

**COMMISSION IMPLEMENTING REGULATION (EU) 2020/1004****of 9 July 2020****approving the basic substance cow milk in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011****(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 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC <sup>(1)</sup>, and in particular Article 13(2) in conjunction with Article 23(5) thereof,

Whereas:

- (1) On 20 September 2017 the Commission received an application from Basic-Eco-Logique for the approval of milk as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009. The applicant was allowed to complete the application, which was finalised in the new version of May 2018. On that occasion the applicant changed the scope of the application to (raw whole) cow milk.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on 22 August 2018 <sup>(2)</sup>. The Commission presented the review report <sup>(3)</sup> and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 21 October 2019 and finalised them for the meeting of that Committee on 24 March 2020.
- (3) The information provided by the applicant shows that cow milk fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council <sup>(4)</sup>. Moreover, it is not predominantly used for plant protection purposes but, nevertheless is useful in plant protection in a product consisting of the substance and water or even undiluted. Consequently it is to be considered as a basic substance.
- (4) Milk which is not intended for human consumption is considered as an animal by-product according to Regulation (EC) No 1069/2009 of the European Parliament and of the Council <sup>(5)</sup>. As such it should comply with that Regulation and Commission Regulation (EU) No 142/2011 <sup>(6)</sup>.
- (5) As due to lactose and milk proteins milk is listed as a substance or product causing allergies or intolerances according to point 7 in Annex II to Regulation (EU) No 1169/2011 of the European Parliament and the Council <sup>(7)</sup> it is appropriate to limit the uses to growth stages at which no fruits are present.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1.

<sup>(2)</sup> EFSA (European Food Safety Authority), 2018. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for milk for use in plant protection as a fungicide. EFSA supporting publication 2018:EN-1482. 42 pp.

<sup>(3)</sup> <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

<sup>(4)</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

<sup>(5)</sup> Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1).

<sup>(6)</sup> Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1).

<sup>(7)</sup> Regulation (EU) No 1169/2011 of the European Parliament and 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).

- (6) It has appeared from the examinations made that cow milk may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve cow milk as a basic substance.
- (7) In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is, however, necessary to include certain conditions for the approval which are detailed in Annex I to this Regulation.
- (8) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(8)</sup> should be amended accordingly.
- (9) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

*Article 1*

**Approval of a basic substance**

The substance cow milk as specified in Annex I is approved as a basic substance subject to the conditions laid down in that Annex.

*Article 2*

**Amendments to Implementing Regulation (EU) No 540/2011**

Implementing Regulation (EU) No 540/2011 is amended as set out in Annex II to this Regulation.

*Article 3*

**Entry into force**

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, 9 July 2020.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

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<sup>(8)</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Specific provisions
Cow Milk CAS No: 8049-98-7	Not available.	Not applicable	30.7.2020	Cow milk shall comply with Regulation (EC) No 1069/2009 and Regulation (EU) No 142/2011.  Cow milk shall be used in accordance with the specific conditions included in the conclusions of the review report on cow milk (SANTE/12816/2019), and in particular Appendices I and II thereto.

<sup>(1)</sup> Further details on identity, specification and manner of use of basic substance are provided in the review report.

## ANNEX II

In Part C of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Specific provisions
'22	Cow Milk CAS No: 8049-98-7	Not available.	Not applicable	30.7.2020	Cow milk shall comply with Regulation (EC) No 1069/2009 and Commission Regulation (EU) No 142/2011.  Cow milk shall be used in accordance with the specific conditions included in the conclusions of the review report on cow milk (SANTE/12816/2019), and in particular Appendices I and II thereto.'

<sup>(1)</sup> Further details on identity, specification and manner of use of basic substance are provided in the review report.