



Brussels, **XXX**
SANTE/10877/2016
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[...] (2016) **XXX** draft

COMMISSION IMPLEMENTING DECISION

of **XXX**

**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**

(Only the English text is authentic)

COMMISSION IMPLEMENTING DECISION

of **XXX**

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

(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 ingredients¹, 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 food² 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 Council³ specifies what is regarded as a significant amount for vitamins and

¹ OJ L 43, 14.2.1997, p. 1.

² EFSA Journal 2016; 14(1):4370.

³ Regulation (EC) 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

minerals. Therefore, it is important to inform the consumer adequately on the presence of vitamin D produced by UV-treatment in the product.

- (9) Regulation (EC) No 1925/2006 of the European Parliament and of the Council⁴ 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,

For the Commission

Vytenis ANDRIUKAITIS

Member of the Commission

⁴ 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).

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).