

APPROVED: 11 December 2019

doi:10.2903/sp.efsa.2019.EN-1767

Outcome of the consultation with Member States and EFSA on the basic substance application for approval of *Allium cepa* bulb extract to be used in plant protection as a fungicide in potatoes, tomatoes and cucumbers

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Allium cepa* bulb extract are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of *Allium cepa* bulb extract as a basic substance to be used in plant protection as a fungicide in potatoes, tomatoes and cucumbers. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

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Keywords: *Allium cepa* bulb extract, basic substance, application, consultation, plant protection, pesticide, fungicide

Requestor: European Commission

Question number: EFSA-Q-2019-00622

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Suggested citation: 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 approval of *Allium cepa* bulb extract to be used in plant protection as a fungicide in potatoes, tomatoes and cucumbers. EFSA supporting publication 2019:EN-1767. 57 pp. doi:10.2903/sp.efsa.2019.EN-1767

ISSN:2397-8325

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Summary

Allium cepa bulb extract is an active substance for which, in accordance with Article 23(3) of Regulation (EC) No 1107/2009, the European Commission received an application from Institut de l'agriculture et de l'alimentation Biologique (ITAB) for approval as a 'basic substance'. Regulation (EC) No 1107/2009 introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest in applying for approval may be limited. Article 23 of Regulation (EC) No 1107/2009 lays down specific provisions for consideration of applications for approval of basic substances.

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in September 2019, EFSA was asked to organise a consultation on the basic substance application for *Allium cepa* bulb extract, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for *Allium cepa* bulb extract, organised by EFSA, was conducted with Member States via a written procedure in June – August 2019. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for *Allium cepa* bulb extract and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Allium cepa L. (Liliaceae) or its varieties and cultivars is most commonly known as "onion" is commercially cultivated worldwide, especially in regions of moderate climate. *Allium cepa* bulb extract is a water extract, a decoction of crude food grade onion.

Accordingly, the basic substance is commonly considered as "onion soup" i.e. food grade quality, therefore no additional toxicological data are needed and no concern for human health is to be expected. It is noted that a few publications in the literature report allergic reactions due to onion ingestion or handling (contact dermatitis, rhinoconjunctivitis, and asthma); a potential to cause eye redness and lacrimation is mostly linked to handling chopped (crude) onions.

EFSA's understanding is that the onion bulbs should be of food grade, meeting the requirements of WHO monographs on selected medicinal plants (Volume 1, Geneva, 1999) on *Bulbus Allii Cepae*. In order to ensure that no microbial or chemical contamination of the treated crops occurs, the user preparing "Allium cepa extract (food grade)" should be expected to comply with the regulations and procedures applicable to any food processor, the extract needs to be used within the next 24 h after its preparation and must be preserved under conditions that guarantee the maintenance of its "food grade" status until application.

The summary of intended uses table in section 3.4 of the application dossier as provided by the applicant was not understandable. EFSA considered that the mass of the decoction liquid that will be applied per ha, sprayed as a further dilution in water, has to be considered the basic substance. Consequently, a comparison of the kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP, could have been made, but was not available.

No information was provided to address the risk to non-target organisms. No information was provided to consider the environmental exposure to be lower for the proposed use in the GAP than the cultivation of onions. For example, a comparison, as indicated above, of the kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP, could have been useful for this purpose. Considering the nature of the substance, commonly considered as "onion soup", the risk may be expected to be likely low; however, in the

absence of any information on the potential exposure, it is not possible to draw a firm conclusion in relation to the intended uses.

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

Regulation (EC) No 1107/2009¹ (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Allium cepa bulb extract is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut de l'agriculture et de l'alimentation Biologique (ITAB) for approval as a 'basic substance' to be used in plant protection as a fungicide in potatoes, tomatoes and cucumbers.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Allium cepa* bulb extract, which was conducted via a written procedure in June – August 2019. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for *Allium cepa* bulb extract and to present EFSA's scientific views on the individual comments received in the format of a reporting table.

The application and, where relevant, any update thereof submitted by the applicant for approval of *Allium cepa* bulb extract as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Institut de l'agriculture et de l'alimentation Biologique (ITAB); 2019ab).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 27 September 2019, EFSA was asked to organise a consultation on the basic substance application for *Allium cepa* bulb extract, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 27 December 2019.

On the basis of the reporting table, the European Commission may decide to further consult EFSA to conduct a full or focussed peer review and to provide its conclusions on certain specific points.

¹ 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. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for *Allium cepa* bulb extract and the conclusions drawn by EFSA are presented in the format of a reporting table.

The comments received are summarised in columns 2 and 3 of the reporting table. The applicant's considerations of the comments, where available, are provided in column 4, while EFSA's scientific views and conclusions are outlined in column 5 of the table.

The finalised reporting table is provided in Appendix A of this report. In addition, an overview table on the identity and biological properties of the substance and the list of intended uses in plant protection (GAP table) are provided in Appendix B and C, respectively.

Documentation provided to EFSA

1. Institut de l'agriculture et de l'alimentation Biologique (ITAB); 2019a. Basic substance application on *Allium cepa* extract submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2019. Documentation made available to EFSA by the European Commission.
2. Institut de l'agriculture et de l'alimentation Biologique (ITAB); 2019b. Basic substance application update on *Allium cepa* bulb extract submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2019. Documentation made available to EFSA by the applicant.

References

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), Silano V, Bolognesi C, Castle L, Chipman K, Cravedi J-P, Engel K-H, Fowler P, Franz R, Grob K, Guertler R, Husøy T, Kaerenlampi S, Milana MR, Pfaff K, Riviere G, Srinivasan J, Tavares Pocas MF, Tlustos C, Woelfle D, Zorn H, Benigni R, Brimer L, Mulder G, Oskarsson A, Svendsen C, van Benthem J, Anastassiadou M, Saarma S and Mennes W, 2018. Scientific Opinion on Flavouring Group Evaluation 74, Revision 4 (FGE.74Rev4): Consideration of aliphatic sulphides and thiols evaluated by JECFA (53rd and 61st meeting) structurally related to aliphatic and alicyclic mono-, di-, tri- and polysulphides with or without additional oxygenated functional groups from chemical group 20 evaluated by EFSA in FGE.08Rev5. EFSA Journal 2018;16(3):5167, 58 pp. <https://doi.org/10.2903/j.efsa.2018.5167>

Abbreviations

a.s.	active substance
a.i.	active ingredient
BBCH	growth stage of mono- and dicotyledon plants
BSA	basic substance application
CLP	classification, labelling and packaging
DC	dispersible concentrate
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
EMA	European Medicines Agency
GAP	good agricultural practice
GHS	globally harmonized system
PHI	pre-harvest interval
PEC	predicted environmental concentration

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Allium cepa* bulb extract and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

1. Purpose of the application					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	2.1	<p>DK: For this purpose, please state for what uses <i>Allium cepa</i> extracts is placed on the market for. The text states only what <i>Allium cepa</i> extract can do, but does not show that it is placed on the market for this reason. A google search revealed that people make the <i>Allium cepa</i> extract themselves for the uses mentioned. Therefore it is not clear that <i>Allium cepa</i> extract is actually marketed.</p> <p>Also, please mention already here what form the <i>Allium cepa</i> extract has, as some <i>Allium cepa</i> extracts sold are on powder form, and further below in this application the formulation is stated as a decoction (liquid).</p>	<p>DK: Add specific information that <i>Allium cepa</i> extract is placed on the market for something (and not used primarily by "home brewers").</p>	<p><i>Allium cepa</i> extract is sold a medicinal product. Reference EMA 2011 added.</p> <p>The same substance is available under different forms. <i>Allium cepa</i> extracts sold are on powder form soluble in water as food and medicinal product.</p> <p>Recipe retained is a common decoction (liquid), as other botanical extracts.</p> <p>Note that it is the first part of the process when powder is produced.</p>	<p>Addressed: Additional information was included in the revised submission (ITAB, 2019b).</p>

1. Purpose of the application

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Please note that it may be ok for basic substances to be homemade e.g. Nettle extract. But it should be explicitly stated.			
1(2)		DK: Please clearly state in this application if the use of both commercially available <i>Allium cepa</i> extract as well as homemade <i>Allium cepa</i> extract is proposed.	DK: Clearly state (and include throughout the application where relevant) if only commercially available <i>Allium cepa</i> extracts or if homemade <i>Allium cepa</i> extracts are also proposed for use as basic substance.	Recipe retained is a common decoction (liquid), as other botanical extracts. <i>Allium cepa</i> Bulb extracts decoction is easily performed at home.	Addressed: The application concerns a decoction of crude onion.

1.1. Contact details of the applicants

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

2. Identity of the substance/product as available on the market and predominant use

2.1. Predominant uses outside of plant protection

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1	EFSA: It is not clear whether the extract is marketed for other uses different than PPP or should be homemade by the farmers	EFSA: Applicant to make it clear whether the allium cepa extract is marketed for other uses different than PPP, if yes which. To clarify which of them are predominant.	The same substance is available under different forms. <i>Allium cepa</i> extracts sold are on powder form soluble in water as food and medicinal product.	Addressed: The application concerns a decoction of crude onion.

2.2. Identity and physical chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(2)	2.2.2	DK: If the reference Galdon is to be used here, then please do not simple copy-paste but please create a useful list out of the information. What is meant by "admitted active compounds"? Are there more active	DK: rewrite/delete some of the beginning of this chapter for a better overview. DK: Please expands the list to include all active compounds in <i>Allium cepa</i> extract as found in literature. Or as a minimum	Chapter modified "Admitted" replaced by "Estimated major relevant active constituents". Composition given in 2.2.3.	Addressed: 2.2.3 concerning the major relevant constituents was updated in the revised submission (ITAB, 2019b).

2.2. Identity and physical chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		compounds that should be on the list?	simply justify that those listed are the major relevant constituents etc.		

2.2.1. Common name of the substance and product and their synonyms/plant nomenclature

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(3)	2.2.1 Proposed name	EFSA: Proposed name: <i>Allium cepa</i> extract. Shouldn't the name clarify that the extract is from bulbs	EFSA: applicant to include in the common name clarification that the extract is from the bulb: <i>Allium cepa</i> bulb extract	Name change for: <i>Allium cepa</i> bulb extract ion the updated BSA.	Addressed: The proposed name was changed in the revised submission (ITAB, 2019b).

2.2.2. Chemical name with CAS, EC and CIPAC numbers

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(4)	2.2.2	EFSA agrees with DK comment, if the paper are needed please extract the useful		Reference moved	Addressed: The reference was removed.

2.2.2. Chemical name with CAS, EC and CIPAC numbers

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(5)	2.2.2	<p>information of them and not just copy the abstracts.</p> <p>EFSA: reported CAS number 8054-39-5 is related with: Extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Allium cepa</i>, Liliaceae.</p> <p>It is not clear if for the use as PPP is intended to be kept all of the possibilities which this definition gives or should be restricted to: aqueous extract of <i>Allium cepa</i>, Liliaceae bulbs (decoction) as it was reported at some parts of the application</p>	<p>EFSA: Applicant to clarify whether for the use as PPP the definition of the substance should be restricted to: aqueous extract of <i>Allium cepa</i>, Liliaceae bulbs (decoction) or to be kept more extensive definition related with CAS 8054-39-5, extractives and their physically modified derivatives such as tinctures, concretes, absolutes, essential oils, oleoresins, terpenes, terpene-free fractions, distillates, residues, etc., obtained from <i>Allium cepa</i>, Liliaceae</p>	<p>CAS number [8054-39-5] attributed is different from CAS number of onion oil (essential oil) [8002-72-0]. EC number possible: 944-860-3 but no corresponding CAS attributed</p>	<p>Addressed: Based on the revised submission (ITAB, 2019b), EFSA is assuming that the basic substance is the aqueous extract of <i>Allium cepa</i>, (Liliaceae) bulbs (decoction).</p> <p>See also 5(12)</p>
2(6)	2.2.2		<p>EFSA: Please clarify whether so called admitted active substances are the main components in the extract, or they are the biological</p>	<p>"Admitted" replaced by "Estimated major relevant active constituents".</p>	<p>Addressed: The text was updated in the revised submission (ITAB, 2019b).</p>

2.2.2. Chemical name with CAS, EC and CIPAC numbers

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
			active components, what is their content.		

2.2.3. Molecular and structural formula, molecular mass

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

2.2.4. Method or methods of manufacture of the substance and of the product

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(7)	2.2.4	DK: Please specify explicitly whether here the <i>Allium cepa</i> extract may be produced privately or if only the commercially available foodstuff is considered for this application.		Recipe retained is a common decoction (liquid), as other botanical extracts. <i>Allium cepa</i> Bulb extracts decoction is easily performed at home. Equivalent extract as foodstuff may be commercially available. References given in the BSA.	Addressed: The application concerns a decoction of crude onion.

2.2.4. Method or methods of manufacture of the substance and of the product

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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2.2.5. Description and specification of purity of the substance and product

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)	2.2.5	EFSA: It is stated: Food sanitary status required under General Food Law (Regulation No 178/2002) It is not clear the meaning of this	EFSA: please explain the statement: Food sanitary status required under General Food Law (Regulation No 178/2002)	Food sanitary status under General Food Law (Regulation No 178/2002) is required and Food Grade is mention in the name also. Necessary to be considered in organic farming.	Addressed: Regulation No 178/2002 is laying down the general principles and requirements of food law, establishing the European Food Safety Authority and is laying down procedures in matters of food safety, but is not dealing with food sanitary status. EFSA's understanding is that the onion bulbs 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> .
2(9)	2.2.5	EFSA: if the extract is produced for different uses, the specifications (purity, impurities)		If the extract is produced for different uses, the specifications should be food	See comment 2(8)

2.2.4. Method or methods of manufacture of the substance and of the product

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		should be reported for the related products		status as described in the BSA	

2.2.6. Identity of inactive isomers, impurities and additives

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

2.2.7. Methods of analysis

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

2.3. Names of substances/products as put on the market

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(10)	2.3	Please provide some example of names for <i>Allium cepa</i> extract	Add a list of some examples of <i>Allium cepa</i> extract foodstuff	Product references added	Addressed:

2.3. Names of substances/products as put on the market

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		products that are placed on the market (at least somewhere in the EU).	products that are currently marketed in the EU.		Examples were included in the revised submission (ITAB, 2019b).

2.4. Manufacturer of the substance/products

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(11)	2.4	EFSA: It is stated: "Not relevant, substance can be done by farmers" Based on this statement seems that the extract is not put on the market for other uses. If this is the case please make it clear, saying; " to be prepared by the farmers, following the receipt/conditions described in 2.6"		Statement modified as requested. Product references added.	Addressed: See comments 2(1), 2(5), 2(7)

2.5. Type of preparation of the substance/product

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

2.6. Description of the preparation for the product to be used for plant protection purposes

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(12)		DE: The preparation of the extract should be described more clearly.	DE: Information should be provided, whether the onions have to be chopped for decoction. The decoction time should be provided. Is the decoction concentrated during boiling? What kind of filter is recommended? Must the extract be immediately used or for how long is the extract stable until it has to be used?	2.6 Recipe modified and clarified Timing added (decoction, infusion, use).	Addressed: The required details for the preparation of the extract were included in the revised submission (ITAB, 2019b).
2(13)	2.6	DK: Please delete " Conclusions §2 : onion bulb decoction / <i>Allium cepa</i> extract is a food additive according to Regulation EC No 178/2002 and subsequently an intrinsic basic substance.". Or at least	DK: Delete sentence or at least change the wording.	Wording modified as requested.	Addressed: The wording in 2.6 Conclusions was updated in the revised submission (ITAB, 2019b).

2.6. Description of the preparation for the product to be used for plant protection purposes

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>change the word „intrinsic“ to „potential“.</p> <p>Please note that use as food additive and use as pesticide are not comparable with regard to e.g. environmental risk or risk to worker (though consumer may be covered in most cases).</p> <p>Furthermore, please include a ready-to-use instruction (guideline) for preparing the <i>Allium cepa</i> extract. For how long (approximately should the onions be boiled to ensure food grade quality. And should the boiled onions + boiling water be pushed through some kind of mesh (or blended) before use, or how is the extract to be prepared exactly? And if this is the definition of <i>Allium cepa</i> extract then how come the a.s. content in the GAP table is set to 10 g/kg? It may be that the content of onion in the extract is 10 g/kg, but as</p>	<p>DK: Add an easy to follow instruction on how to prepare the <i>Allium cepa</i> extract (if homemade extracts is included in this application, which is not yet clear. See other comments from DK).</p> <p>In any case please correct anywhere in this application where it is stated that the <i>Allium cepa</i> extract has a concentration of 10% a.s.. As the extract itself is the a.s. However, it may be stated (if demonstrated true) that the <i>Allium cepa</i> content of the extract is 10 %.</p>	<p>Food status of onions is usefull in organic farming plant protection.</p> <p>2.6 Recipe modified and clarified</p> <p>Timing added (decoction, infusion, use).</p> <p>Bulbs should be of food quality Bulbs are chopped before decoction</p> <p>Concentration specified in GAP</p> <p>GAP clarified</p>	<p>Addressed: The required details for the preparation of the extract were included in the revised submission (ITAB, 2019b). See also comments 2(12) and 2(8)</p> <p>The applicant provided new updated GAP (table 3.4 in ITAB, 2019b), however EFSA highlights that it was still not understandable. The user cannot tell how much decoction needs to be applied per ha in what (if any) dilution.</p>

2.6. Description of the preparation for the product to be used for plant protection purposes

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>the a.s. is defined as the extract as a whole, without other ingredients, then the concentration must be 100% (that will then be further diluted when use as pesticide)</p>			<p>EFSA considered based on the revised submission that the mass of the decoction liquid that will be applied per ha, sprayed as a further dilution in water, is the substance considered as basic substance. The GAP table has been updated accordingly (see Appendix C).</p>
2(14)	2.6	<p>EFSA: Conclusions §2, it is not correct. The extract itself is not authorised as a food ingredient under Regulation (EC) No 1333/2008 or Regulation (EC) No 1334/2008 (food additive or food flavouring). Two of the so called admitted substances are authorised as food flavourings: dipropyl disulphide (FL No 12.014) and dipropyl trisulfide (FL No 12.023). It should be noted that dipropyl trisulfide (FL No 12.023) was re-evaluated by EFSA in 2018 and conclusion on its safety is still pending. The third substance cycloallin</p>	<p>EFSA: Information on the regulatory status of the extract and the admitted substances to be correctly reported in the application.</p>	<p>Food status of onions is useful in organic farming plant protection.</p> <p>2.6 Recipe modified and clarified</p> <p>Timing added (decoction, infusion, use).</p> <p>Components are described as present and potent "active components" of the mixture, not as "food ingredient" themselves.</p>	<p>Addressed: The wording of the conclusion was updated, however EFSA emphasizes that this is still not correct: Regulation No 178/2002 is laying down the general principles and requirements of food law, establishing the European Food Safety Authority and is laying down procedures in matters of food safety, however that legislation is not the basis of the decision if a product is or not a food additive.</p>

2.6. Description of the preparation for the product to be used for plant protection purposes

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		(CAS 15042-85-0) is not authorised as a food ingredient.			

3. Uses of the substance and its product for plant protection

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3.2. Effects on harmful organisms or on plants (including mode of action)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: The upregulation of glutathione s-transferase expression was demonstrated <i>in vitro</i> in rat cells, it is however questionable if the superficial application (spraying) of <i>Allium cepa</i> extract on plants would have the same effect.	DE: The hypothesis of the mode of action should be relativised.	Mode of action was not fully investigated but targets are using glutathione s-transferase expression.	Mode of action was not fully investigated.
3(2)		DE: Quite a number of references are provided that demonstrate some antifungal activity of <i>Allium cepa</i> extract. However, only two studies tested the efficiency of <i>Allium cepa</i>	DE: Either change the intended uses (in section 3.1 and 3.4), or provide data as a proof for efficiency against <i>Phytophthora infestans</i> and <i>Alternaria solani</i> .	More proofs of antifungal properties are added in the updated BSA. References added.	Addressed: Additional information was included in the updated submission (ITAB, 2019b), showing some efficiency against <i>Phytophthora nicotianae</i> , <i>Phytophthora</i>

3.2. Effects on harmful organisms or on plants (including mode of action)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>extract against <i>Botrytis cinerea</i>. These studies indicate a week to moderate efficiency. Only one study investigated the efficiency against <i>Phytophthora infestans</i>, and no fungicidal activity against this pathogen was detected. There is no study that provides efficiency data for <i>Alternaria solani</i>. Thus, the usefulness for plant protection is proved only to some degree for <i>Botrytis cinerea</i>, but not for the other pathogens that are intended to be controlled.</p>			<p><i>citrophthora</i> and <i>Phytophthora palmivora</i>. Khallil Abdel-Raouf M. 2001 was added to the updated submission showing that the extracts of <i>Allium cepa</i> exhibited remarkable inhibitory effects against <i>Alternaria solani</i>.</p>
3(3)	3.2	<p>DK: Please write a summary of the effects of <i>Allium cepa</i> extract on fungal pathogens including the secondary MoA as a plant elicitor, and then list all the references, This would be much more helpful and give a better overview. As it is the chapter is specific for <i>Allium cepa</i> extracts but to an equal degree also for many other</p>	<p>DK: Please rewrite into the form of a summary. All the relevant information to make this summary seems to be present; however, the information is not made readily available for the reader.</p>	<p>Mode of action was not fully investigated. More References added but all References mention all kinds of plant extracts. More than dozen references show antifungal activity of the extract.</p>	<p>Addressed: All the relevant information to make the summary under section 3.2 of the application dossier seems to be present, however, the applicant did not make the information readily available for the reader.</p>

3.2. Effects on harmful organisms or on plants (including mode of action)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		plant extracts not relevant here. Also, for this purpose (basic substance application) a nice summary (with references listed) would be helpful instead of this compilation of abstracts.			

3.2.1. Mode of action

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(4)	3.2.1	DK: See comment above (3.2). Please simple state the mode of action. "Specific in vitro inhibitory effect" is not a mode of action. Please write a short overview of the mode of action of <i>Allium cepa</i> (with references given e.g. at the end), and remove the compilation of abstracts.	DK: Please rewrite into the form of a summary. With the different mode of action listed. All the relevant information to make this summary seems to be present; however, the information is not made readily available for the reader.	Overview added.	Addressed: All the relevant information to make the summary under section 3.2 of the application dossier seems to be present, however, the applicant did not make the information readily available for the reader.

3.3. Usefulness in the framework of plant protection

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(5)	3.4 summary of intended uses	NL: Is there a reason for only claiming late crop stages in the table of uses? (after bbch 51 in potato, after bbch 75 in tomato and cucumber)? The claimed pathogens also occur before these crop stages.		BSA corrected	Addressed: The GAP table was updated in the revised submission (ITAB, 2019b).
3(6)	3.4 summary of intended uses	NL: A PHI of seven days is claimed for potato in column 'm' of the summary of intended uses, and a PHI of one day for tomato and cucumber. PHI is normally only used if there are residue issues, and the		BSA corrected PHI = 0 No residue expected.	Addressed: According to the applicant's response in column 4 the PHI is zero, however the GAP was not updated in the revised submission (ITAB, 2019b).

3.4. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>addition of a PHI seems to be at odds with the residue chapter.</p> <p>What is the reason for not allowing product use closer to harvest?</p>			<p>The PHI was amended accordingly by EFSA in Appendix C.</p> <p>See also comment 2(13)</p>
3(7)	3.4 GAP table	<p>DK: Is it intentional that only field uses are considered in this application?</p> <p>Also, please consider if these fungal diseases are relevant for other vegetable crops.</p> <p>Column (i): the concentration of a.s. as defined as <i>Allium cepa</i> extract is 100 %not 10 g/kg. However it may be the case that the <i>Allium cepa</i> content of the extract is 10 %. And why is the concentration given as kg when it is a liquid (liter). Or is is <i>Allium cepa</i> extract powder that could be used as well?</p>	<p>DK: Please indicate greenhouse uses (G) if intended (and acceptable with regard to worker risk).</p> <p>Please consider adding more vegetable crops if possible/relevant.</p>	<p>G added for Tomato and cucumber.</p> <p>No other results available at this stage.</p> <p>Corrected in the GAP</p>	<p>Addressed:</p> <p>The greenhouse use for tomato was added in the revised submission, however the other modifications were not included in the revised GAP.</p> <p>The applicant provided new updated GAP (table 3.4 in ITAB, 2019b), however EFSA highlights that it was still not understandable. The user cannot tell how much decoction needs to be applied per ha in what (if any) dilution.</p> <p>See EFSA considerations in comment 2(13)</p>

4. Classification and labelling of the substance

Classification and labelling of the substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)	Section 4	NL: It is indicated that ECHA considers onion extract to be flammable and irritating to the skin. However, this is not a harmonised classification, these are the classifications provided by companies.		Water extract should not be flammable! This sentence may be removed from chapter §4. Corrected	Addressed: The flammability was removed from the revised submission (ITAB, 2019b).
4(2)	4	DK: Please include the CLP classification categories, and not just the GHS symbols. Also, please add the GHS-numbers to the symbols for correctness.		Chapter modified Corrected	Addressed: The substance is self-classified as skin irritant 2 (no harmonised classification), it is unknown whether this self-classification corresponds to the same <i>Allium cepa</i> extract referred in this application. See also 5(4, 9)

5. Impact on Human and Animal Health

5. General

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5	DK: Please delete the text. If anything, this should be added to the introduction of this application. Please keep in mind that there is a difference between consuming soup and the use as pesticide (spraying) with regard to risk to the environment and human health.		Initial Text deleted. Text moved. New text added	Addressed: The text has been revised as: " <i>Allium cepa</i> bulb extract is a decoction of onion bulb".

5.1. Toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.1.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.1.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	Chapter 5. Impact on human and animal health, 5.1.2.	DE: The information on acute toxicity ("foodstuff, not applicable") is considered insufficient. It is well known that cut onion causes in the eye redness and lacrimation. Therefore, an eye irritating effect cannot be excluded. It is proposed that this effect is discussed in the application paper. However, <i>Allium cepa</i> extract is prepared by decoction of onion and it can be expected that the potential eye irritating effect disappears in result of decoction.		Information added	Addressed: Information on the potential to cause eye redness and lacrimation when handling chopped onions has been added in the toxicity section 5.1.

5.1.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)	Chapter 5. Impact on human and animal health, 5.1.2.	DE: There is no information in the application template on the sensitising potential of <i>Allium cepa</i> . However, indications of skin sensitising properties of <i>Allium cepa</i> can be found in the public literature (Enrique et al., Involvement of lipid transfer protein in onion allergy. <i>Annals of allergy, Asthma & Immunology</i> , 98, Nr. 2, 2007). It is proposed to perform a literature research and to report the results in a revised application template.		Reference Enrique 2007 added in chapter 5.4.	Addressed: Few publications in the literature report allergic reactions due to onion ingestion or handling (contact dermatitis, rhinoconjunctivitis, and asthma). See also 5(9)
5(4)	5.1.2 acute toxicity	NL: It is referred to use as foodstuff. However, this only considers oral exposure, whereas due to the use as PPP also dermal and inhalation exposure can occur. Please note that some medicinal data on dermal treatment is available and classification as skin irritant is indicated by companies to ECHA.		Topical uses were found (provided in 5.4) in literature, this is contradictory to skin irritation.	See 4(2)

5.1.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.1.4. Long-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.1.5. Genotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)	5.1.5	DK: If the applicant claims not applicable then the example given from literature Arranz <i>et al.</i> 2007 may be deleted.		Reference moved	Addressed.

5.1.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(6)	Chapter 5. Impact on human and animal health, 5.1.6.	DE: In the application template a publication is reported (Takare Vishnu et al., 2009) which describes antifertility activity of ethanolic extract of <i>Allium cepa</i> . It is considered necessary that this paper is not only reported in the application paper but also discussed in relation to the application as basic substance. However, DE considers this publication to be of low reliability and limited relevance because an ethanolic extract was tested and no ethanol control was used in the test. The animal number is very low (6 per group) and there are strong deviations from the OECD guidelines on reproductive toxicity.		Applicant agrees, no (ethanol) control treatment to definitively conclude about antifertility of the extract. Ethanol extract compare to water extract (decoction) in the corresponding BSA recipe.	Addressed: The paper by Takare Vishnu et. al., 2009 is of low relevance to this application. See also 5(7)
5(7)	5.1.6 reproductive toxicity	NL: More information in literature is available on possible effects on fertility (e.g. effects on sperm). These should be included in the assessment.		Reference cited	See 5(6)

5.1.7. Neurotoxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.1.8. Toxicity of metabolites or impurities

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(8)	5.1.8	DK: Please delete the text "Supported active molecule used in skin care". This is not relevant here, and a metabolite or impurity may be toxic regardless of the use of the substance as skin care.		Text deleted and moved	Addressed.

5.1.9. Medical data: adverse effects reported in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(9)	Section 5.1.9	NL: there are some reports on allergic reactions, please address these. Also considering classification as skin irritant is indicated by companies to ECHA.		Skin irritant but topical medicinal applications so conclusion are weak. No real proof of skin irritation were found.	See 4(2) and 5(3)
5(10)	5.1.9	DK: For clarity: It is stated that raw onions cause tearing; please explicitly add whether <i>Allium cepa</i> extract does the same or not.		Allium extract as decoction is more less similar to onion soup known to be non-irritant. Cooking may destroy some irritant component. Finally, this irritation does not forbidden onions in kitchen, and some people eat those bulb raw as well.	Addressed.

5.2. Reference values: Acceptable Daily Intake, Acute reference Dose, Acceptable Operator Exposure Level

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

5.3. Exposure to the substance and impurities in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.3.1. Exposure through the use for plant protection purposes

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.3.2. Background exposure (exposure to the substance through other means)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.3.3. Comparison of exposure through use for plant protection and the background exposure

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.4. Impact on human and animal health arising from exposure to the substance or impurities contained in it

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

5.5. Additional information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(11)	Section 5.5	NL: There is also an evaluation available by EMA on allium cepa L. regarding herbal preparations.		Reference added in the updated BSA.	Addressed.

5.6. Additional information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(12)	Section 5.6	EFSA: the comment made under 2(5) needs to be clarified to be in agreement on the status of the product as food grade quality. Other needs for clarifications are expressed under 6(1). Provided that the product is an aqueous extract of <i>Allium cepa</i> , Liliaceae bulbs (decoction) commonly known as onion soup and free of other contaminants, it is agreed that no additional toxicological data are needed and no concern for human health is to be expected.		No comment from applicant	Addressed: Based on the revised submission (ITAB, 2019b), EFSA is assuming that the basic substance is the aqueous extract of <i>Allium cepa</i> , (Liliaceae) bulbs (decoction) of food grade quality; accordingly, no additional toxicological data are needed and no concern for human health is to be expected. See 2(5)

6. Residues

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	6. Residues	<p>EFSA: In principle, it is agreed that chemical residues derived from the application of what is commonly known as "onion soup" are not expected to be of concern for the human health and further investigations with respect to their potential residues are not needed. However, there is a lack of clarity on the exact nature and regulatory status of the "basic substance" referred as "<i>Allium cepa</i> extract (food grade)" in the application. The claim that it is a food additive according to Regulation EC No 178/2002 (see Application 2.6) is not exact since <i>Allium cepa</i> extract is not listed neither as food additive nor as flavouring in the EU regulations. Two of the chemical components reported to be present in <i>Allium cepa</i> extract (dipropyl</p>	<ul style="list-style-type: none"> - Application should not claim that <i>Allium cepa</i> extract (as such) is an approved food additive or flavouring. - Application should emphasize that refers exclusively to the aqueous extract obtained by decoction and that other onion derived products (oils, alcohol extracts, distillates etc...) are excluded. - Application should clarify if it refers to already prepared extracts available in the market (eg as "onion soups") or homemade extracts prepared by the farmers. - In case the application intends to refer to commercially available extracts sold as food, it would need to be checked whether other possible ingredients in those 	<p>EFSA suggested that <i>Allium cepa</i> (common Onion) is not food but no reference is provided!</p> <p>Essential oil of onion is already a basic substance, please follow your own evaluations, please! Reg. (EU) 2018/1295 and EFSA supporting publication 2017:EN-1315. 36pp. doi:10.2903/sp.efsa.2017.EN-1315</p> <p>Recipe modified Expected to be done at farm level</p> <p>Commercially available dry extract were not tested!</p>	<p>Addressed</p> <p>Based on the revised submission (ITAB, 2019b), EFSA is assuming that the basic substance is the aqueous extract of <i>Allium cepa</i>, (Liliaceae) bulbs (decoction).</p> <p>The application concerns a decoction of crude onion.</p> <p>See 2(5)</p> <p>EFSA's understanding is that the onion bulbs 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>.</p> <p>See 2(8)</p>

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>disulfide CAS n 629-19-6 and dipropyl trisulfide CAS 6028-61-1) are listed in the Regulation 1334-2008 as food flavouring substances, but not the cycloallin component. In addition, it is noted that the evaluation by EFSA of the component dipropyl trisulfide (CAS n 629-19-6; [FL-no: 12.023]) is still pending (See EFSA 2018² for further information). The scientific literature presented in the application refers to several different kinds of extracts, distillates and oils obtained from onion. However, it seems that the application only applies to the aqueous extract obtained by decoction (which can be</p>	<p>preparations are or not suitable for the use as plant protection product and list which other ingredients can or not be acceptable (and which levels).</p> <ul style="list-style-type: none"> - In case the application refers to homemade extracts prepared from raw onions by the farmer, further indications would be needed in order to guarantee the "food grade" status of it. For example, it should be made clear that the onions used are suitable to be marketed as food (eg compliance with MRL's or not rotten) and that the extract must be prepared with drinking water, in devices suitable for the 	<p>Recipe is to be proceed at farm level</p> <p>Component are only described</p> <p>Onion essential oil is already approved basic substance!</p> <p>This is not an extension of use</p>	<p>In order to ensure no microbial or chemical contamination of treated crops, the user preparing "Allium cepa extract (food grade)" should be expected to comply with the regulations and procedures applicable to any food processor, the extract needs to be used within the next 24 h after its preparation and must be preserved under conditions that guarantee the maintenance of its "food grade" status until application.</p> <p>Regulation No 178/2002 is laying down the general principles and requirements of food law, establishing the European Food Safety Authority and is laying down</p>

² EFSA (2018): EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), Silano V, Bolognesi C, Castle L, Chipman K, Cravedi J-P, Engel K-H, Fowler P, Franz R, Grob K, Guertler R, Husøy T, Kaerenlampi S, Milana MR, Pfaff K, Riviere G, Srinivasan J, Tavares Pocas MF, Tlustos C, Woelfle D, Zorn H, Benigni R, Brimer L, Mulder G, Oskarsson A, Svendsen C, van Benthem J, Anastassiadou M, Saarma S and Mennes W, 2018. Scientific Opinion on Flavouring Group Evaluation 74, Revision 4 (FGE.74Rev4): Consideration of aliphatic sulphides and thiols evaluated by JECFA (53rd and 61st meeting) structurally related to aliphatic and alicyclic mono-, di-, tri- and polysulphides with or without additional oxygenated functional groups from chemical group 20 evaluated by EFSA in FGE.08Rev5. EFSA Journal 2018;16(3):5167, 58 pp. <https://doi.org/10.2903/j.efsa.2018.5167>

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>regarded as equivalent to what is commonly known as the food preparation "onion soup"). If this is the case, it would need to be clarified and emphasized, specifically excluding other kind of extracts or distillates from onion.</p> <p>Already prepared onion soups are marketed as food in EU. However, they are likely to contain other ingredients and spices apart from the onion water extract. Therefore, it is unlikely that all commercially available onion soups are suitable to be used as plant protection products. If the application is proposing the use of the commercially available "onion soups" it would be necessary to indicate which other ingredients may or not be contained by the ones suitable to be used as PPP. On the other hand, if the application is proposing the</p>	<p>preparation of food and readily before use (or stored frozen), in order to avoid any kind of potential microbial or heavy metals contamination. In conclusion, the farmer preparing "<i>Allium cepa</i> extract (food grade)" should be expected to comply with the regulations and procedures applicable to any food processor.</p>		<p>procedures in matters of food safety, however that legislation is not the basis of the decision if a product is or not a food additive. <i>Allium cepa</i> extract (as such) is not an approved food additive or flavouring.</p> <p>See also 2(14)</p> <p>The required details for the preparation of the extract were included in the revised submission (ITAB, 2019b).</p> <p>See also comments 2(13) 2(12) and 2(8)</p>

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>extract to be prepared by the farmer from raw onions, further indications would be needed in order to guarantee the "food grade" status of it. For example, it should be made clear that the onions used are suitable to be marketed as food (eg compliance with MRL's or not rotten) and the extract to prepared with drinking water, in devices suitable for the preparation of food, readily before use (or stored frozen) in order to avoid any kind of potential microbial or heavy metals contamination. Finally, it is noted that EFSA does not give any opinion on the qualification of a homemade extract as basic substance according Regulation (EC) No 1107/2009 as it is considered a risk management issue.</p>		<p>Is baking an onion soup supposed to be risky, and is the suggestion of oaken bulbs supposed to be different from an onion soup? Of course, too hot, it presents obvious risks if it is ingested too quickly, but that makes sense. This one seems a little lost in this evaluation.</p>	
6(2)	6. Residues. 3.4 Summary of intended uses.	EFSA: There is no justification provided for the PHI of 7 days proposed for potatoes.		GAP modified	See 3(6)

Residues					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		See also comment 3(6).			

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)	7.1	NL: considering the nature of the active substance and the relatively low application rates, the information provided is sufficient. No risk for groundwater is expected.		No comment from applicant	Addressed.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(2)	7.1	NL: considering the nature of the active substance and the relatively low application rates, the information provided is sufficient. The environmental exposure is expected to be lower due to use than due to cultivation of onions. No risk for groundwater is expected;		No comment from applicant	See comment 7(3) below.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		PEC calculations are not considered necessary.			
7.2.1. Exposure through the use for plant protection purposes					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(3)	7.1	EFSA: A comparison of the Kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP has not been presented.	Such a calculation should be provided and compared to typical yield values for growing onions. For this calculation to be carried out would require further clarifications to be provided in the summary of intended uses table in section 3.4. In particular what is considered the a.i. in this table? Is this the dry weight of onion that is applied per ha? The fresh weight of onion that would be applied per ha? Or is it the mass of the decoction liquid that will be applied per ha sprayed as a further dilution in water?	GAP modified consequently	A comparison of the kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP has not been presented. The update to the summary of intended uses table in section 3.4 of the application dossier was not understandable. The only aspect that has been clarified is that dry weight of the onion is not relevant here. EFSA considered that the mass of the decoction liquid that will be applied per ha, sprayed as a further dilution in water, has to be

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
					considered the basic substance. Consequently, a comparison of the kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP, could have been made, but was not available.

7.2.2. Background exposure (exposure to the substance through other means)					
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

7.2.3. Comparison of exposure through use for plant protection and the background exposure

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	5.1.6, Reproductive toxicity	DE: It is stated that <i>Allium cepa</i> extract showed significant antifertility activity. Can these effects occur by the intended uses of <i>A. cepa</i> concentrate in potatoes, tomatoes and cucumbers?		The ban on onion should be considered by the European Commission as soon as possible in order to preserve the populations.	No information was provided to address the risk to non-target organisms. For example, a comparison, as indicated in comment 7(3), of the kg of mature onions in a ha field before harvest against the equivalent quantity of onion material that would be applied as a result of the intended use GAP, could have been useful for this purpose, but was not provided.
8(2)	8.1	NL: It is stated that "Onion bulbs extract as food stuff exhibit no harmful effect on vertebrates". However, there are some reports of toxicity to dogs and cats (e.g. KOVALKOVIČOVÁ et al., Some food toxic for pets. Interdisc Toxicol. 2009; Vol. 2(3): 169–176). In addition, this section should not only	The applicant is advised to discuss the potential effects on birds and mammals, e.g. by comparing the levels at which effects are seen to the exposure level expected in the field.	No comment from applicant. At this stage of negative suggestions in order to obtain the non-approval of a compound 1000 or 10000 times less concentrated than the essential oil of onion approved in basic substance we refuse to comment	See 8(1)

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		<p>address vertebrates but also birds, and it is common knowledge that onions may have negative effects on birds (e.g. https://avianexoticvet.com/10-everyday-items-that-are-toxic-to-birds/). The application as spray on potatoes, tomato and cucumber may cause exposure of birds and other animals which is not comparable to the already existing exposure expected from onion cultivation. However, exposure in the field from spray of onion extract may be low.</p>		(which could be particularly negative).	
8(3)	8. effects on non-target organisms	<p>EFSA: no specific information was provided to address the risk to non-target organism. If the potential exposure following the use of <i>Allium cepa</i> according to the GAP is below the exposure due to the typical yield values for growing onions, no further data are needed.</p>	See 7(3)	No experiments were done due to lack of money for these ecotox assessment.	See 8(1)

8.1.1. Mammals

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(4)	Ibid.	DE: Both submitted studies are not suitable to describe the risk of the intended uses of <i>A. cepa</i> concentrate for aquatic organisms.		No experiments were done due to lack of money for these ecotox assessment.	See 8(1)
8(5)	8.2	NL: Our fate-colleagues consider the environmental exposure to soil and surface water to be lower due to the proposed use than due to cultivation of onions (see comment to section 7). Therefore, we agree that there is no unacceptable risk to aquatic organisms.	Not relevant.	No comment from applicant	See 8(1) No information was provided to consider the environmental exposure to soil and surface water to be lower for the proposed use in the GAP than the cultivation of onions.

8.3. Effects on bees and other arthropods species

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(6)	Ibid.	DE: If there is a repellent effect of <i>A. cepa</i> on arthropods, what are the effects of the intended uses on non-target arthropods?		Requested effect is fungistatic, different from essential onion oil approved as basic substance	
8(7)	8.3	NL: Section 3.2 describes acaricidal activity of onion extract. Also, section 8.3 mentions repellency. Thus, there may be adverse effects on (part of) the NTA population. The application as spray on potatoes, tomato and cucumber may cause exposure of foliar/flower-dwelling arthropods which is not comparable to the exposure expected from onion cultivation.	The applicant is advised to discuss the potential effects on non-target arthropods including bees. The discussion may include considerations of the duration of the effect (short-term?).	No experiments were done due to lack of money for these ecotox assessment.	See 8(1)

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(8)	Ibid.	DE: <i>A. cepa</i> has anthelmintic properties. Which effects on the soil macroorganisms are caused by the intended uses?		No experiments were done due to lack of money for these ecotox assessment.	See 8(1)
8(9)	Ibid.	DE: If <i>A. cepa</i> extract solution can be used for extracting earthworms from soil, it is possible that there is an unwanted effect on these organisms by the intended uses.		No experiments were done due to lack of money for these ecotox assessment.	See 8(1)
8(10)	8.4	NL: Our fate-colleagues consider the environmental exposure to soil and surface water to be lower due to the proposed use than due to cultivation of onions (see comment to section 7). Therefore, we agree that there is no unacceptable risk to earthworms and other soil macro-organisms.	Not relevant.	No comment from applicant	See 8(1) and 8(5)

8.5. Effects in soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(11)		DE: <i>A. cepa</i> has antibacterial properties. Which effects on the soil microorganisms are caused by the intended uses?		No experiments were done due to lack of money for these ecotox assessment.	See 8(1)
8(12) 8.5		NL: Our fate-colleagues consider the environmental exposure to soil and surface water to be lower due to the proposed use than due to cultivation of onions (see comment to section 7). Therefore, we agree that there is no unacceptable risk to earthworms and other soil macro-organisms.	Not relevant.	No comment from applicant	See 8(1) and 8(5)

8.6. Effects on other non-target organisms (flora and fauna)

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

8.8. Overall conclusion on effect on non-target organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
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No comments.

9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

Overall conclusions with respect of eligibility of the substance to be approved as basic substance

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)		DE: We agree with an approval of <i>Allium cepa</i> extract which is prepared by decoction of onion according to the application document chapter 2.6, Description of the preparation. Decoction is considered a condition for approval because otherwise an eye irritating effect cannot be excluded.		Decoction retained for recipe. No further comment from applicant	The approval is a risk management issue.

10. Other comments

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
No comments.					

Appendix B – Identity and biological properties

Common name (ISO)	<i>Allium cepa</i> bulb extract (not ISO)
Chemical name (IUPAC)	not applicable, the substance is a complex mixture
Chemical name (CA)	not applicable, the substance is a complex mixture
Common names	Onion, ext.
CAS No	8054-39-5
CIPAC No and EEC No	232-498-2
FAO specification	Not available
Minimum purity	Not relevant, the substance is a complex mixture Purity is depending on the origin
Relevant impurities	None
Molecular mass and structural formula	Not relevant, the substance is a complex mixture
Mode of Use	Spray applications
Preparation to be used	Dispersible concentrate (DC) (decoction)
Function of plant protection	Fungicide

Appendix C – List of uses

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)	No. of application min/max (k)	Interval between applications (min)	kg a.i./hl min max (kg/hl)	Water l/ha min max	Total rate each application kg a.i./ha min max (kg/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>Lycopersicon esculentum</i>			F G	Tomato late blight <i>Phytophthora infestans</i>				75 days after planting BBCH 21-75					3 to 4 days			15 (0.75 kg onion bulb/ha)
Cucumber <i>Cucumis Sativus</i>				Cucumber gray mold <i>Botrytis cinerea</i>									7 days			

* 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

