



Basic Substance
Allium cepa L. bulb extract
SANTE/10842/2020 Rev2
21 October 2020

Final Review report for the basic substance *Allium cepa* L. bulb extract (onion bulbs) finalised by the Standing Committee on Plants, Animals, Food and Feed on 22 October 2020 in view of the approval of *Allium cepa* L. bulb extract (onion bulbs) as basic substance in accordance with Regulation (EC) No 1107/2009¹

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Allium cepa* L. bulb extract, made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009² 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 4 September 2018 an application from l'Institut de l'agriculture et de l'alimentation Biologiques (ITAB), hereafter referred to as the applicant, for the approval of the substance *Allium cepa* bulb extract as basic substance. This application was not complete and a revised application has been received on 28 May 2019.

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 required 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 cepa* bulb extract on 12 December 2019³.

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), 2019. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for *Allium cepa* bulb extract for use in plant protection as a fungicide in potatoes, tomatoes and cucumbers. EFSA supporting publication 2019:EN-1767. doi:10.2903/sp.efsa.2019.EN-1767.

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 22 October 2020.

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) 2021/81⁴** concerning the approval of the *Allium cepa* L. bulb extract as basic substance under 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 178/2002⁵, in particular with respect to the responsibility of operators, following the approval of the *Allium cepa* L. bulb extract 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 the sections 4, 5 and Appendices I and II of this review report.

EFSA will make 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

⁴ OJ L 29, 28.1.2021, p. 12.

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.

EFSA, is that there are clear indications that it may be expected that the *Allium cepa* L. bulb extract fulfils the criteria of Article 23.

For plant protection purposes, a decoction of *Allium cepa* L. bulbs in water is used. The onion bulbs (*Allium cepa* L.) used should be of food grade meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on *Bulbus Allii Cepae*.

Allium cepa L. bulbs (onions) are a common foodstuff. The *Allium cepa* L. bulb extract that is used for plant protection purposes is a water extract of onion bulbs that are of food grade quality. The *Allium cepa* L. bulb extract therefore fulfils the criteria of a ‘foodstuff’ as defined in Article 2 of Regulation (EC) No 178/2002. When the aqueous extract of *Allium cepa* L. bulbs (decoction) is of food grade quality, no concern for human health is to be expected, according to EFSA.

In order to ensure no microbial or chemical contamination of treated crops, the user preparing the “*Allium cepa* L. bulb extract (food grade)” 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 fungi in potatoes, tomatoes and cucumbers.

According to the classification information provided by a limited number of companies to ECHA, some onion extracts have skin irritating properties (Category 2). There is however no harmonised classification in Annex VI to the CLP Regulation applicable to all extracts.

Since the *Allium cepa* L. bulb extract to be used is a water extract of the onion bulbs of food grade quality and considering the low amounts to be used, it can be assumed that residues are of no concern.

According to EFSA, a comparison of the quantity of mature onions in a hectare field before harvest against the equivalent quantity of onion bulb extract that would be applied as a result of the intended use GAP for *Allium cepa* L. bulb extract, would have been useful to know for the assessment of the fate and behaviour of the substance and the ecotoxicology. This was not presented in the dossier. However, the yield of an onion field is on average several tons per hectare. The amounts of onions used to prepare the extract, according to the GAP in Annex II, is 300 g – 500 g of onions per treatment per hectare and up to 0.9 kg – 2.5 kg of onions (to prepare the extract) per hectare for the total amount applied (3-5 applications). The amount of applied substance is thus considerably lower than the natural amounts in an average mature onion field.

As a consequence, considering the nature of the active substance and the relatively low application rates, the environmental exposure is expected to be much lower due to the use of the substance than due to the cultivation of onions. No risk to soil, surface and groundwater is therefore expected. It can also be assumed that there is no unacceptable risk to non-target organisms from intended uses of the *Allium cepa* L. bulb extract as a basic substance.

Therefore, considering the EFSA conclusions, the rate of application and the conditions of use which are described in detail in Appendix I and II, it is concluded that the use of the *Allium cepa*

L. bulb extract, would not lead to concerns for human health. Furthermore, no residues or unacceptable effects on the environment are expected given the conditions of use.

The *Allium cepa* L. bulb extract does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and it is not predominantly used for plant protection purposes but nevertheless is useful in plant protection. Finally, it is not placed on the market as a plant protection product.

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 supported uses as described in Appendix II.

In fact, these indications 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 Community 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 main properties of the *Allium cepa* L. bulb extract are given in Appendix I.

The *Allium cepa* L. bulb extract should be of food grade meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on *Bulbus Allii Cepae*.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Allium cepa* L. bulb extract

The *Allium cepa* L. bulb extract 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 cepa* L. bulb extract in Part C of Annex of the Regulation (EC) No 540/2011⁶.

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 the review report SANTE/10842/2020 Rev2, 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 cepa L. bulb extract

Common name (ISO)	not relevant														
Chemical name (IUPAC)	not relevant														
Chemical name (CA)	not relevant														
Botanical classification	<i>Allium cepa</i> L.														
Common names	Bulb onion or common onion is a vegetable that is the most widely cultivated species of the genus <i>Allium</i> .														
Part used	Bulbs														
CAS No	Not relevant														
CIPAC No and EEC No	Not relevant														
FAO specification	Not relevant														
Purity	The onion bulbs used to prepare the extract should be of food grade meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on <i>Bulbus Allii Cepae</i>														
Molecular formula	Not relevant														
Molecular mass and structural formula	Not relevant														
Mode of Use	Spray application														
Preparation to be used	<p>Dispersible concentrate (DC) (decoction) A decoction of crude onion can be prepared: 500 g of crude onion bulbs in 10 L of boiling water. Onions are chopped before decoction. Decoction: boil 500 g of the chopped onions in 10 liters of water for ten minutes then let infuse for a quarter of an hour. Filter the mixture with a metal strainer. To be used in the next 24h.</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th></th> <th style="text-align: center;">Mode of preparation</th> <th style="text-align: center;">Weight of <i>Allium cepa</i> L. bulbs in the extraction (g/L)</th> <th style="text-align: center;">Weight of <i>Allium cepa</i> L. bulbs in the preparation (g/L)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Step 1</td> <td style="text-align: center;">Decoction (100°C) 10 min.</td> <td rowspan="3" style="text-align: center; vertical-align: middle;">50 g/L As in GAP Table</td> <td rowspan="3" style="text-align: center; vertical-align: middle;">500 g / 10 L</td> </tr> <tr> <td style="text-align: center;">Step 2</td> <td style="text-align: center;">Infusion 15 min.</td> </tr> <tr> <td style="text-align: center;">Step 3</td> <td style="text-align: center;">Filtration</td> </tr> </tbody> </table>				Mode of preparation	Weight of <i>Allium cepa</i> L. bulbs in the extraction (g/L)	Weight of <i>Allium cepa</i> L. bulbs in the preparation (g/L)	Step 1	Decoction (100°C) 10 min.	50 g/L As in GAP Table	500 g / 10 L	Step 2	Infusion 15 min.	Step 3	Filtration
	Mode of preparation	Weight of <i>Allium cepa</i> L. bulbs in the extraction (g/L)	Weight of <i>Allium cepa</i> L. bulbs in the preparation (g/L)												
Step 1	Decoction (100°C) 10 min.	50 g/L As in GAP Table	500 g / 10 L												
Step 2	Infusion 15 min.														
Step 3	Filtration														
Function of plant protection	Fungicide														

APPENDIX II
List of uses supported by available data
ALLIUM CEPA L. BULB EXTRACT

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 g of a.i. /kg (i)	Method kind (f-h)	Growth Stage & season (j)	Nb. of application min/max (k)	Interval between applications (min)	l a.i./hl min max (kg/hl)	Water l/ha min max	Total rate each application l a.i./ha min max (l/ha) (l)		
Potatoes <i>Solanum tuberosum</i>	All MS	-	F	Early blight <i>Alternaria solani</i>	Dispersible concentrate (DC) (decoction)	100 % of the decoction infusion (50 g onion bulb/L)	Spray	BBCH 21-85	3 to 5	7 days	1	600 to 1000	6 to 10 (0.3 to 0.5 kg onion bulb/ha)	-	
Vegetable Gardening Tomato <i>Lycopersicum esculentum</i>			F	Tomato Late Blight <i>Phytophthora infestans</i>									15 (0.75 kg onion bulb/ha)		
Cucumber <i>Cucumis Sativus</i>			G	Cucumber Gray Mold <i>Botrytis cinerea</i>									7 days		

<p>* For uses where the column „Remarks. As above or other conditions to take into account</p> <p>(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)</p> <p>(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)</p> <p>(c) <i>e.g.</i> pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor</p> <p>(d) <i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..</p> <p>(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989</p> <p>(f) All abbreviations used must be explained</p> <p>(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench</p> <p>(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated</p>	<p>(i) g/kg or g/L. Normally the rate should be given for the substance (according to ISO)</p> <p>(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</p> <p>(k) Indicate the minimum and maximum number of application possible under practical conditions of use</p> <p>(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)</p> <p>(m) PHI - minimum pre-harvest interval</p>
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