TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for onion oil for use in plant protection as repellent

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 onion oil 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 onion oil as a basic substance for use as repellent in carrots. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: onion oil, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2017-00617

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Summary

Onion oil 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 Bionext 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 August 2017, EFSA was asked to organise a consultation on the basic substance application for onion oil, 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 onion oil, organised by EFSA, was conducted with Member States via a written procedure in April-June 2017. 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 onion oil and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Onion oil is the volatile oil obtained by steam distillation of the bulbs of onions, *Allium cepa* L. The quality of the oil should meet the requirements of Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods, concerning natural flavourings produced by means of distillation. The composition of the oil may vary according to the onion cultivar and the growing conditions of the crop.

Onion oil is used as a flavour and fragrance agent in the food industry and also in traditional medicine and phytotherapy.

The proposed use is as basic substance on crops belonging to the *Umbrelliferae* (carrots, celeriac, parsnip, parsley root) against carrot root flies, by masking the scent of the umbelliferous crops.

According to the classification provided by companies to ECHA in CLP notifications, onion oil is harmful if swallowed, causes serious eye irritation, skin irritation and may cause respiratory irritation. Allyl propyl disulphide could be considered the major volatile component of onion oil. The EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) concluded that for allyl propyl disulfide, the NOEL of 4.6 mg/kg bw per day for the structurally related substance diallyl trisulphide from a 90-day study in rats, might be used to estimate the margin of exposure regarding dietary exposure. Regarding non-dietary exposure, occupational exposure limits are available, i.e. 15 min STEL: 18 mg/m^3 and 8 h TWA: 12 mg/m^3. In some European countries lower exposure limits are used; e.g. for Spain 8h TWA: 3 mg/m^3 and Germany 15 min STEL: 12 mg/m^3. Non-dietary exposure calculations as provided by the applicant indicated an exposure below these limits.

The consumer exposure assessment to onion oil residues cannot be concluded on. Sufficient evidence should be provided to demonstrate that the proposed use of onion oil on the crops under consideration will lead to much lower levels of sulphide compounds (considered as the pertinent compounds in onion oil) than the levels of these compounds naturally occurring in the field when growing onion crops. This request is also underpinned by the fact that a NOEL of 4.6 mg/kg bw per day set for allyl propyl disulphide has been derived to estimate the margin of exposure regarding dietary exposure.

Data on effects on non-target organisms were not available. However, for the representative uses and method of application, exposure to non-target organisms can be assumed to be very low.

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1. Introduction

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

Regulation (EC) No 1107/2009[1] (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.

Onion oil is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Bionext for approval as a 'basic substance' for use in plant protection as repellent, to prevent egg-laying from carrot root flies.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for onion oil, which was conducted via a written procedure in April-June 2017. 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 onion oil 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 onion oil 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 (Bionext 2017a,b).

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 7 August 2017, EFSA was asked to organise a consultation on the basic substance application for onion oil, 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 7 November 2017.

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 onion oil 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 C and D, respectively.

Documentation provided to EFSA

1. Bionext, 2017a. Basic substance application on onion oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. April 2017. Documentation made available to EFSA by the European Commission.

2. Bionext, 2017b. Basic substance application update on onion oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. September 2017. Documentation made available to EFSA by the applicant.

References

EFSA CEF Panel (EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids), 2014. Scientific Opinion on Flavouring Group Evaluation 91, Revision 2 (FGE.91Rev2): Consideration of simple aliphatic and aromatic sulphides and thiols evaluated by the JECFA (53rd and 68th meetings) structurally related to aliphatic and alicyclic mono-, di-, tri-, and polysulphides with or without additional oxygenated functional groups evaluated by EFSA in FGE.08Rev5 (2012). EFSA Journal 2014;12(6):3707, 77 pp. doi:10.2903/j.efsa.2014.3707

NIOSH (National Institute for Occupational Safety and Health), 2007. Pocket Guide to Chemical Hazards. September 2007. DHHS (NIOSH) Publication No. 2005-149. http://www.cdc.gov/niosh.

Abbreviations

a.s.	active substance
CLP	Classification, Labelling and Packaging
DAR	draft assessment report
EC	European Commssion
ECHA	European Chemicals Agency
GAP	good agricultural practice
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MRL	maximum residue level
MS	Member State
MSDI	Maximised Survey-derived Daily Intake
MSDS	Material Safety Data Sheets
NESTI	national estimated short-term intake
NOAEL	no observed adverse effect level
NOEL	No observed effect level
OECD	Organisation for Economic Co-operation and Development
STEL	short-term exposure limit
TMDI	theoretical maximum daily intake
TWA	time-weighted average

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for onion oil and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

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
1(1)	General	DK: Please consider if other MSs than NL should be on the GAP. This is an application for NL only, which show especially in section 1 and 3. However, other MSs may benefit from the use of this basic substance.	Insert "All MSs" in column 3 on the GAP table in section 3.3. Update the text in section 1 to fit all MSs rather than NL only.	We have altered the GAP table and updated text in section 1 following the suggestion	Addressed: The application is for all MS
1(2)	General	DK: Latin names should be in *italic* e.g. *Psila rosea* and *Pimephales promelas*..		Changes in application: - *Allium cepa* in pt.2.2.1 - *Psila rosae* in pt.1 and GAP table - *Pimephales promelas* in Pt.8.2	Addressed: The formatting was changed accordingly.
1(3)	2.2.6 and 2.4 General comment	NL: It should be made clear that the specification submitted in Annex II is not only valid for the TOP flavours manufacturer, but for all 3		The onion oil marketed in the EU is produced in the Netherlands and Egypt. The TOP onion oil specification (Annex II to the Application	Addressed: The onion oil should be of food grade. The quality of the oil should be in accordance with Regulation (EC) 1334/2008[2],

[2] Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC. OJ L 354, 31.12.2008, p. 34–50.

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**
		relevant commercial manufacturers.		Template) with its variation in composition, covers the composition of the other oils	natural flavourings produced by means of distillation.
1(4)	8 General comment	NL: The Annex I listed active substance 'garlic extract' should be referenced in the application. Many of the repellent components are similar. Therefore, a differentiation should be made and an argumentation be provided on why onion oil use in dispensers is eligible for a registration as basic substance. No information was given on the level of microbial contamination and the mechanism for the control of such contamination and its possible increase on storage.		Garlic extract is not similar to onion oil. Garlic extract is concentrated garlic juice, whereas onion oil (just as garlic oil) is produced through steam distillation. The differences are presented in Annex I to the reporting Table. On the choice of onion oil in carrot root fly control: in preliminary experiments of the Dutch Research Station for Arable Farming and Field Production of Vegetables, onion oil seemed to give better results. Furthermore, onion oil is cheaper than most other etheric oils. See also comment 2(2)	Addressed: Onion oil is produced through steam distillation of the chopped onions followed by separation of oil from the oil/water mixture with a centrifuge, while garlic extract is a pasteurized garlic juice concentrate obtained from crushed cloves of garlic. The composition of garlic extract is different from that of garlic oil.
1(5)	General comment	NL: According to EC 1107/2009		Existing evaluations of onion oil	Addressed:

General					
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		Art. 23 3 a; and SANCO /10363/2012[3] rev9 2014) applications for basic substances should be accompanied by any existing evaluations of the substance. Please provide information about earlier or other evaluations of onion oil if this was evaluated earlier.		are not available. The OECD eChem Portal (the Global Portal to Information on Chemical Substances) only presents information delivered by the companies in their MSDSs; see Annex I to the application. Regulation (EC) No 1334/2008 states in par.15 that "Flavouring preparations produced from food do not need to undergo an evaluation or an approval procedure for use in and on foods unless there is doubt about their safety". See also article 8(1)a.	Existing evaluations of onion oil are not available. Notified classification and labelling according to CLP criteria available. See comment 5(1)

[3] Working document on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation (EC) No 1107/2009. SANCO/10363/2012 rev.9. 21 March 2014

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

2.1. Identity and Physical and 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(1)	2.2.4 Method of manufacture, p.7	EFSA: a more detailed description of the manufacturing process would be needed.	As the substance proposed as basic is onion oil obtained by hydrodistillation which is, as described in Annex V, not just a very simple procedure, but includes several steps, it would be useful to present a more detailed description of the process	In the opinion of the applicants, hydrodistillation is comparable with steam distillation. In the turbo hydrodistillation procedure of Mnayer – an experimental device at the university – the bulbs are soaked in water and thereafter chopped during the distillation. In the steam distillation procedure of TOP Flavours, the onions are not soaked but direct chopped with water. The results of the two procedures (oil-yield per unit raw material) are the same: • Mnayer (page 20046) – turbohydrodistillation: 1000 kg onions -> 60-130 g oil, that is 0.006-0.013% • TOP Flavours (application pt. 2.2.4) – steam distillation: 8000 kg onions -> 1 kg oil, that is 0.0125%.	Addressed: More details of the process were presented in the updated submission.

2.1. Identity and Physical and 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)	2.2.4 Method of manufacture, p.7	EFSA: if onions discarded for human consumption are used for production, how it is assured that final product is free for any possible contaminants?		In Pt.2.2.4 …discarded for human consumption (because of quality defects like damage, missing skin etc., these bulbs are not suited for marketing to consumers). After… Addition to 2.2.6; The onion oil is food grade. The quality of the oil is in accordance with Regulation (EC) 1334/2008, natural flavourings produced by means of distillation. In case of plant protection products, soluble in the oil, the MRLs are in force. Exceedance of the MRLs has never been observed. The oil is sterile and has antimicrobial properties, see e.g. Annex III and the use in traditional medicine. It is stored in the original packing (oil) or in plastic bottles (granules). It has to be remarked that the oil is not applied to the crop by spraying. See pt.6 Residues for potential contamination of the leaves and roots.	Addressed: The onion oil should be of food grade. The quality of the oil should be in accordance with Regulation (EC) 1334/2008, natural flavourings produced by means of distillation.

2.2. Current Former and in case proposed trade names

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)	2.3 Proposed trade names, p.8	EFSA: for a basic substance a proposed trade name should be avoided	Any type of onion oil proposed in 2.4 can be used, without having a trade name	T.O.P. Onion oil, T.O.P. uienolie removed in Pt2.3. New text: the oils marketed in the EU are labelled with the name of the producer or trader and sometimes the country of origin.	Addressed: The information concerning the trade name was updated in the updated basic substance application.

2.3. 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

No comments

2.4. Type of preparation

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

2.5. Description of the recipe for the 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(1)	2.6	DE: Suggestion: …30 g granules which are impregnated with the oil in a ratio of 1 g oil to 5,8 g granules (that is 4,4 g oil included in 30 g of treated granules).		In Pt 2.6: (that is 4.4 g oil included in 30 g of treated granules)	Addressed: The description of the recipe was updated in the updated basic substance application.
2(2)	2.6 Description of the recipe for the product to be used	NL: The term 'granule' is very broad and refers also to granules that are probably not applicable (marbles may also be considered as granules) The type of granule and the commercial availability of the granules should be specified.		Type of granules: ethylene vinyl acetate, ovalround 3 x 5 mm. Commercial availability: wholesale traders in synthetics.	Addressed: The description of the recipe was updated in the updated basic substance application.

3. Uses of the substance and its product

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**
3(1)	3.1 Field of use, p.9	EFSA: is there any information available about the rate of evaporation of the oil? The 20		An estimation of the rate of evaporation is presented in pt.5.14.1.b Exposure	Addressed: An estimation of the rate of evaporation is presented in

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
		ml of oil assures the protection from April to November?		calculations. In the experiments the dispensers were never replenished. Nevertheless, efficacies up to 90% could be obtained. Furthermore, it has to be emphasized that the carrot root fly has 2-3 generations per year. Prevention of population build-up in the first generation(s) already lessens the total population and as a result the damage by the larvae to the roots.	pt.5.14.1.b Exposure calculations

3.2. Effects on harmful organisms or on plants

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)	3.2 Effects on harmful organisms, p.9	EFSA: the efficacy of onion oil based on the experiments presented seems to be very limited		Already mentioned in pt.1 Purpose of the application, many cultivation measures influence the activities of the carrot root fly and, as a consequence, the efficacy of the disorientation technique. To	Addressed.

3.2. Effects on harmful organisms or on plants

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
				support the decision when to apply the technique, Naturim developed a model for risk assessment, based upon landscape, kind of other crops, sowing date, etc. The model can be used by the farmers to get an indication of the carrot root fly risk and the necessity of pest control (see pt.3.1). The disorientation technique supports other preventive cultivation measures.	

3.3. 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

No comments

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)	4 –Classification and labelling of the substance	DK: In DK we do not accept plant protection products classified due to human toxicology for private/amateur use. As basic substances are for both professional and amateur use the classifications of onion oil listed here is a problem. However, a more explicit risk assessment with regard to worker (and bystander) exposure etc. from the two dispenser types could make the use not unacceptable for amateurs.	Please explicitly include specific information on both the pot and granule dispensers mentioned on the GAP table (chapter 3.3) in section 3 as well as include the dispensers explicitly in the risk assessment text were relevant in chapter 5 (human health). Make sure that the risk assessment in chapter 5 covers both dispenser types.	In view of : • the application rate (4-8 dispensers per ha umbelliferous crop), whereas hobby gardeners grow a lot of crops on a small parcel of land • the handling of oil/granules at the end of the growing season, according to the prescriptions in the MSDS, the disorientation technique is not suited for hobby gardeners. Addition to the GAP-table, column 14: Professional use only. The risk assessments worker and bystander in pt 5.14 are based on the evaporation from the pot dispensers, so worst case. They cover the evaporation from the granule dispensers.	See comment 5(1)

5. Impact on Human and Animal Health

5.1. 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

No comments

5.2. 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

No comments

5.3. 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
5(1)	Page 13	EFSA: as indicated in the report allyl propyl disulphide might be considered the major volatile component of onion oil. Regarding short-term toxicity the	The application should be updated to include relevant information from EFSA CEF Panel Scientific Opinion on allyl propyl disulphide. Changes in the updated document	Pt 5.1 Effects having relevance: *Paragraph 1 has been removed * Addition: because allyl propyl disulphide is considered the major volatile component of the oil, it is used as "marker	According to the classification provided by companies to ECHA in CLP notifications onion oil is harmful if swallowed, causes serious eye irritation, causes skin irritation and may cause respiratory irritation. Allyl propyl disulphide could be

5.3. 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
		EFSA CEF Panel concluded that for allyl propyl disulphide [FL-no: 12.021], the NOEL of 4.6 mg/kg bw per day for the structurally related substance diallyl trisulphide [FL-no: 12.009] from a 90-day study in rats (Morgareidge and Oser, 1970b) might be used to estimate the margin of exposure regarding dietary exposure (EFSA CEF Panel, 2014).	should be highlighted for easy reference.	substance" in the risk assessments in pt 5.2, 5.5, 5.9 and 5.14 Pt. 5.2 Toxicokinetics: • Sentence "Since the harvested products are not contaminated by the oil (see pt.5.1) this item is not applicable" has been removed. • Addition: EFSA CEF Panel Scientific Opinion on Flavouring Group Evaluation 91, Revision 2 (EFSA Journal 2014;12(6):3707) concluded about allyl propyl disulphide: "no safety concern at the estimated level of intake based on the MSDI approach". Since the possible contamination of the harvested product by the oil is comparable with or far less than the contamination through natural background levels	considered the major volatile component of onion oil. The EFSA CEF Panel concluded that for allyl propyl disulphide, the NOEL of 4.6 mg/kg bw per day for the structurally related substance diallyl trisulphide from a 90-day study in rats (Morgareidge and Oser, 1970b) might be used to estimate the margin of exposure regarding dietary exposure (EFSA CEF Panel, 2014). Regarding non-dietary exposure occupational exposure limits are available, i.e. 15 min STEL: 18 mg/m3 and 8 h TWA: 12 mg/m3 (NIOSH, 2007). In some European countries lower exposure limits are used; e.g. Spain 8h TWA 3 mg/m3 and Germany 15 min STEL 12 mg/m3. Non-dietary exposure calculations as provided by the applicant indicated exposure below these limits.

5.3. 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
				during onion crop harvest or crop destruction (see Chapter 6), an estimation of the margin of exposure regarding dietary exposure is not of relevance. Moreover, the EFSA CEF conclusion on allyl propyl disulphide was based on the NOAEL (etc.), see table 7 Summary of Safety Evaluation by the JECFA.	

5.4. 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(2)	Page 13	EFSA: as indicated in the report allyl propyl disulphide might be considered the major volatile component of onion oil. Please consider the genotoxicity assessment done by EFSA CEF Panel, 2014 on allyl propyl disulphide.	The application should be updated to include relevant information from EFSA CEF Panel Scientific (EFSA CEF Panel, 2014) Opinion on allyl propyl disulphide. Changes in the updated document should be highlighted for easy reference.	Pt.5.5 of the application: • Onion oil: no data available • Allyl propyl disulphide: genotoxicity negative (EFSA Journal 2014;12(6):3707) Changes in the updated document are highlighted with a blue colour.	Allyl propyl disulphide is negative in the Ames test (EFSA CEF Panel, 2014).

5.5. 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

No comments

5.6. 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

No comments

5.7. 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 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments

5.8. Toxicity studies on metabolites

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

5.9. 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

No comments

5.10. 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

No comments

5.11. 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**

No comments

5.12. 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

5.13. 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 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**

No comments

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)	2.2.4	NL: General comment: In the application at the point: methods of manufacture of the substance and of the product it is stated that the bulbs remained after oil extraction are used as animal feed. However, onion bulbs are not part of animal feed (nor they are included in the dietary burden calculation). Therefore, this part should be removed.		Pt 2.2.4: last sentence "The bulb remainders are used as animal feed or as raw material in methane gas production" has been removed.	Addressed.
6(2)		EFSA: It is noted that the oil evaporates from dispensers that are placed in the field just above the crop, each dispenser containing 20 ml of onion oil. With a maximum dosage of 160 ml/ha of onion oil, is there any information or measurement of the concentration of onion oil and/or the degradation products that are formed when the oil evaporates and that can be recovered on the	At least analysis for the determination of the major compounds of onion oil, i.e. 'disulphides' and 'trisulphides' on carrot leaves and roots following the use of onion oil according to the intended use should be conducted in order to exclude any consumer exposure to residues of these components or to any other degradation product of onion oil.	New text for Chapter 6 Residues. The rate of evaporation of sulphide containing onion oil (components in the disorientation technique (80 g/ha) is far less than the application rate of sulphide containing active substances in EC approved garlic extract products directly used on the carrot crop (up to 7.7 kg/ha). So, the indirect exposure of the crop by a possible	EFSA disagrees on. The composition of garlic extract is different from that of onion oil and any comparison of the contamination of the crops by onion oil and by its marker compound 'allyl propyl disulphide' with the contamination after application of garlic extract as a plant protection product is not acceptable. Sufficient evidence should be demonstrated that the

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
		leaves? Is there any assessment of potential translocation of these degradation products to the carrot roots?		contamination of the leaves and roots with deposited onion oil components and (foto)oxidated degradation products during the application of the disorientation technique is far less than the direct exposure by the application of the garlic extracts. See Annex XII of the application template. Furthermore, in pt.1 of the application the intercropping of carrots with onions or leek is mentioned as one of the preventive control measures. The oil components, evaporating from the onion crop, may deposit upon and contaminate the carrot crop. Obviously without toxicological problems. Therefore, it can be assumed that the exposure of the carrot crop to evaporated onion oil components and to degradation products will not cause a residue hazard.	proposed use of onion oil on the crops under consideration will lead to much lower sulphide compounds (allyl propyl disulphide) levels considered as the pertinent compounds in onion oil than the levels of these compounds naturally occurring in the field when growing onion crops. This request is also underpinned by the fact that an NOEL of 4.6 mg/kg bw per day set for allyl propyl disulphide has been derived to estimate the margin of exposure regarding dietary exposure.

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

No comments

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(1)	7.2 comparison with natural levels	EFSA: The calculations presented appear reasonable and are transparent and cover the two application types presented in the Good Agricultural Practice (GAP) table (section 3.3), though the actual calculation available was just for the pot dispensers.	No action necessary.	-	Noted

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)	8.1	NL: The toxicity to birds and mammals, bees, non-target arthropods, soil organisms and microorganisms was not addressed, because the proposed application is not expected to lead to higher exposure than through natural background levels during crop harvest. This is acceptable in the context of the application in dispensers. This needs to be made clearer in the final text.		See updated document	Addressed Data on effects on non-target organisms were not available. However, for the representative uses and method of application, exposure to non-target organisms can be assumed to be very low.

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

No comments

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(2)		NL: The toxicity to bees and other arthropods species was not addressed, because the proposed application is not expected to lead to higher exposure than through natural background levels during crop harvest. This is acceptable in the context of the application in dispensers. This needs to be made clearer in the final text.		See updated document	See comment 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(3)		NL: The toxicity to soil organisms was not addressed, because the proposed application is not expected to lead to higher exposure than through natural background levels during crop harvest. This is acceptable in		See updated document	See comment 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
		the context of the application in dispensers. This needs to be made clearer in the final text.			

No comments

8.5. Effects on 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(4)		NL: The toxicity to microorganisms was not addressed, because the proposed application is not expected to lead to higher exposure than through natural background levels during crop harvest. This is acceptable in the context of the application in dispensers. This needs to be made clearer in the final text.		See updated document	See comment 8(1)

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

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

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)	Eligibility of onion oil as basic substance	DE: According to the submitted application template the following classification and labelling is notified for onion oil: Acute tox. 4, H302; Skin irrit. 2, H315; Eye irrit. 2, H319; STOT SE 3, H335. Therefore, onion oil does not meet the criteria of article 23(a) of Regulation (EC) No 1107/2009.	It is proposed to regulate onion oil as botanical active substance according to Guidance Document SANCO/11470/2012[4].		Addressed: The onion oil should be of food grade. The quality of the oil should be in accordance with Regulation (EC) 1334/2008, natural flavourings produced by means of distillation.
9(2)	9. Overall conclusion	EFSA: it is stated that onion oil is a 'foodstuff', however for the production onions discarded for human consumption are used. This is a contradiction.		See specification pt.2.2.4 of 'onions discarded for human consumption'	Addressed: The onion oil should be of food grade. The quality of the oil should be in accordance with Regulation (EC) 1334/2008, natural flavourings produced by means of distillation.

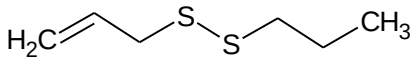
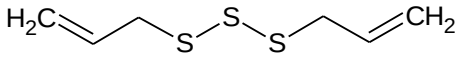
[4] Guidance document on botanical active substances used in plant protection products. SANCO/11470/2012– rev. 8 20 March 2014, 28 pp.

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 – Used compound codes

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
allyl propyl disulphide	3-(propyldisulfanyl)prop-1-ene CCCSSCC=C	
diallyl trisulphide	di(prop-2-en-1-yl)trisulfane C=CCSSSCC=C	

(a): The compound name in bold is the name used in the report.

Appendix C – Identity and biological properties

Common name (ISO)	Onion oil
Chemical name (IUPAC)	Not applicable (complex mixture)
Chemical name (CA)	Not applicable (complex mixture)
Common names	*Allium cepa* oil, Onion oil natural, Onion oil organic
CAS No	8002-72-0
CIPAC No and EEC No	232-498-2 (EINECS)
FAO specification	none
Minimum purity	Not relevant(complex mixture)
Relevant impurities	none
Molecular mass and structural formula	Not relevant (complex mixture)
Mode of Use	Oil dispensers
Preparation to be used	(Others), impregnated granules
Function of plant protection	repellent, scent masking

Appendix D – List of uses

Crop and/or situation (a)	Member State for use	Example product name as available on the market	F G I (b)	Target (c)	Product **		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (kg/hl)	Kg L product l/ha min max	kg a.i./ha min max (kg/ha) (l)	kg a.i./ha min max (kg/ha) (l)		
Umbelliferous crops (carrots, celeriac, parsnip, parsley root)	All MS		F	Carrot root fly (*Psila Rosae*)			Masking the smell of the umbelliferous crop by onion oil evaporated from dispensers	Shortly after planting or crop emergence (around mid- April) until end of November (before harvest)	1		-	Pot dispensers 0.08-0.160 L/ha Granule dispensers 0.0175 – 0.035 L/ha	-	-	Not relevant	4-8 dispensers per ha Professional use only

(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,
(i): g/kg or g/L. Normally the rate should be given for the active 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 between the plant – type of equipment used must be indicated