



2024/2878

11.11.2024

COMMISSION IMPLEMENTING REGULATION (EU) 2024/2878

of 8 November 2024

approving the basic substance *Allium fistulosum*, processed, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending 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 5 March 2021, the Commission received an application from Institut Technique de l'Agriculture Biologique ('the applicant') for the approval of *Allium fistulosum* extract as a basic substance to be used in plant protection as a bactericide for soil treatment before tomato sowing in the field and in permanent greenhouses. A revised application was submitted by the applicant in June 2021, and it was accompanied by the information required under Article 23(3), second subparagraph, of Regulation (EC) No 1107/2009.
- (2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance pursuant to Article 23(4) of Regulation (EC) No 1107/2009. The Authority provided the Commission with a technical report on *Allium fistulosum* on 31 October 2023 ⁽²⁾.
- (3) The application has been made for '*Allium fistulosum* extract'. However, the documentation provided by the applicant shows that the *Allium fistulosum* plant can be used in two different formulations: as a water extract or in the form of chopped fresh pieces of the plant. It was therefore considered appropriate to include both processing methods in the name of the basic substance and to define the scope of the application as covering '*Allium fistulosum*, processed'.
- (4) The information provided by the applicant shows that *Allium fistulosum* fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and the Council ⁽³⁾. Moreover, it is not predominantly used for plant protection purposes but nevertheless *Allium fistulosum*, processed, is useful for plant protection purposes when contained in a product consisting of either the substance itself or the substance and a simple diluent. Consequently, it is to be considered as a basic substance.
- (5) Based on the information provided in the application and the technical report from the Authority, it can also be concluded that *Allium fistulosum*, processed, is not a substance of concern, and it does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects. Furthermore, it is not placed on the market as a plant protection product. Consequently, *Allium fistulosum*, processed, meets the conditions set out in Article 23(1) second subparagraph, of Regulation (EC) No 1107/2009.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1, ELI: <https://eur-lex.europa.eu/eli/reg/2009/1107/oj>.

⁽²⁾ EFSA (European Food Safety Authority), 2023. Overall conclusions on the application for approval of *Allium fistulosum* as a basic substance to be used in plant protection as a bactericide. EFSA supporting publication 2023: EN-8433. 119pp.; doi:10.2903/sp.efsa.2023.EN-8433.

⁽³⁾ 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, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

- (6) The examination of the application and all related documents has led to the conclusion that *Allium fistulosum*, processed, satisfies 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 *Allium fistulosum*, processed, as a basic substance.
- (7) In accordance with Article 23(5) of Regulation (EC) No 1107/2009, read 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, as laid down in Annex I to this Regulation.
- (8) The Commission presented the review report ⁽⁴⁾ and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed, on 23 May 2024 and 11 July 2024, respectively.
- (9) In accordance with Article 23(5) of Regulation (EC) No 1107/2009, read in conjunction with Article 13(4) thereof, the Annex to Commission Implementing Regulation (EU) No 540/2011 ⁽⁵⁾ should be amended accordingly.
- (10) 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 *Allium fistulosum*, processed, 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

The Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

⁽⁴⁾ Final Review report for the basic substance *Allium fistulosum*, processed, finalised by the Standing Committee on Plants, Animals, Food and Feed on 3 October 2024 in view of the approval of *Allium fistulosum*, processed, as basic substance in accordance with Regulation (EC) No 1107/2009.

⁽⁵⁾ 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, ELI: http://data.europa.eu/eli/reg_impl/2011/540/oj).

*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, 8 November 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Specific provisions
<i>Allium fistulosum</i> , processed CAS No: Not available CIPAC No: Not available	Not available	Food grade compliant with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾ , Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ , Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 ⁽⁴⁾ .	1 December 2024	<i>Allium fistulosum</i> , processed, shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium fistulosum</i> , processed, (PLAN/2024/798) and in particular Appendices I and II thereof.

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

⁽²⁾ 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, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁽³⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/2024-05-11>).

⁽⁴⁾ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>).

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 ⁽¹⁾	Date of approval	Specific provisions
'27	<i>Allium fistulosum</i> , processed CAS No: Not available CIPAC No: Not available	Not available	Food grade compliant with the provisions of Regulation (EC) No 178/2002 of the European Parliament and of the Council ⁽²⁾ , Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽³⁾ , Commission Regulation (EU) 2023/915 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 ⁽⁴⁾	1 December 2024	<i>Allium fistulosum</i> , processed, shall be used in accordance with the specific conditions included in the conclusions of the review report on <i>Allium fistulosum</i> , processed, (PLAN/2024/798) and in particular Appendices I and II thereof.

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

⁽²⁾ 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, ELI: <http://data.europa.eu/eli/reg/2002/178/oj>).

⁽³⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/2024-05-11>).

⁽⁴⁾ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>).