel food in accordance with Regulation (EC) No 258/97.
- (6) On 10 December 2015, EFSA concluded in its opinion on the safety of UV-treated milk as a novel food ⁽²⁾ that UV-treated milk is safe under the intended conditions of use.
- (7) That opinion gives sufficient grounds to establish that UV-treated milk as a novel food complies with the criteria laid down in Article 3(1) of Regulation (EC) No 258/97.
- (8) The UV treatment of the pasteurised milk results in an increase in the vitamin D content of the milk. Regulation (EU) No 1169/2011 of the European Parliament and of the Council ⁽³⁾ specifies what is regarded as a significant amount for vitamins and minerals. Therefore, it is important to inform the consumer adequately on the presence of vitamin D produced by UV-treatment in the product.

⁽¹⁾ OJ L 43, 14.2.1997, p. 1.

⁽²⁾ *EFSA Journal* 2016; 14(1):4370.

⁽³⁾ Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004 (OJ L 304, 22.11.2011, p. 18).

- (9) Regulation (EC) No 1925/2006 of the European Parliament and of the Council ⁽¹⁾ lays down requirements on the addition of vitamins and minerals and certain other substances to foods. The use of UV-treated milk should be authorised without prejudice to the requirements of that legislation.
- (10) 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 milk as specified in Annex I to this Decision may be placed on the market in the Union as a novel food for the uses defined and at the maximum levels established in Annex II to this Decision without prejudice to the specific provisions of Regulation (EC) No 1925/2006.

Article 2

The designation of UV-treated milk authorised by this Decision for the labelling of the foodstuffs shall be 'UV-treated'.

Where UV-treated milk contains an amount of vitamin D that is considered significant in accordance with Point 2 of Part A of Annex XIII to Regulation (EU) No 1169/2011 of the European Parliament and of the Council, the designation for the labelling shall be accompanied by 'contains vitamin D produced by UV-treatment' or 'milk containing vitamin D resulting from UV-treatment'.

Article 3

This Decision is addressed to Dairy Crest Ltd, Claygate House, Littleworth Road, Esher, Surrey, KT10 9PN, United Kingdom.

Done at Brussels, 19 July 2016.

For the Commission
Vytenis ANDRIUKAITIS
Member of the Commission

⁽¹⁾ 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).

ANNEX I

SPECIFICATION OF UV-TREATED MILK

Definition:

UV-treated milk is cow's milk (whole and semi-skimmed) to which a treatment with ultraviolet (UV) radiation via turbulent flow is applied after pasteurisation. The treatment of the pasteurised milk with UV radiation results in an increase in the vitamin D₃ (cholecalciferol) concentrations by conversion of 7-dehydrocholesterol to vitamin D₃.

UV radiation: a process of radiation in ultraviolet light within the wavelength of 200-310 nm with energy input of 1 045 J/l.

Vitamin D₃:

Chemical name	(1S,3Z)-3-[(2E)-2-[(1R,3aS,7aR)-7a-methyl-1-[(2R)-6-methylheptan-2-yl]-2,3,3a,5,6,7-hexahydro-1H-inden-4-ylidene]ethylidene]-4-methylidenecyclohexan-1-ol
Synonym	Cholecalciferol
CAS No	67-97-0
Molecular weight	384,6377 g/mol

Contents:

Vitamin D ₃ in the final product	Whole milk ⁽¹⁾ : 0,5–3,2 µg/100 g ⁽²⁾ Semi-skimmed milk ⁽¹⁾ : 0,1–1,5 µg/100 g ⁽²⁾
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⁽¹⁾ As defined by Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007 (OJ L 347, 20.12.2013, p. 671).

⁽²⁾ HPLC

ANNEX II

AUTHORISED USES OF UV-TREATED MILK

Food category	Range of vitamin D ₃
Pasteurised whole milk ⁽¹⁾	5–32 µg/kg for general population excluding infants
Pasteurised semi-skimmed milk ⁽¹⁾	1–15 µg/kg for general population excluding infants

⁽¹⁾ Consumed as such.