Commission Implementing Regulation (EU) 2018/1295 of 26 September 2018 approving the basic substance Onion oil 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)

COMMISSION IMPLEMENTING REGULATION (EU) 2018/1295

of 26 September 2018

approving the basic substance Onion oil 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[(1)], and in particular Article 23(5) in conjunction with Article 13(2) thereof,

Whereas:

(1) On 12 December 2016 the Commission received an application from Bionext, for the approval of Onion oil as a basic substance. That application was later completed by the information required by the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.

(2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a technical report on Onion oil on 31 October 2017[(2)].

(3) The Commission presented the draft review report[(3)] on 25 May 2018 and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 19 July 2018 and finalised them for the meeting of that Committee on 20 July 2018.

(4) The documentation provided by the applicant shows that Onion oil 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[(4)]. Moreover, it is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance. Consequently, it is to be considered as a basic substance.

(5) It has appeared from the examinations made that Onion oil may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1295. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes

particular with regard to the uses which were examined and detailed in the Commission review report. It is therefore appropriate to approve Onion oil as a basic substance.

(6) 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.

(7) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(5)] should be amended accordingly.

(8) 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 Onion oil is approved as a basic substance as laid down in Annex I.

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, 26 September 2018.

For the Commission

The President

Jean-Claude JUNCKER

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2018/1295. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

ANNEX I

Common Name, Identification Numbers	**IUPAC Name**	**Purity[a]**	**Date of approval**	**Specific provisions**
Onion oil CAS No: 8002-72-0	Not applicable	Food grade	17 October 2018	Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto.

a Further details on identity, specification and manner of use of the 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[a]**	**Date of approval**	**Specific provisions**
‘20	Onion oil CAS No: 8002-72-0	Not applicable	Food grade	17 October 2018	Onion oil shall be used in accordance with the specific conditions included in the conclusions of the review report on Onion oil (SANTE/10615/2018) and in particular Appendices I and II thereto.’

a Further details on identity, specification and manner of use of basic substance are provided in the review report.