TECHNICAL REPORT

APPROVED: 22 May 2016

Outcome of the consultation with Member States and EFSA on the basic substance application for *Origanum vulgare* L. essential oil for use in plant protection as a fungicide, bactericide and insecticide

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 *Origanum vulgare* L. essential 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 *Origanum vulgare* L. essential oil as a basic substance for use in plant protection as a fungicide, bactericide and insecticide. 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: *Origanum vulgare* L. essential oil, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00234

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Summary

Origanum vulgare L. essential 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 Institut Technique de l'Agriculture 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 March 2016, EFSA was asked to organise a consultation on the basic substance application for *Origanum vulgare* L. essential 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 *Origanum vulgare* L. essential oil, organised by EFSA, was conducted with Member States via a written procedure in December 2015 - February 2016. 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 *Origanum vulgare* L. essential oil and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

The information in the application is considered insufficient to appropriately characterise *Origanum vulgare* L. essential oil, to understand what material is proposed to be used in plant protection. The applicant has failed to confirm that the material that they are proposing should be used, would comply with the ISO standard (ISO/CD 13171) and or the quality / characterisation described in the European Pharmacopoeia.

Origanum vulgare L. essential oil is intended to be used as a fungicide, bactericide and insecticide to control several fungal and bacterial pathogens, aphids and biting / sucking insects in a range of crops, including perennial crops in orchards and grapevines.

Regarding the impact on human and animal health, *Origanum vulgare* L. essential oil would require classification regarding acute toxicity (Acute Tox 4, H302). Skin, eye and possibly respiratory tract irritation, as well as skin sensitisation potential are to be expected for the botanical mixture considering the toxicological properties of its constituents. Contradictory results have been found regarding the genotoxicity potential of the botanical preparation and/or its respective components; it is unknown whether the preparation contains the eugenol derivative, methyl eugenol, known as a genotoxic carcinogen. An inconclusive assessment has been reported by the EFSA panel on Food Additives and Nutrient Sources Added to Food (ANS panel) on the use of oregano and lemon balm extracts as food additive due to reported cytotoxicity and lack of data regarding genotoxicity, reproductive and developmental toxicity. On the other hand, an increased rate of embryonic cell death was reported in mice treated with *ca.* 150 mg/kg bw *Origanum vulgare* L. essential oil and a direct action on the central nervous system. Thus the genotoxic potential of the botanical preparation should be clarified and the lack of adverse effects upon long term exposure, reproduction, development and nervous system have not been substantiated. The use as food additive of the essential oil has not been demonstrated since it cannot be readily compared with its use as fresh or dried aromatic herb in food. It is therefore concluded that, either a hazard identification and characterisation of the essential oil would be needed to perform a dietary and non-dietary exposure risk assessment, or a robust demonstration of the natural background level of human exposure.

Despite the lack of sufficient toxicological data, the information in the application is insufficient to conduct reliable consumer dietary exposure and risk assessments for the intended uses, or any

comparison to dietary exposure resulting from natural sources or foods containing *Origanum vulgare* L. essential oil as food or feed additive. The applicant conceded that alteration of components of *Origanum vulgare* L. essential oil, predominantly thymol and carvacrol, occurs already within 24 hours given the observed decrease of activity of *Origanum vulgare* L. essential oil under the conditions of use. Any information or rationale regarding the nature of potentially resulting residues was not submitted.

The information in the application is insufficient to carry out a robust environmental exposure assessment. The uses requested would result in carvacrol environmental exposure up to 200 times higher than was assessed by EFSA when this compound is used as a feed additive in chicken feed.

In the ecotoxicology section, some adverse effects caused by exposure to *Origanum vulgare L*. essential oil (or its components) were seen in terrestrial vertebrates, aquatic organisms, bees and other non-target arthropods, soil organisms and terrestrial plants. However, no risk assessment was presented for any of these non-target organisms. Furthermore, information on potential adverse effects of other major constituents of the essential oil was not submitted. Considering these two aspects, no conclusion can be drawn regarding the representative uses under evaluation.

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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.

Origanum vulgare L. essential oil is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as fungicide, bactericide and insecticide.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Origanum vulgare* L. essential oil, which was conducted via a written procedure in December 2015 - February 2016. 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 *Origanum vulgare* L. essential 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 *Origanum vulgare* L. essential 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 (ITAB, 2016).

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 22 March 2016, EFSA was asked to organise a consultation on the basic substance application for *Origanum vulgare* L. essential 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 was prepared by EFSA. The agreed deadline for providing the finalised report was 22 June 2016.

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 *Origanum vulgare* L. essential 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. ITAB, 2015. Basic substance application on *Origanum vulgare* L. essential oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2015. Documentation made available to EFSA by the European Commission.

2. ITAB, 2016. Basic substance application update on *Origanum vulgare* L. essential oil submitted in the context of Article 23 of Regulation (EC) No 1107/2009. May 2016. Documentation made available to EFSA by the applicant.

References

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2016a. Diarr-Stop S Plus® for pigs for fattening. EFSA Journal 2016;14(5):4472, 15 pp. doi:10.2903/j.efsa.2016.4472

EFSA (European Food Safety Authority), 2016b. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for *Satureja montana* L. for use in plant protection as fungicide and bactericide on various crops. EFSA supporting publication 2016:EN-1051, 65 pp.

EFSA (European Food Safety Authority), 2012a. Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663, 60 pp. doi:10.2903/j.efsa.2012.2663.

EFSA (European Food Safety Authority), 2012b. Conclusion on the peer review of the pesticide risk assessment of the active substance thymol. EFSA Journal 2012;10(11):2916, 43 pp. doi:10.2903/j.efsa.2012.2916

EFSA FEEDAP Panel (EFSA Panel on Additives and Products or Substances used in Animal Feed), 2012c. Scientific Opinion on the safety and efficacy of phenol derivatives containing ring-alkyl, ring-alkoxy and side-chains with an oxygenated functional group (chemical group 25) when used as flavourings for all species. EFSA Journal 2012;10(2):2573, 19 pp. doi:10.2903/j.efsa.2012.2573

EFSA ANS (Food Additives and Nutrient Sources added to Food), 2010. Scientific Opinion on the use of oregano and lemon balm extracts as a food additive. EFSA Journal 2010; 8(2):1514, 19 pp. doi:10.2903/j.efsa.2010.1514

European Commission, 2014. Guidance Document on botanical active substances used in plant protection products. SANCO/11470/2012–rev. 8, 20 March 2014

IARC (International Agency for Research on Cancer), 2004. Methyleugenol. IARC Monographs on some Chemicals Present in Industrial and Consumer Products, Food and Drinking-water, vol. 10. Lyon, France

ISO (International Organization for Standardization), under development. No 1371: Essential oil of oregano [*Origanum vulgare* L. subs. Hirtum (Link) Ietsw]

United Kingdom, 2011. Draft Assessment Report (DAR) on the active substance thymol prepared by the rapporteur Member State the United Kingdom in the framework of Directive 91/414/EEC, June 2011.

WHO (World Health Organization), 2010. Monographs on medicinal plants commonly used in the Newly Independent States (NIS), Geneva, Switzerland, 450 pp.

Abbreviations

a.s.	active substance
DAR	draft assessment report
GAP	good agricultural practice
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
NTO	non-target organism
NTTP	non-target terrestrial plants
RMS	rapporteur Member State

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Origanum vulgare* L. essential 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)		DE: It is not agreed to approve *Origanum vulgare* L. essential oil as basic substance for several reasons: First, a relevant ingredient (up to 4 %) is the active substance thymol. For thymol classification with R22, R34, R41 and R43 was proposed in result of the EU assessment (EFSA Journal 2012;10(11):2916). Second, carvacrol another relevant ingredient (up to 87 %) is proposed to be classified with H302, H315, H317 and H319. Thus, *Origanum vulgare* L. essential oil does not meet the conditions laid down in Article 23 of Regulation (EC) No 1107/2009. It is proposed that the		*Origanum* E.O. is used as food additive and preservative. As such, it is entitled as basic substance and even intrinsic basic substance regarding Reg. 178/2002[2]. Later admissibility was pronounced on this basis by the Commission. The European Commission is sovereign in this matter, even if we sometimes discuss, for public health reasons, the validity of some pronounced inadmissibility. If thymol is of concern, please ask EU and claim urgently its removal of the approval at Reg. 1107/2009. Substance also allowed as a feed additive for pigs for	*Origanum vulgare* L. essential oil contains two components thymol and carvracol that are proposed to be classified as R22, R34, R41 and R43 and H302, H315, H317 and H319 respectively. This means that these two components are not without hazard, so a credible risk assessment would need to be presented in any application for a basic substance that contained them. Comments on the risk assessment available which appears incomplete are included in this report.

[2] 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.

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**
		application for authorisations of plant protection products containing *Origanum vulgare* L. essential oil should be based on the guidance document on botanical active substances (SANCO/11470/2012).		fattening. You may read later guidance document on botanical active substances (SANCO/11470/2012) that mention "basic substance" as a possible issue for approval.	
1(2) A		NL: No comments.			Noted.

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)		NL: No comments.			Noted.
2(2)		PL: No comments.			Noted.
2(3)	Identity, p.14-15	EFSA: As the composition of the essential oil extracted from the oregano herb is characterized by large variations, attributable, among others, to the great morphological and chemical	It is acknowledged that the content of the individual substances may be very much dependent on the time of production, etc. and some of these values may fall outside of the ISO standard as it is shown in Table 8 on	Specifications of pharmacopeia are restrictive, but due to vegetal origin range of composition is possible. Having natural products in hands we have no idea of more restrictive specifications than	The applicant has not clearly confirmed that the basic substance that they are applying for would meet the prescriptions of the European Pharmacopoeia 5 and 7 and standard ISO/CD 13171

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**
		diversity within the genus *Origanum vulgare* L., place of production, date of extraction, mode of extraction, etc. it is important to have a clear specification of the substance. Our understanding is that the proposed basic substance is meeting the prescriptions of the European Pharmacopoeia 5 and 7 and standard ISO/CD 13171 (*Origanum vulgare* L. ssp. hirtum)	p.17 (Simonnet et al.)	pharmacopeia requirement. If different or more restrictive standard is mandatory at the end of this evaluation, we agree to include this in required specifications.	(*Origanum vulgare L. ssp. hirtum*). For this basic substance, originating from plants, a specification that the material would need to comply with is missing. The use of the European Pharmacopoeia, ISO standards or another specification provided by the applicant would be essential. Currently the characteristics of this basic substance are inadequately defined in the application that has been made. See also 5(31)
2(4)	2.1.5 Description and specification of purity, p.13	EFSA: in the "Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements" (EFSA Journal 2012;10(5):2663) beta-thujone and 1,8-cineole were mentioned as compounds of concern on which to focus the assessment. As at least 1,8-cineole is part of some		1 8-cineole (eucalyptol) is actually used in medicine. The European Commission approved the use of sheets (internally) and essential oil (internally and externally) of Eucalyptus globulus to "treat airway inflammation," as well as external applications of eucalyptus essential oil to "relieve rheumatic pain." ESCOP also recognized the same uses for the essential oil	The fact that 1,8-cineole has medicinal uses confirms that it has biological activity that would need assessing in the context of a risk assessment. Doses and routes of exposure from medicinal uses need to be compared to the levels and routes of exposure that would result from the proposed use. Such a comparison does not appear to be available.

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**
		Origanum vulgare L. essential oil of European origin, was the relevance of this substance assessed further? Their determination would be also important to identify the raw material not originating from Europe.		of eucalyptus. The World Health Organization recognizes the use of essential oil to treat inflammation of the airways, throat or mucous membranes of the mouth (internally) and to "relieve rheumatic pain" (by externally)	
2(5)	2.1.2 Major constituents, p.11	EFSA: how it is possible to differentiate *Origanum vulgare* L. essential oil from *Satureja montana* L. oil from an oil from *Origanum majorana* L. for example? A specification of some specific/characteristic components might be a solution, however it is also true that the chemical composition depends on the location of the plant but also on its stage of development and climate conditions. Without a specification of this oil the identification might be difficult.		*Origanum vulgare* L. is totally different from *Satureja montana* L. oil. Differentiate *Origanum vulgare* L. oil from an oil from *Origanum majorana* L. is may be difficult due to confusion made by producers, including confusion with CAS number.	As noted at comment 2(3) a definitive specification is essential but is not available.
2(6)	2.1.6 Identity of inactive isomers, impurities, p.17	EFSA: according to WHO monograph, 2010, Herba Origani may contain also eugenol. Was any attempt done to check for eventual	Methyl eugenol is a genotoxic carcinogen and a maximum level of 0.05 g/kg was set in the specification of eugenol, and for consistency of the risk	Methyl eugenol is not described to be present in oregano by IARC. Same in Baratta, 1998. Ref added IRAC, 2004	As noted at comment 2(3) a definitive specification is essential but is not available. Such a specification should include a maximum level for

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**
		amounts of methyl eugenol?	assessment it is important to know if it *Origanum vulgare* L. oil can contain it or no.		methyl eugenol. Whilst IARC, 2004 does not list *Origanum vulgare* L. essential oil as a source of methyl eugenol, this is not definitive evidence that it can never be present in all essential oils produced from the species from all origins world wide.

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(7)		NL: No comments.			Noted.
2(8)		PL: No comments.			Noted.

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**
2(9)		NL: No comments.			Noted.
2(10)		PL: No comments.			Noted.

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
2(11)		NL: No comments.			Noted.
2(12)		PL: No comments.			Noted.
2(13)	2.1.7 Methods of analysis. p.18	EFSA: *Origanum vulgare* L. essential oil is extracted from the aerial parts is considered the formulation and statements are made about its properties, without supporting data.	A 4 years of shelf life is claimed without any supporting data of the content of the constituent components and physical and chemical properties before and after storage.	This was information from resellers of the essential oil, supressed in BSA.	Evidence for the claimed storage stability of materials is not available in the application documentation.
2(14)	2.4 Type of preparation, p.22	EFSA: were the properties of an EC formulation checked?	Usually for an EC formulation the following minimum properties are indicated: emulsion stability, persistent foam, law and high temperature storage stability	Basic substance is designated to be used readily not to be stored; E.O. is added to continuously stirred water. No storage is envisaged or allowed.	There is no evidence in the application that the material that might be sprayed would be fit for purpose / have the properties to enable it to be effectively applied.
2(15)	2.4 Type of preparation, p.22	EFSA: was the statement of not highly flammable and not auto-flammable based on studies?	A study or a case should be submitted to support the statement.	Flash point 63.89 °C (closed cup) according to MSDS. MSDS Aldrich 2016 added	Statements on not being highly flammable and not being auto-flammable are now underpinned by a flash point temperature from published material safety data sheets.

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(16)		NL: No comments.			Noted.

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)		DE: No specific data were provided which allow a detailed description of the cited GAPs.		More references added.	4 References from 2016 and a PHD thesis from 2005 have been added to the application. There is still no transparent link presented / evaluated between the GAP proposed in the application and the available efficacy publications cited.
3(2)		NL: No comments.			Noted.
3(3)		PL: No comments.			Noted.
3(4)	3.4 Summary of intended uses	EFSA: The GAP is not clear. The total rate column indicates kg a.i./ha whilst the rate per treatment indicates both g a.i./ha and kg/ha?	It is essential that this is clarified. i.e. is the use as fungicide on lettuce 7 x 2 g a.i. / ha or 7 x 2 kg a.i./ha. Clarification is needed for all the different crops and uses.	CAP table refined with 2015 results.	Whilst correction to a column heading has been made from g/ha to kg /ha which has removed some inconsistency in the description of the intended uses clarifying that kg quantities per ha will be applied, a new uncertainty has been introduced in a single column where both g a.s./ha and g/hl are indicated in the column heading of the fungicidal use table 1 (Appendix D). Column heading contains contradictory units.
3(5)	3.4.2 Bactericidal	EFSA: small typos in the name of		Corrected	Further clarification on the

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**
	use, p.39	*Erwinia amylovora.* Clarification is also needed on the method of application.			method of drip application that involves 'a patented system' has not been provided.

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(6)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in the uses described should be expected	DE: In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exists.	First, MOA is not compulsory. More references added.	The mode of action remains unclear. More references were not added to the application in section 3.2.2.
3(7)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	DE: Please provide reasons for your opinion that no phytotoxicity must be expected.	Phytotoxicity was observed first year at 2% we have now range up to 0.2%.	Information on phytotoxicity was not included in the updated application. The information in column 4 is not in the application.
3(8)		NL: No comments.			Noted.
3(9)		PL: No comments.			Noted.

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
3(10)		NL: No comments.			Noted.
3(11)		PL: No comments.			Noted.

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)		NL: No comments.			Noted.
4(2)		PL: No comments ECHA classification in progress Note: The *Origanum spp*. essential oil is classified as GRAS (*Generally Recognized as Safe)* by the U.S Food and Drug Administration		No further comment	Noted.
4(3)		EFSA: The main compound of the essential oil (carvacrol, 34-87%) appears to be a skin and eye irritant, a skin sensitiser and harmful if swallowed. p-cymene (3-23%) appears to	EFSA: Classification of the botanical preparation should be established. Data presented indicate the need to classify as Acute Tox 4, H302. Skin, eye and possibly	Classification given is about the E.O. although Oregano E.O. is considered as G.R.A.S. Concentration of E.O. in preparation is low (0.2 % max). Identically as previous	The statement given by the applicant regarding the preparation is not followed since it is stated that no formulation is used (Aldrich, 2016 MSDS).

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**
		be irritant to skin, eyes and respiratory tract γ-terpinene (1-26%) appears also to be irritant, harmful if swallowed and possibly by inhalation and a skin sensitiser. Thymol (0.35-3.57%) has a harmonised classification as Acute Tox 4 'harmful if swallowed' and Skin Corr. 1B 'Causes severe skin burns and eye damage' that may be relevant to the whole mixture classification. Therefore a classification for the mixture is expected to include these hazards classes.	respiratory tract irritation, as well as skin sensitisation potential are to be expected for the botanical mixture considering the properties of each constituent.	statement, if those substances approved as active substances are of concern remove all previous approval as for post-approval Risk management measures. As matter of fact pure Thymol A.S. is a mixture with Eugenol and Geraniol Harmful to aquatic organisms!	The mixture would require classification regarding Acute Tox 4, H302. Skin, eye and possibly respiratory tract irritation, as well as skin sensitisation potential are to be expected for the botanical mixture considering the properties of each constituent. See also 5(6)

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
5(1)		NL: No comments.			Noted.
5(2)	Zhiri & Baudoux, 2005	PL: reference not relevant	PL: Please remove the reference and insert in chapter 5.10.1	Reference moved	Noted.

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
5(3)		NL: No comments.			Noted.
5(4)	Mancini et al., 2014	PL: reference not relevant	PL: Please remove	Reference removed	Noted.
5(5)	Gad, 2012	PL: Reference relevant to acute toxicity and short-term toxicity	PL: Please insert this reference additionally in subchapter 5.3	MSDS Aldrich 2016 added	Noted.
5(6)	Tisserand & Young, 2013 Azizi, Ebrahimi, Saadatfar, Kamalinejad & Majlessi, 2012	EFSA: the acute toxicity data presented indicate that the mixture should be considered as harmful if swallowed. No data on skin and eye irritation or skin sensitisation were submitted.	EFSA: See classification proposal in 4(3)	MSDS Aldrich 2016 added Substance allowed as a feed additive for pigs for fattening EFSA reference added in the BSA	See 4(3)

5.3. Short-term toxicity

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
5(7)		NL: No comments.			Noted.
5(8)	Marcela Boroski et al., 2012	PL: reference not relevant	PL: Please remove	Reference removed	Noted.

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(9)		NL: No comments.			Noted.
5(10)	European Food Safety Authority, 2010 Scientific Opinion on the use of oregano and lemon balm extracts as a food additive EFSA Journal 2010; 8(2):p1514 (p. 43) Karpouhtsis et al., 1998 (p. 47)	EFSA: In its Scientific Opinion of 2010, the EFSA ANS panel considered that the presumption of safety could not be confirmed in the absence of genotoxicity data. On the other hand, the paper by Karpouhtsis, I. *et. al.* 1998 shows contradicting results as it indicates that thymol may be mutagenic but not the essential oil of *O. vulgare subsp. hirtum*. Is the formulation exempt of eugenol and derivative methyl eugenol (known genotoxic carcinogen)?	EFSA: Genotoxicity potential of the botanical preparation and its respective components should be clarified.	According to EFSA comment Thymol may be mutagenic. Please remove approval of thymol urgently if BA Oregano E.O. is not approved based on evaluation conclusion. Abort Eugenol approval as well, then clove oil, although all are in annex IV of MRL. Since this EFSA comment may be absolutely in contradiction with these 3 active substance approval, all registered with annex IV of MRL (396/2005), it must therefore be proceeded to removal of Terpenoid blend QRD-460 since p-cymene and	Data gap: Contradictory results have been found regarding the genotoxicity potential of the botanical preparation and/or its respective components; it is unknown whether the preparation contains the eugenol derivative methyl eugenol, known as genotoxic carcinogen. The genotoxic potential of the botanical preparation should be clarified.

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
				γ-terpinene are also common and may be of concern.	

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
5(11)		NL: No comments.			Noted.
5(12)	Begnini et al., 2014	PL: reference not relevant	PL: Please remove the reference from this subchapter and insert it in subchapter 5.4	Reference moved	Noted.
5(13)	European Food Safety Authority, 2010 Scientific Opinion on the use of oregano and lemon balm extracts as a food additive EFSA Journal 2010; 8(2):p1514 Begnini, et al. 2014 (p. 49)	EFSA: the lack of long term toxicity data on oregano essential oil was considered one of the data gaps leading to an inconclusive assessment of the safety of the botanical preparation by the EFSA ANS panel. Cytotoxicity is reported, long term adverse effects cannot be ruled out.	EFSA: the lack of adverse effects upon long term exposure should be substantiated.	Substance allowed as a feed additive for pigs for fattening EFSA reference added in the BSA	Data gap: The lack of adverse effects upon long term exposure has not been substantiated, while an inconclusive assessment has been reported by the EFSA ANS Panel (2010) on the use of oregano and lemon balm extracts as food additive due to reported cytotoxicity.

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
5(14)		NL: No comments.			Noted.
5(15)	European Food Safety Authority, 2010 Scientific Opinion on the use of oregano and lemon balm extracts as a food additive EFSA Journal 2010; 8(2):p1514 Tisserand & Young, 2013	EFSA: the lack of reproductive and developmental toxicity data on oregano essential oil was considered one of the data gaps leading to an inconclusive assessment of the safety of the botanical preparation by the EFSA ANS panel. Contradictive papers presented did not clarify this endpoint since increase in the rate of embryonic cell death was observed in mice treated with *O. vulgare* essential oil at ~ 150 mg/kg bw.	EFSA: the lack of adverse effects on the reproduction and development should be substantiated.	Substance allowed as a feed additive for pigs for fattening EFSA reference added in the BSA	Data gap: The lack of adverse effects on the reproduction and development has not been substantiated, while an inconclusive assessment has been reported by the EFSA ANS Panel (2010) on the use of oregano and lemon balm extracts as food additive. Lack of data was mentioned. On the other hand, an increased rate of embryonic cell death was reported in mice treated with ~150 mg/kg bw *O. vulgare* essential oil.

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
5(16)		NL: No comments.			Noted.
5(17)	Abdel-Massiha et al., 2010	PL: Reference not relevant	PL: Please remove the reference from this subchapter and insert it in subchapter 5.10.1	Reference moved	Noted.

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
5(18)		EFSA: see 5(31) below			See 5(25)

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
5(19)		NL: No comments.			Noted.
5(20)	All data	PL: Not relevant			Noted.

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
5(21)		NL: No comments.			Noted.
5(22)	Llana-Ruiz-Cabello et al., 2014	PL: Not relevant	PL: Please remove the reference from this subchapter and insert it in subchapter 5.10.1	Reference moved	Noted.

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
5(23)		NL: No comments.			Noted.
5(24)	All data submitted in chapter 5 prior to the subchapter 5.1	PL: References not relevant to general information in respect to Impact on Human and Animal Health	PL: Insert all the references in this subchapter	References moved	Noted.
5(25)	Zhion As of feb 2015, p. 51-52	EFSA: Adverse effects are reported in this chapter, inclusive direct action on the central nervous system at low dose levels.	EFSA: lack of adverse effects on the nervous system should be substantiated.	Substance allowed as a feed additive for pigs for fattening EFSA reference added in the BSA	Data gap: The lack of adverse effects on the nervous system should be substantiated since adverse effects, including direct action on the central nervous system has been reported at low dose levels.

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
5(26)		NL: No comments.			Noted.
5(27)	Rudrappa, 2009 Oregano nutrition facts, p. 54	EFSA: the use of oregano as fresh or dried aromatic herb in food cannot be readily compared with its use as an essential oil extract.	EFSA: The use as food additive should be demonstrated for the essential oil.	Applicant agrees the comment but individual substances are still present and concentrated in dry herb.	Data gap: The use as food additive of the essential oil should be demonstrated since it cannot be readily compared with its use as fresh or dried aromatic herb in food.

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
5(28)		NL: No comments.			Noted.
5(29)	Draft Assessment Report (DAR) 2011 on Thymol.	EFSA: the hazard identification and characterisation could not be concluded for either the separate components or the essential oil mixture, therefore no dietary or non-dietary risk assessment can be performed. The reference values proposed by the RMS on Thymol could not be confirmed by the peer review.	EFSA: either a hazard identification and characterisation of the essential oil or a robust demonstration of natural background level of human exposure would be needed to perform a dietary and non-dietary exposure risk assessment.	Applicant agrees but still no MRL was defined (annex IV of Reg. 396/2005) indicating no concern.	Data gap: Regarding thymol or its separate components, EFSA concluded in 2012 (EFSA, 2012b) that either a hazard identification and characterisation of the essential oil or a robust demonstration of natural background level of human exposure would be needed to perform a dietary and non-dietary exposure risk assessment. Neither of these elements have been addressed in relation to thymol containing *O. vulgare* essential oil. See also 2(30)

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
5(30)	5.0.2. and 5.12.2 Thymol	DE: One of the main constituents of *Origanum vulgare* oil is thymol. Thymol is, in the EU, considered an active substance in PPP that underwent the EU evaluation process including submission of certain toxicological data. Even reference values have been established. It would be a contradiction to consider the oil as basic substance but not the individual constituents.		*Origanum vulgare* oil is a natural product and an intrinsic basic substance, as declared admissible by DGSanté. AS matter of fact, a.s. thymol is not a single compound (mixture of substances), therefore it is a formulated compound not acceptable as basic substance. Anyhow, individual substances even chemically synthetized may be applied as basic during renewal.	See 5(29)
5(31)	General comment	DE: It is apparent that the chemical composition of the oil may differ, depending on its origin. For approval for plant protection products, the quality should be defined instead of general recognition as a "basic substance".		Specifications are described with range. Clearly it is not synthetic substance with defined purity although thymol a.s. is not thymol! (mix of molecules)	See 2(3)
5(32)		NL: No comments.			Noted.
5(33)		EFSA: refer to 5(36)			Typo: See 5(6) See also 5(10, 13, 15, 25, 27, 29)

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)		NL: No comments.			Noted.
6(2)		PL: No comments.			Noted.
6(3)		EFSA: The total application rate is unclear from the Use Table, however is essential to estimate whether consumer exposure from the uses of *Origanum vulgare* L. essential oil will indeed be negligible compared to exposure from other dietary roots (as claimed by the applicant).		GAP table changed	Addressed. Total application rate was clarified in the 'Summary of intended uses' table.
6(4)		EFSA: Despite the lack of sufficient toxicological information on thymol, a major component of *Origanum vulgare* L. essential oil, consumer exposure estimates have not been submitted that would consider potential residues of *Origanum vulgare* L. essential oil upon treatment of crops, in particular when used on fruit crops with a short PHI. The applicant's claim that "the		Field trials show that E.O. are not present anymore after 24h. Ref added.	Field trials showing that *Origanum vulgare* L. essential oil components are not present anymore after 24h were not submitted. The reference mentioned refers to an FDA database extract in the category Medical devices. The use assessed by FDA and its relevance for the PPP uses has not been clarified. The use as pesticide is different and not

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
		potential residues in crops and animal products resulting from application of this essential oil are considered negligible regarding the other uses" has to be substantiated by evidence (calculated or analytically determined maximum residue levels on crops, intake calculations, comparison with estimated consumer intakes from other dietary sources…)		Substance allowed as a feed additive for pigs for fattening EFSA reference added in the BSA. Residues should have been evaluated at this stage; otherwise it is not of concern together with no MRLs. Noticeably, when applications are coming from companies, no concern is formulated.	addressed. To demonstrate consumer safety, a use related risk assessment has to be provided. It is not clear what the applicant tries to suggest with their concluding remark. A claim has to be supported by evidence and reasoning. If this is not the case, a request for further clarification is warranted but does not necessarily mean a "concern is formulated". Data gap: A comparative consumer exposure assessment should be provided concerning the potential residues of *Origanum vulgare* L. essential oil upon treatment of crops according to the intended uses. The applicant should demonstrate by submission of evidence (data, calculations etc.) that consumer exposure to potential residues in crops

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**
					and animal products resulting from application of this essential oil is negligible in view of other (non-plant-protection) uses or natural background levels. The request for submission of toxicological information and/or clarification regarding the food additive use and natural background levels requested in Section 5 above is noted.
6(5)		EFSA: Exposure to sunlight and microorganisms in the environment (when applied on crops outdoors) may alter essential oils in their composition. Is there any knowledge with regard to resistance or susceptibility of the components of *Origanum vulgare* L. essential oil (such as thymol, carvacrol, terpineols) to degradation or alteration processes under the conditions the oil is intended to be used?		Exposure to sunlight and microorganisms may alter everything, including mixture described as a.s. thymol. Alteration occurs; substance is active for 24h then activity decreases.	Usually, this kind of alterations to a substance are addressed by radio-labelled studies investigating the resulting compound pattern from degradation and metabolism processes to assess the toxicological relevance of the generated residue compounds. Radio-labelled studies are not requested and may not be necessary for components of *Origanum vulgare* L. essential oil, however if alteration / degradation of e.g. thymol occurs within 24 hours, the resulting compounds should be further addressed.

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
					Data gap: Information is missing regarding the nature of potential degradation products of the components of *Origanum vulgare* L. essential oil

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)		NL: No comments.			Noted.
7(2)		PL: No comments.			Noted.
7(3)	7.1.1. Carvacrol	EFSA The EFSA FEEDAP Panel 2012 environmental assessment as a feed additive assessed 5mg carvacrol/kg feed? This has to be related to the annual g/ha dose being requested for this use. Using the standard assumptions in the FEDAP Panel environmental assessment guidance regarding chicken manure spreading on land the dose rate assessed would have been 24 g carvacrol /ha.	Applicant needs to update the reference to the FEEDAP Panel opinion to express environmental exposure in g / ha and not mg carvacrol/kg feed. They also need to clarify the GAP being requested in this application. Is the highest rate being requested for the plant oil 14 g/ha or 14 kg/ha i.e. 11.2 g carvacrol/ha or 11.2kg carvacrol /ha? An environmental exposure assessment will be necessary if the use required is 11.2kg carvacrol /ha as this would not be covered by the FEEDAP panel assessment that only assessed 24 g carvacrol /ha.	GAP rates modified and reduced following last field results.	The EFSA FEEDAP Panel (2012) environmental assessment only covers application rates of up to 24 g carvacrol /ha. In the updated GAP table provided the maximum annual total application rate is stated to be 6 kg plant oil /ha which would be 4.8 kg carvacrol /ha. Therefore the uses being requested have not been covered by the EFSA FEEDAP Panel (2012) environmental assessment from use as a feed additive, where the rate assessed was 200 times lower.
7(4)	7.1.2. Thymol	EFSA The EFSA conclusion on thymol from 2012 that assessed a good agricultural practice on grapes of 4x260 g thymol/ha basically had the environmental risk open and identified a critical area of concern relating to	Applicant needs to use the peer review conclusion of EFSA on thymol and not the earlier draft assessment report of the RMS. Unfortunately this identifies environmental exposure and risk issues for an annual dose of 1.04kg thymol/ha. They also	Peer review show risk issue of concern but substance was approved with no MRL.	The EFSA conclusion on thymol (EFSA, 2012b) from 2012 identifies environmental exposure and risk issues for an annual dose of 1.04 kg thymol/ha including a critical area of concern relating to groundwater exposure. Even if

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
		groundwater exposure. This assessment supersedes any assessment of the RMS in the DAR of 2011.	need to clarify the GAP being requested in this application. Is the highest rate being requested for the plant oil 14 g/ha or 14 kg/ha i.e. 0.84 g thymol/ha or 0.84kg thymol /ha? Applicant needs to find a better estimate of thymol soil adsorption than was in the EFSA conclusion from 2012.		the use being requested here is lower (0.36 kg thymol /ha), there is no assessment available indicating that there would not be a groundwater exposure issue for thymol from this use. A good estimate of thymol soil adsorption remains unavailable in the information supporting this application.
7(5)	7.1.4. ΄Υ-terpinene	EFSA The statements made for ΄Υ-terpinene do not appear to have any references to any data underpinning them.	Applicant needs to provide references to data on the fate and behaviour of ΄Υ-terpinene that could underpin an assessment.	No data available	The statements in section 7.1.4. on ΄Υ-terpinene are not underpinned by anything so should not be relied upon.

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(6)		NL: No comments.			Noted.
7(7)		PL: No comments.			Noted.
7(8)		EFSA: Relevant information was not available. See also comment 7(4) that indicates that the available assessment	See column 3 entries at comments 7(3), 7(4) and 7(5).	Oregano E.O. is used as soil enhancer.	Relevant information on the estimation of the short and long-term exposure of relevant environmental media (soil,

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**
		in the EFSA conclusion for thymol indicates for the representative uses of thymol, a groundwater exposure concern for thymol.			groundwater, surface water) has not been provided.

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)	8.1.2. Mammals	DE: In section 5.2 a LD_{50} of 1.85 g/kg for rats is described. It is unclear whether this value can be reached in wildlife mammals through the intended uses of the application.	DE: Show in a sound risk assessment that there is no unacceptable risk for wildlife mammals caused by the intended uses.	Applicant agrees conclusion, but at the same time substance was allowed as a feed additive for pigs for fattening.	Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major constituents was presented for non-target vertebrates, despite data were available. It should be noted that Diarr-Stop S Plus®, (evaluated in EFSA FEEDAP Panel, 2016a) is a mixture of sodium salt of ethylenediaminetetraacetic acid (Na2EDTA), a tannin-rich extract of *Castanea sativa*, thyme oil and oregano oil (at the concentration of 0,8% w/w) to be used at a recommended dose of 1,000 mg/kg feed (8 mg/kg oregano oil). Information cannot be extrapolated to support the present application without further considerations on the exposure levels following the representative uses of the basic substance under evaluation.

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
					See relevant comments in section 5 and Data gaps in 5(13), 5(15), 5(25).
8(2)	8.1.2. Mammals	DE: In section 5.6 it is mentioned that there is an increase in the rate of embryonic cell death in pregnant mice at 150 mg/kg when *O. vulgare* oil was fed for two weeks. It is unclear whether this value can be reached in wildlife mammals through the intended uses of the application.	DE: Show in a sound risk assessment that there is no unacceptable risk for wildlife mammals caused by the intended uses.	Applicant agrees conclusion, but at the same time substance was allowed as a feed additive for pigs for fattening.	See data gap in 8(1).
8(3)		NL: No comments.			Noted.
8(4)		PL: No comments.			Noted.
8(5)	Giannenas et al., 2003	EFSA: the relevance of the study for the purposes of the present application is considered questionable.	EFSA: Please consider removing the study or highlighting the non-relevance of the findings. If considered more appropriate, please, provide an accurate study summary (including details on test design, materials methods, detailed results) and clearly highlight in the conclusions how the findings were considered relevant and adequate to support the present applications with reference to the uses in GAP.	Ref removed	Addressed
8(6)	Neill et al., 2006	EFSA: The study is considered of	EFSA: Please consider removing the	Reference maintained. This	Although the study could be

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
		low relevance for the present application.	study or highlighting the non-relevance of the findings. If considered more appropriate, please, provide an accurate study summary (including details on test design, materials methods, detailed results) and clearly highlight in the conclusions how the findings were considered relevant and adequate to support the present applications with reference to the uses in GAP.	reference does not support the present applications with reference to the uses in GAP, but show non toxicity to mammals according to chapter 8 question. "In the described experimental conditions, the addition of antimicrobial in the food increased the performances of growth of piglets in nursery while the addition of oregano oil with diverse concentrations had **no negative effect**."	considered somehow informative, it does not allow drawing solid conclusions with regard to the potential effects on NTOs.
8(7)	Brenes and Rourab, 2010	EFSA: the study is not considered relevant; it is poorly summarised and it is not a primary research. The applicant highlighted that "No influence on performance parameters has been reported by different authors (…) using oregano essential oil, thymol, cinnamaldehyde, pepper, garlic powder and a commercial blend of EO containing thymol." It is not explained what these parameters are and whether they have any ecotoxicological relevance.	EFSA: Please consider removing the study or highlighting the non-relevance of the findings. If considered more appropriate, please, provide an accurate study summary (including details on test design, materials methods, detailed results) and clearly highlight in the conclusions how the findings were considered relevant and adequate to support the present applications with reference to the uses in GAP.	Reference maintained. This reference does not support the present applications with reference to the uses in GAP, but show non toxicity to mammals according to chapter 8 question. Conclusion for the BSA added: "**No negative effect of E.O. is to be notified**."	Although the study could be considered somehow informative, it does not allow drawing solid conclusions with regard to the potential effects on NTOs.

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(8)	Benchaar et al., 2008	EFSA: it is stated that "oregano has a beneficial effect for ruminant without sign of toxicity." The statement should be further supported. Several findings form the review were cited, but none of them seem to be an *in vivo* test. It is considered that, based on the findings highlighted it can be concluded that *Origanum vulgare* essential oils have antimicrobial properties.	EFSA: Please, remove or amend the conclusion if sufficiently supported and, if so, add relevant supportive information/data.	This reference does not support the present applications with reference to the uses in GAP, but show non toxicity to mammals according to chapter 8 question. All these antimicrobial properties are not a problem for mammals.	The claim that oregano has a beneficial effect for ruminant without sign of toxicity is not considered supported without further clarifications.
8(9)	Botsoglou et al., 2004	EFSA: The study is considered of low relevance for the present application.	EFSA: Please consider removing the study or highlighting the non-relevance of the findings. If considered more appropriate, please, provide an accurate study summary (including details on test design, materials methods, and detailed results) and clearly highlight in the conclusions how the findings were considered relevant and adequate to support the present applications with reference to the uses in GAP.	Reference not removed. Substance is allowed as a feeding additive for pigs for fattening. EFSA reference added in the BSA.	Although the study could be considered somehow informative, it does not allow drawing solid conclusions with regard to the potential effects on NTOs.
8(10)	8.1.1. Birds 8.1.2. Mammals	EFSA: The information provided does not allow for a risk assessment of *Origanum*	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to	Substance is allowed as a feeding additive for pigs for fattening.	Data gap The risk assessment to birds was not carried out for

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
		vulgare essential oil.	demonstrate a low risk to birds and mammals (acute and long-term). The assessment should consider the risk from the *O. vulgare* essential oil when used according to the GAP. In addressing the issue the applicant might refer to the available relevant endpoints for the single constituents (information might be available form relevant sources: DARs, toxnet etc..).	EFSA reference added in the BSA	*Origanum vulgare* L. essential oil or for its major constituents although some toxicological data were available (e.g. EFSA conclusion on thymol (EFSA, 2012b)).
8(11)	8.1.1. Birds 8.1.2. Mammals	EFSA: information on the potential adverse effect of major constituents of the essential oil was not submitted.	EFSA: provide information for addressing the risk to birds and wild mammals.		See data gap in 8(10).

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(12)	7.2. Estimation of the short- and long-term exposure of relevant environmental media (soil, ground water, surface	DE: The highest three rates of added Origano resulted in an increase in the pH. The addition of Origano resulted in a lower decomposition of organic matter.	DE: Show in a sound risk assessment that the intended uses cause no unacceptable risk for aquatic organisms through the increase of the pH and the lower decomposition of organic matter.	Oregano oil is administered to fish. More Reference added to BSA.	Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major constituents was presented for aquatic organisms. There is indication that major

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
	water)				constituents of the basic substance may exert toxic effects to fish, crustacean and algae (toxicity endpoints available in the EFSA conclusion on the active substance thymol (EFSA, 2012b)).
8(13)		NL: No comments.			Noted.
8(14)		PL: No comments.			Noted.
8(15)	Romero et al., 2012	EFSA: the relevance of the article is considered questionable. It is not a primary research. It reviews the current knowledge regarding antibiotic use in aquaculture systems. Some relevant information might be extrapolated, however no adequate summary was provided.	EFSA: Please consider removing the study or highlighting the non-relevance of the findings. If considered more appropriate, please, provide an accurate study summary (including details on test design, materials methods and detailed results) and clearly highlight in the conclusions how the findings were considered relevant and adequate to support the present applications with reference to the uses in GAP.	Reference removed	Addressed.
8(16)	Zheng et al., 2009	EFSA: Please provide a more informative summary, including experimental data and results.		Athanassopoulou, F. et al. 2004 more accurate paper. More Reference added to BSA.	The study by Athanassopoulou et al., 2004 (ITAB, 2016) aims to assess the efficacy of alternative treatments on infected fish. It does not provide solid evidence allowing

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
					to draw robust conclusions.
8(17)	Pyrgoou et al., 2010	EFSA: "Trout fillet treatment with oregano EO also extended the shelf life by 7 to 8 days for fresh trout fillets." How was the information considered relevant for the present application?	Please remove the reference.	Reference removed	Addressed.
8(18)	8.2. Effects on aquatic organisms	EFSA: The information provided does not allow for a risk assessment of *O. vulgare* essential oil to aquatic organisms. Data were not submitted for aquatic organisms other than fish. It should be noted that essential oil has insecticidal properties.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low risk aquatic organisms (acute and long-term). The assessment should consider the risk from the *O. vulgare* essential oil when used according to the GAP. In addressing the issue the applicant might refer to potentially available relevant endpoints for the single constituents (information might be available form relevant sources: DARs, toxnet etc..).	*O. vulgare* E.O. may be administrated to aquatic organisms see Athanassopoulou, F. et al. 2004 More Reference added to BSA.	See data gap in 8(12). The study by Athanassopoulou et al., 2004 (ITAB, 2016) aims to assess the efficacy of alternative treatments on infected fish. It does not allow drawing solid conclusions.

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(19)	8.3 Effects on bees and other arthropods species	DE: Lensky et al. (1996) found that the use of pure Origanum oil or 30 % thymol during summer was harmful for bees depending on dose and ambient temperature. In the application, the insecticidal effect of Origanum oil is emphasised: "It is creating a stressful situation for the larvae, resulting in a reduction in glucids, proteins and lipids reserves. Thus, adults from these larvae are more susceptible to future external attacks. The substance also seems to have a repellent effect on adults and would act on hatching" (section 3.3). The effect of the intended uses on non-target arthropods are unclear.	DE: Show in a sound risk assessment that there are no unacceptable effects on non-target arthropods caused by the intended uses.	Thymol is used, registered and marketed in beehives for varroa destructor treatment. Please remove all marketed products is risk assessment show inacceptable risk for bees.	Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major constituents was presented for bees and other NTAs. Based on the available dataset, potential toxic effects of the substance on honeybee larvae cannot be excluded (this information is substantiated by other literature data on lethal and sub- lethal effects of thymol on honeybee larvae). The substance is intended to be used to control insect pests. The representative uses envisage the foliar application of *O. vulgare* during flowering on highly attractive crops for bees.
8(20)		DE: The presented data are not appropriate to assess the risk to honey bees.	DE: Please indicate in dossier.		See data gap 8(19).
8(21)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	DE: Please indicate in dossier.		See data gap 8(19).

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(22)		NL: No comments.			Noted.
8(23)		PL: No comments.			Noted.
8(24)	8.3.1 effects on bees 8.3.1 effects on other non-target arthropods	EFSA: The information provided does not allow for a risk assessment of *O. vulgare* essential oil to bees and non-target arthropods. it should be noted that: -the substance has been reported to exert insecticidal properties and to be harmful to bees (Lensky et al.). -the representative uses envisage the foliar application of *O. vulgar*e during flowering on highly attractive crops (e.g. pome fruits).	EFSA: Some form of risk assessment should be submitted in order to demonstrate a low risk to bees and non-target arthropods. At the present stage the RA for bees and other NTAs could not be finalised.	How a harmful substance to bees with unacceptable risk for bees could be registered for bee treatment? See Thymovar®	See data gap 8(19).

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(25)		DE: Robust experimental studies carried out with relevant soil macro-organisms (e.g. the standard test earthworm	DE: Please indicate in the dossier.		Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major

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**
		Eisenia fetida) were not submitted.			constituents was presented for soil macro-organisms. No relevant evidence was submitted to assess the risk to earthworms and other soil macro-organisms. Potential toxic effects on earthworms due to the exposure to *Origanum* vulgare L. essential oil and its major constituents (e.g. Carvacrol and Thymol - see EFSA technical report for the basic substance application for *Satureja montana* L. (EFSA, 2016b)) cannot be excluded.
8(26)		NL: No comments.			Noted.
8(27)	8.4. Effects on earthworms and other soil macro-organisms	EFSA: No information has been provided to perform a risk assessment for earthworms.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to earthworms. The assessment should consider the risk from the *O. vulgare* essential oil when used according to the GAP.		See data gap in 8(25).

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(28)	8.5 Effects on soil microorganisms	DE: No robust experimental reports were submitted from which information about effects on soil micro-organisms can be derived.	DE: Please indicate in the dossier.	Soil stimulation by E.O. is described. References added.	Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major constituents was presented for soil microorganisms. There is evidence of potential detrimental effects of *Origanum vulgare* L. essential oils and/or its main components on soil microorganisms (e.g., see Gougoulias et al., 2010 in ITAB, 2016).
8(29)		DE: It is concluded: "The addition of Origano oil modifies the balance of the microorganisms and changes the soil chemical composition."	DE: Show in a sound risk assessment that these changes cause no unacceptable risk for soil macro- and microorganisms.	Soil stimulation by E.O. is described. References added.	See data gap in 8(28).
8(30)		NL: No comments.			Noted.
8(31)	8.5. Effects on soil micro-organisms	EFSA: No information has been provided to perform a risk assessment for soil microorganisms. It should be noted that potentially harmful effect were highlighted in Gougoulias et al., 2010.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to soil microorganisms. The assessment should consider the risk from the *O. vulgare* essential oil when used according to the GAP.	Soil stimulation by E.O. is described. References added.	See data gap in 8(28).

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
8(32)	8.6 Effects on other non-target organisms (flora and fauna)	DE: It is concluded: "Thyme and Origano oils inhibited both germination and radicle elongation at a dose of 1.25 µg/mL." It is not clear which effects the intended uses may have on non-target plants.	DE: Show in a risk assessment that the intended uses cause no unacceptable risk for non-target plants.	No phytotoxicity was observed in 2015 assays. References added.	Data gap No risk assessment for *Origanum vulgare* L. essential oil and/or its major constituents was presented for NTTPs. There is evidence suggesting that *Origanum vulgare* L. essential oil may exert toxic effects on NTTPs (Almeida et al., 2010 and ITAB, 2016).
8(33)		NL: No comments.			Noted.
8(34)	8.6. Effects on other non-target organisms	EFSA: No information has been provided to perform a risk assessment for NTTPs. It should be noted that based on de Almeida et al 2010, *O. vulgare* essential oil was substantially active against germination and early radicle growth of *Lepidium sativum*, *Raphanus sativus* and *Lactuca sativa*.	EFSA: Some form of risk assessment and/or scientific justification should be submitted in order to demonstrate a low to NTTPs. The assessment should consider the risk from the *O. vulgare* essential oil when used according to the GAP.	Following last field trials, quantities are reduced in GAP accordingly.	See data gap in 8(32).

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
8(35)		NL: No comments.			Noted.

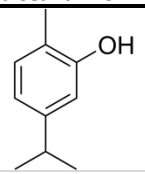
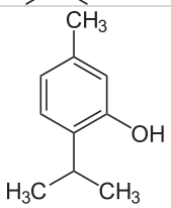
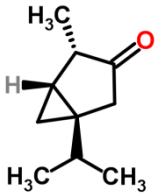
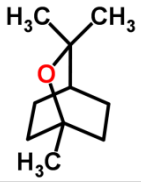
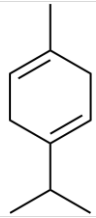
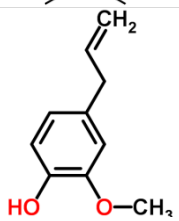
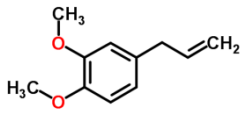
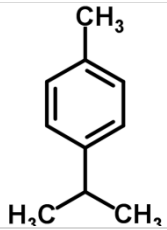
9. Overall conclusions with respect of eligibility of the substance to be approved as basic substance

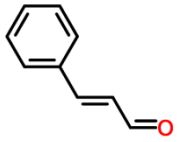
Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to 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: If such precautions are necessary can Origano oil be considered as not being a substance of concern and hence be assessed as a basic substance?		DE M.S. suggests assessment of Oregano E.O. as active substance. Is the payment of a fee would change the outcome of the evaluation?	Not under EFSA's remit, this is a risk management decision.
9(2)		NL: No comments.			Noted.

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**
10(1)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorisation of basic substances is that no product approval takes place after the final decision on the a.s.	DE: Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	Regulation 1107/2009 is referring to "utility". For side effects…	Not under EFSA's remit, this is a risk management decision.
10(2)		NL: No comments.			Noted.

Appendix B – Used compound codes

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
carvacrol	5-Isopropyl-2-methylphenol Cc1ccc(cc1O)C(C)C	
thymol	thymol 2-isopropyl-5-methylphenol Cc1ccc(c(c1)O)C(C)C	
β-thujone	(1S,4S,5R)-1-Isopropyl-4-methylbicyclo[3.1.0]hexan-3-one C[C@H]1[C@H]2C[C@]2(CC1=O)C(C)C	
1,8-cineole eucalyptol	1,3,3-Trimethyl-2-oxabicyclo[2.2.2]octane CC1(C2CCC(O1)(CC2)C)C	
γ-terpinene	1-Isopropyl-4-methyl-1,4-cyclohexadiene CC1=CCC(=CC1)C(C)C	
eugenol	4-Allyl-2-methoxyphenol COc1cc(ccc1O)CC=C	
methyl eugenol	4-Allyl-1,2-dimethoxybenzene COc1ccc(cc1OC)CC=C	
***p*-cymene** cymene	1-Isopropyl-4-methylbenzene Cc1ccc(cc1)C(C)C	

cinnamaldehyde	(2E)-3-Phenylacrylaldehyde c1ccc(cc1)/C=C/C=O	

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

Appendix C – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture of chemical substances
Chemical name (CA)	Not relevant, the substance is a complex mixture of chemical substances
Common names	*Origanum vulgare L.* essential oil
CAS No	8007-11-2
CIPAC No and EEC No	EINECS/ELINCS(EU) :616-905-4
FAO specification	Not available
Minimum purity	Not pertinent for a plant oil
Relevant impurities	As an extract of plant material does not include impurities from synthesis
Molecular mass and structural formula	Not relevant for a plant extract that is a mixture of components. See Appendix B for structural formulae of the main components Carvacrol, thymol, *p*-cymene, *γ*-terpinene
Mode of Use	Foliar application spraying, drip
Preparation to be used	Emulsifiable concentrate (EC)
Function of plant protection	fungicide, bactericide and insecticide

Appendix D – List of uses

1. Fungicidal use

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (l)
					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 (days)	# g a.i./h min max (g/hl)	Water l/ha min max	kg a.i./ha min max (*) (kg/ha)	kg a.i./ha min max (kg/ha) (l)		
Pear tree *Pyrus communis*	France & All member states	Solution of essential oil of *Origanum vulgare L.*	F	Pear scab *Venturia pirina*	EC	2 (0.2%)	Foliar application spraying	BBCH 53 to 54	1 to 4	7	200	500	1	1 to 4	15 to 30	The mix with essential oil to must be used 24h after Preparation
Apple tree *Malus sp.* and fruits				Apple scab *Venturia inaequalis*												
Grapvine *Vitis vinifera*				Powdery mildew *Plasmopora viticola*				BBCH 12		7 to 10		150 to 300	0.3 to 0.6	0.3 to 2.4		
Gardening Potatoes *Solanum Tuberosum*				Late blight *Phytophthora infestans*				BBCH 11-29		7		200 to 300	0.4 to 0.6	0.4 to 2.4	7	
Gardening Lettuce *Lactuca sativa*				Lettuce mildew *Bremia lactucae*		0.1 to 2 (0.01 to 0.2%)		BBCH 17-19		7 to 10	10 to 100	1000	0.1 to 1	0.1 to 4	n.a	
Citrus, eucalyptus, ornemental plants like *hydrangeas*, *camellias*, *Nerium oleander*.				*fumagine*		0.67 (0.06 %)		When biting Sucking insects : aphids, mealybugs and *Metcalfa Pruinosa* drop off honeydew		7	67	150	0.1	0.1 to 0.4	n.a	
Orchard of kiwi *Actinidia chinensis*						1 (0.1%)			2	20	100	1000	1	2	n.a	

column heading contains contradictory units, see comment 3(4).

2. Bactericidal use

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (l)
					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)	g a.i./hl min max (g/hl)	Water l/ha min max	g a.i./ha min max (*) (kg/ha)	kg a.i./ha min max (kg/ha) (l)		
Pear tree, *Pyrus communis*, apple tree *Malus sp.*, hawthorn *Crataegus sp.*, rowan tree *Sorbus sp*	France & All member states	Solution of essential oil of *Origanum vulgare L.*	F	Fireblight *Erwinia* amylovora	EC	20 (2 %)	drip	spring	n.a	n.a	2000	(30 to 150 l/ha) 15 to 75 mL/tree	0.6 to 3	n.a	n.a	The drip consisting of a needle and a small tank is employed. *

* The drip system is patented by E. Petiot.

3. Insecticidal use

Crop and/or situation (a)	Member State	Product Name	F G I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (l)
					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 (days)	g a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (*) (kg/ha)	kg a.i./ha min max (kg/ha) (l)		
Orchard apple *Malus sp.*	France & All member states	Solution of essential oil of *Origanum vulgare L.*	F	Woolly aphid colonies *Eriosoma lanigerum*	EC	5 (0.5%)	Spray Application foliar	Spring Flowering stage	2 to 3	7	500	400	2	4 to 6	n.a	The mix with essential oil to must be used 24 h after preparation
Peach tree, apple tree,apricot tree, kiwi tree, plum tree, citrus tree, vine, aubergine, mulberry, soybean, sunflower, wheat, barley, corn, …				Biting sucking insects like *Metcalfa pruinosa*		0.6 (0.06%)		Spring Larval stage	n.a	n.a	67	150	0.1	n.a	n.a	

(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 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