



Basic Substance
Allium fistulosum, processed
PLAN/2024/798 RR
3 October 2024 ⁽¹⁾

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

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Allium fistulosum*, processed, made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009 ⁽²⁾ concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 5 March 2021 an application from Institut Technique de l'Agriculture Biologique, hereafter referred to as the applicant, for the approval of the substance *Allium fistulosum* extract as basic substance. This application was not complete, and a revised application has been received in June 2021.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission requested scientific assistance on the evaluation of the application to the EFSA, who delivered its views on the specific points raised in the commenting phase.

EFSA submitted to the Commission the results of its work in the form of a technical report for *Allium fistulosum* on 31 October 2023 ⁽³⁾.

The application has been made for “*Allium fistulosum* extract”. In the Technical Report, EFSA proposed the substance to be named “*Allium fistulosum*”. However, the documentation provided by the applicant shows that the *Allium fistulosum* plant can be prepared for use 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 reflect the processing steps in the name of the basic substance and to define the scope of the application as covering “*Allium fistulosum*, processed”.

⁽¹⁾ Review Report established in accordance with Art. 13 of Regulation (EU) No 1107/2009; it does not necessarily represent the views of the European Commission.

⁽²⁾ OJ L 309, 24.11.2009, p. 1-50.

⁽³⁾ 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.

The Commission examined the application, the comments by Member States and EFSA and the EFSA Technical report on the substance together with the additional information and comments provided by the applicant, before finalising the current review report, which was referred to the Standing Committee on Plants, Animals, Food and Feed for examination. The review report was finalised by the Standing Committee on 3 October 2024.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the EFSA technical report, and the comments and clarifications submitted, all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of **Commission Implementing Regulation (EU) 2024/2878** ⁽⁴⁾ of 8 November 2024 approving the basic substance *Allium fistulosum*, processed, in accordance with Regulation (EC) No 1107/2009.

The review report will be published and made available to any interested party.

Without prejudice to the provisions of Regulation (EC) No 178/2002 ⁽⁵⁾, in particular with respect to the responsibility of operators, following the approval of *Allium fistulosum*, processed, as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and the conditions established in sections 4 and 5, and Appendices I and II of this review report.

EFSA has made available to the public all background documents and its final Technical Report as well as the application without the Appendices in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with the derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, and the comments and further additional information provided by the applicant to address the open points identified in the Technical Report from EFSA, is that there are clear indications that it may be expected that *Allium fistulosum*, processed, fulfils the criteria of Article 23 for the uses specified in Appendix II.

Allium fistulosum is used and placed on the market as foodstuff. It is listed in the EU Novel food catalogue according to Regulation (EU) No 2015/22835. It is cultivated since the Middle Ages, mainly in Asia and Africa. It is placed on the EU market either in a dry form or as a fresh plant.

⁽⁴⁾ OJ L, 2024/2878, 11.11.2024, ELI: http://data.europa.eu/eli/reg_impl/2024/2878/oj

⁽⁵⁾ OJ L 31, 1.2.2002 p. 1-24 - 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.

For plant protection purposes, fresh stems and leaves of *Allium fistulosum* are chopped and incorporated in the soil, or, alternatively, dried *Allium fistulosum* stems and leaves are extracted with water. Both fresh and dried *Allium fistulosum* stems and leaves should be of a food grade. The aqueous extract of dried *Allium fistulosum* stems and leaves is also expected to be of food grade quality. In order to ensure no microbial or chemical contamination of treated crops, the user preparing the *Allium fistulosum* extract (dispersable concentrate) should comply with the regulations and procedures applicable to any food processor, the extract needs to be used within the next 24h after its preparation and must be preserved under conditions that guarantee the maintenance of its “food grade” status until application.

The proposed use as basic substance is supported to control soil born bacteria in tomatoes.

The outcome of the risk assessment as documented in the EFSA Technical Report mentioned irritant properties of some constituents of *Allium fistulosum*, processed. However, considering that *Allium fistulosum* is available to the general public as food, a quantitative non-dietary exposure assessment was considered not necessary for the intended uses. It can be reasonably assumed that the users will be aware of the properties of onion plants, which include *Allium fistulosum*, and may consider using commonly available methods to reduce exposure to irritating components from the plants during the preparation and use of the substance.

EFSA also concluded that based on the available information, there is no evidence that *Allium fistulosum*, processed, has endocrine disrupting, neurotoxic or immunotoxic potential.

With regard to residues in food and feed, EFSA indicated that the use of *Allium fistulosum*, processed, on tomatoes is of no concern to consumers under the proposed GAP.

No specific environmental fate and behaviour data were available for *Allium fistulosum*, processed. However, the Technical Report of EFSA mentioned that *Allium fistulosum* is expected to be non-persistent in the environment. As regards the comparison of the expected environmental exposure resulting from the intended uses of *Allium fistulosum*, processed, and the background levels in the environment, EFSA indicated that the potential levels of bioactive molecules in *Allium fistulosum* that would be released to the environment according to the intended uses would be lower than what would be expected to be left in an agricultural *Allium fistulosum* field after harvesting.

As regards the non-target organisms, EFSA indicated that based on the available information, it is not expected that the substance will have an unacceptable effect on non-target organisms. The low risk to aquatic organisms could not be concluded due to insufficient data available, however, there were also no specific concerns identified. The EFSA Technical Report indicated that surface water exposure cannot be excluded for spray uses. However, in greenhouses, the exposure through spray drift was considered negligible. Furthermore, the substance is not considered to be persistent, and the potential levels of *Allium fistulosum* bioactive molecules that would be released to the environment would be lower than what is expected in an agricultural field after harvesting.

Therefore, considering the EFSA Technical Report and the conditions of use which are described in detail in Appendices I and II, it is concluded that the use of *Allium fistulosum*, processed, would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected for this use.

Allium fistulosum, processed, is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

Overall, it can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the preparation for use in Appendix I and for the uses as described in Appendix II.

These conclusions were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Union level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. Identity and biological properties

The properties of *Allium fistulosum*, processed, are given in Appendix I.

The *Allium fistulosum* plant to be used for preparation as a basic substance should be of food grade and thus in compliance with provisions of Regulation (EC) 178/2002¹⁴, Regulation (EC) No 396/2005¹⁵ and Commission Regulation (EU) 2023/915¹⁶.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Allium fistulosum*, processed

Allium fistulosum, processed, must be identified by the given specifications in Appendix I and must be used in compliance with the method of preparation and conditions of use as reported in Appendices I and II.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments, as well as of the results of the examination of any information referred to the Commission in the framework of Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection, as appropriate, with any amendment of the approval conditions for the *Allium fistulosum*, processed, in Part C of Annex of the Regulation (EC) No 540/2011⁽⁶⁾.

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will not be placed on the market as plant protection product hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users of the substance on the existence of this review report.

Further to the publication of this review report, it is recommended that the competent authorities of Member States will make it additionally available to the general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

⁽⁶⁾ OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I

Identity and biological properties

Allium fistulosum, processed

Common name (ISO)	<i>Allium fistulosum</i> (not ISO)
Chemical name (IUPAC)	Not applicable
Chemical name (CA)	Not applicable
Botanical classification	<i>Allium fistulosum</i> L.
Common names	Welsh onion, stone leek, Chinese onion, Chinese spring onion, Japanese bunching onion
Part used	Stems and leaves
CAS No	Not applicable
CIPAC No and EEC No	Not applicable
FAO specification	FAO not available.
Purity	<i>Allium fistulosum</i> plants used as a basic substance should be food grade, and consequently it should comply with provisions of Regulation (EC) 178/2002, Regulation (EC) No 396/2005 and Commission Regulation (EU) 2023/915.
Relevant impurities	Not applicable
Molar mass and structural formula	Not applicable
Mode of Use	Spray application Soil incorporation
Preparation to be used	Dispersible concentrate (DC): 500 g of crushed dried <i>Allium fistulosum</i> bulbs and leaves are mixed with 1 L of tap water at room temperature for 1 min, and filtered. Plant Rodlet (PR): Fresh raw <i>Allium fistulosum</i> bulbs and leaves are washed with water, processed by chopping into 1-2 cm pieces, and incorporated into the soil at the application rate of 250 g of <i>Allium fistulosum</i> , processed, per 1 kg of soil.
Function of plant protection	Bactericide

APPENDIX II
List of uses supported by available data
ALLIUM FISTULOSUM, PROCESSED

Crop and/ or situation (a)	Member State or Country	Example product name as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate				PHI (days) (m)	Remarks *
					Type (d-f)	Conc of a.i. g/L (i)	Method kind (f-h)	Growth stage & season (j)	No. of Application min max (k)	Interval between applications (min) (days)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha) (l)	Total rate each year (g/ha)		
Tomato (LYPXP)	All MS	Welsh onion/ Scallion/ Japanese brunching onion/ oignon peyi/cive antillaise/oignon pays	F G#	Soilborne diseases <i>Ralstonia solanacearum</i> RALSSO	Dispersible concentrate (DC)	500 g dried <i>A. fistulosum</i> /L**	Soil treatment spray	15 to 30 days before sowing and (BBCH00) All seasons	1 per crop =1-3 per		50 kg <i>A. fistulosum</i> /hl	650 to 750 l/ha	Extract From 325 to 375 kg of dried <i>A. fistulosum</i> per ha		N/A	*The product can be used only for soil treatment before plantation
Tomato (LYPXP)	All MS	Welsh onion/ Scallion/ Japanese brunching onion/ oignon peyi/cive antillaise/oignon pays	F G#	Soilborne diseases <i>Ralstonia solanacearum</i> RALSSO	Plant rodlet (PR)	Raw <i>A. fistulosum</i> plant	Soil Amendment (buried)	15 to 30 days before sowing and (BBCH00) All seasons	1 per crop =1-3 per year		250g of raw <i>A. fistulosum</i> / 1kg soil	0	1300 to 1500 kg of raw <i>A. fistulosum</i> per ha		N/A	*The product can be used only for soil treatment before plantation

**Prepared by mixing dried *Allium fistulosum* plant pieces with water following by filtration and application of the filtrate

#Permanent greenhouse

NOTE: The list of uses was developed by EFSA based on the information submitted by the applicant, as described in the EFSA Technical Report (page 119).

* For uses where the column „Remarks. As above or other conditions to take into account (a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure) (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I) (c) e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor (d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc.. (e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989 (f) All abbreviations used must be explained (g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated	(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO) (j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application (k) Indicate the minimum and maximum number of application possible under practical conditions of use (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha) (m) PHI - minimum pre-harvest interval
--	---