

**COMMISSION IMPLEMENTING REGULATION (EU) 2016/560****of 11 April 2016****approving the basic substance whey 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 23(5) in conjunction with Article 13(2) thereof,

Whereas:

- (1) In accordance with Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 20 April 2015 an application from the Institut Technique de l'Agriculture Biologique (ITAB) for the approval of sweet whey as a basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3). The applicant was allowed to complete the application, which was finalised in the new version of September 2015. On that occasion the applicant changed the scope of the application to whey.
- (2) The Commission asked the European Food Safety Authority (hereinafter 'the Authority') for scientific assistance. The Authority presented to the Commission a Technical Report on 28 October 2015 <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 11 December 2015 and finalised them for the meeting of that Committee on 8 March 2016.
- (3) The documentation provided by the applicant shows that whey 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. Consequently, it is to be considered as a basic substance.
- (4) It has appeared from the examinations made that whey 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 whey as a basic substance.
- (5) 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.
- (6) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 <sup>(5)</sup> should be amended accordingly.
- (7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

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

<sup>(2)</sup> European Food Safety Authority, 2015; Outcome of the consultation with Member States and EFSA on the basic substance application for sweet whey for use in plant protection as a fungicide on grape vine, tomatoes, cucumber and zucchini squash. EFSA supporting publication 2015:EN-879, 34 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> 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).

HAS ADOPTED THIS REGULATION:

*Article 1*

**Approval of a basic substance**

The substance whey 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 in accordance with 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, 11 April 2016.

*For the Commission*  
*The President*  
Jean-Claude JUNCKER

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## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Specific provisions
Whey CAS No: 92129-90-3	Not available	CODEX STAN 289-1995 <sup>(2)</sup>	2 May 2016	Whey shall be used in accordance with the specific conditions included in the conclusions of the review report on whey (SANTE/12354/2015) and in particular Appendices I and II thereof.

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

<sup>(2)</sup> Available online: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>

## ANNEX II

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

'10	Whey CAS No: 92129-90-3	Not available	CODEX STAN 289-1995 (*)	2 May 2016	Whey shall be used in accordance with the specific conditions included in the conclusions of the review report on whey (SANTE/12354/2015) and in particular Appendices I and II thereof.
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(\*) Available online: <http://www.fao.org/fao-who-codexalimentarius/standards/list-of-standards/en/>