European Food Safety Authority

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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for *Artemisia vulgaris* for use in plant protection as insecticide/repellent on orchards, vineyards and vegetables [1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

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 *Artemisia vulgaris* 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 *Artemisia vulgaris* as a basic substance. *Artemisia vulgaris* is intended to be used as insecticide/repellent for plant protection on orchards, vineyards and vegetables. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.

KEY WORDS

Artemisia vulgaris, basic substance, application, consultation, plant protection, pesticide

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SUMMARY

Artemisia vulgaris is an active substance for which in accordance with Article 23(3) of Regulation (EC) No 1107/2009 (hereinafter referred to as 'the Regulation') the European Commission received an application from the 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 of 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 on February 2014, EFSA was asked to organize a commenting on the basic substance application for *Artemisia vulgaris*, 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 3 months of acceptance of the specific request.

A consultation on the basic substance application for *Artemisia vulgaris*, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in February 2014-April 2014. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by the EFSA on the basic substance application for *Artemisia vulgaris* and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

The *Artemisia vulgaris* product is the aerial parts extract of the *Artemisia vulgaris* L. (mugwort) dry plant. It is a complex mixture of natural compounds; however neither the purity nor the concentration of the active substances is defined in the submission. The product is proposed on the market as a natural powder or dried plants material, intended to be used as insecticide/repellent for plant protection on orchards, vineyards and vegetables. However no real efficacy trials data are available.

The Regulation states the following "A basic substance is an active substance which is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent". This is not the case for this material as it is extracted by boiling for 45 minutes. It is also proposed that the pH is corrected with vinegar the primary constituent of which (acetic acid) is already approved as an active substance and there is also an application for approval as a basic substance (EFSA, 2014). This means that *Artemisia vulgaris* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance is being prepared for these substances.

As for the mammalian toxicology section, the available information is not sufficient to reliably conclude on the toxicity and genotoxicity potential of *Artemisia vulgaris*. Based on the limited available data, indicating health effects of potential concern, *Artemisia vulgaris* cannot be considered a basic substance. In addition, data do not allow setting of reference values.

Since the available data are not sufficient to conclude on the toxicity of *Artemisia vulgaris* extracts and since information related to the residues has not been provided, a consumer risk assessment could not be completed.

The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.

The available ecotoxicological data are not considered sufficient to address the risk to non-target organisms (birds, mammals, aquatic organisms, honey bees, non-target arthropods, earthworms, soil macroorganisms other than earthworms).

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (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.

Artemisia vulgaris is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from the Institut Technique de l'Agriculture Biologique (ITAB) for approval as a "basic substance".

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for *Artemisia vulgaris*, which was conducted via a written procedure in February 2014-April 2014. The comments received were collated by EFSA in the format of a Reporting Table. Subsequently, the applicant was invited to address the comments in column 3 of the Reporting Table. The comments received and the response of the applicant thereon, together with the application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

The current report aims to summarise the outcome of the consultation process organised by the EFSA on the basic substance application for *Artemisia vulgaris* 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 *Artemisia vulgaris* as a "basic substance" in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (Institut Technique de l'Agriculture Biologique (ITAB), 2013a, 2013b).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 the European Commission requested the 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 February 2014, EFSA was asked to organise a commenting on the basic substance application for *Artemisia vulgaris*, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table.

To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. The agreed deadline for providing the finalised report is 12 September 2014.

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.

[3] 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.

EVALUATION

The comments received on the basic substance application for *Artemisia vulgaris* and the conclusions drawn by the EFSA are presented in the format of a Reporting Table.

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

The finalised Reporting Table is provided in the Appendix of this report.

DOCUMENTATION PROVIDED TO EFSA

1. Institut Technique de l'Agriculture Biologique (ITAB), 2013a. *Artemisia vulgaris*. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. October 2013. Submitted by Institut Technique de l'Agriculture Biologique (ITAB). Documentation made available to EFSA by the European Commission.

2. Institut Technique de l'Agriculture Biologique (ITAB), 2013b. *Artemisia vulgaris*. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2013. Submitted by Institut Technique de l'Agriculture Biologique (ITAB). Documentation made available to EFSA by the applicant.

REFERENCES

EFSA (European Food Safety Authority), 2014. Outcome of the consultation with Member States and EFSA on the basic substance application for vinegar and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2014:EN-641. 37 pp.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *ARTEMISIA VULGARIS* 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1(1)	General	NL: Please translate studies which are not submitted in English. Studies submitted in French should not be considered unless a translation in English is available.	All previous papers in Japanese Russian have been translated at our expense. On legal basis in European Community, French, English and German are legal languages in Europe. Commission européenne ; Direction Générale de la Traduction Etudes sur la traduction et le multilinguisme ; La traduction à la Commission: 1958-2010 2/2009 Furthermore, we have no funding for translation.	Everything that is not in English will not be used.
1(2)		ES: No comments	-	Noted

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

2.1. Predominant Use				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	General comment	ES: It might be useful to clarify the nature of basic substance. Oil, extract, dried plant, fresh plant, etc., are terms used along the report. Maybe the cover of the report should also include this information (e.g. *Artemisia vulgaris* "extract").	All references to essential oils are deleted in the Basic substance application. *Artemisia vulgaris* product in this Basic substance application is the aerial parts extract (leaves and stems). Title can be changed with more restrictive description as "*Artemisia vulgaris* p aerial parts extract" upon request.	Addressed.
2(2)	General comment 2.2.5. Description and specification of purity of the active substance and product	ES: Are the rates among the major components constant?	Chemotypes show variations (actually more papers describe essential oil composition)	See section 2.6.
2(3)	2.2.1. Common name of the substance and product and their synonyms/plant nomenclature	ES: It might be useful to include the synonym in Spanish.	Corrected	Addressed.
2(4)	BSA Artemisia vulgaris oct2 2013;	NL: It should be reconsidered whether the current CASnr (84775-45-1) is accurate and whether the CASnr for *Artemisia vulgaris* L. essential	We used CAS nr (84775-45-1) as CAS nr for *Artemisia vulgaris* L. (whole plant) extract. *Artemisia vulgaris* L. essential oil (CAS: 8008-93-	Addressed.

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	2.2.2. chemical name	oil (CAS: 8008-93-3 or 68916-13-2) or the CASnrs of the 3 major components eucalyptol, chlorogenic acid, camphor (470-82-6, 327-97-9, 76-22-2) would be more appropriate.	3 or 68916-13-2) is cited for difference. CAS nrs of the 3 major components are listed as active compounds present in the plant, we have no goal to get approval for single active purified compound. All references to essential oils are deleted in the Basic substance application.	
2(5)	BSA Artemisia vulgaris oct2 2013; 2.2.5.specification of the active substance and plant	NL: The following is stated here: *The active substance is a dried plant. It is a complex mixture of natural compounds; the purity of the active substance cannot be defined.* This does not seem sufficient. The plant material could be analysed and the complex mixture of natural components could be separated. Determining a minimum purity might be difficult, at least some kind of range per major component would be established. At least to have some indication. According to **EFSA 2009 Compendium of botanicals that have been reported to contain toxic, addictive, psychotropic or other substances of concern; *EFSA Journal* 7(9):281** 1L: it may contain up to 3.7% eucalyptol in essential oil and 1.3% of thujone (CoE, 2005) This number for eucalyptol does not seem to correspond to the one indicated in the BSA oct 2013 although reference is made to the same EFSA compendium for botanicals. Please clarify.	More references are cited. Further attempt to clarify composition is made. Pharmacopeia identification is cited. EFSA 2009 is dealing with essential oil, reference supressed. Essential oil is not the basic substance described in the BSA. All references to essential oils are deleted in the BSA. COE 2005 ref not provided: essential oil.	Addressed. Pharmacopeia identification is cited.

2.2. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(6)	2.2.7.2; Analytical methods for determination of impurities	NL: The description of a method consists of 2 lines. This does not seem to be the method description here. At least some kind of summary of the method should be given here.	Pharmacopeia references and methods added	Addressed: Methods are given in the pharmacopeia.
2(7)	2.2.7.3; Analytical methods for determination of residues	NL: No statement or study is indicated here, the section seems to be empty. At least some kind of statement should be given here.	Pharmacopeia references and methods added	Addressed: Methods are given in the pharmacopeia.

2.3. Current Former and in case proposed trade names				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted

2.4. Manufacturer of the substance/products				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted

2.5. Type of preparation				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: No comments	-	Noted

2.6. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	Description of the recipe for the product to be used	EFSA: The Regulation states the following. 'It is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling for 45 minutes. It is also proposed that the pH is corrected with vinegar which is already approved as an active substance and there is also an application for it to be a basic substance. This means that the *Artemisia vulgaris* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance has been prepared for these substances.	Vinegar is an intrinsic basic substance in accordance to EC regulation 178/2002. Vinegar was submitted as basic substance previously, evaluation is ongoing. Vinegar is not already approved at PPP regulation; Acetic acid [64-19-7] is instead approved. As soon as vinegar will be approved as basic substance it will be possible to mix it with *Artemisia*, although approval for pH correction is not intended in Vinegar BSA. It will be then necessary to place a new BSA for vinegar as pH correcting agent. Guidance document cited (in fact 10470/2012 rev. 8) is clearly mentioning basic substance (Art. 23) application as possible issue for plant extract, and *Equisetum* plant extract, recently approved, confirms this opportunity.	The Regulation states the following. 'It is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling for 45 minutes. It is also proposed that the pH is corrected with vinegar the primary constituent of which (acetic acid) is already approved as an active substance and there is also an application for it to be a basic substance. This means that the *Artemisia vulgaris* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance has been prepared for these substances.
2(2)	General comment	ES: Macerate until which point? The preparation of the sample to carry out the decoction should be described in more detail. Was the efficacy of this decoction tested?	Corrected duration of maceration is then mentioned in revised BSA Bertrand C. 2010 Projet CASDAR - 4P Evaluation et caractérisation chimique de plantes	Addressed: Details of the extraction are given.

2.6. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		And its accuracy?	Included in the BSA	

2.7. Function on plant protection				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)		ES: 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		ES: No comments	-	Noted

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature speculates on the mode of action. It remains unclear. Overall, only limited effect in some uses described should be expected.	More examples of utility were added. Corrected, information added	No real efficacy trials data are available.
3(2)		ES: In the group of orchard, plum should be included apart from apple tree, which appears in the GAP table.	Corrected, information added	Addressed.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 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 the detailed description of GAPs. In the label it should be made clear that no sufficient	Corrected, information added	No real efficacy trials data are available.

3.3. Summary of intended uses				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		experience on efficacy with regard to the intended uses exists.		
3(2)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Answered, added in BSA	No real efficacy trials data are available.
3(3)	General comment	ES: It is not possible to define the purity of the active substance. The active substance is a dried plant. It is a complex mixture of natural compounds (see issue 2.2.5 of the report). Therefore, how the concentration of the active ingredient is fixed (Conc of a.i. g/kg)? See also above the comments to the issue "2.6. Description of the recipe for the product to be used"	Concentration mentioned is as if all material is dissolved. As matter of fact water soluble extractive fraction is only 9.6 % w/w. Juvatkar PV., Kale MK., Jalalpure SS., Waghulde Sandeep., Naik Pravin., Jain Vishal 2012 Antimicrobial activity of Leaves of *Artemisia vulgaris* L *In Proceedings of the 16th Int. Electron. Conf. Synth. Org. Chem.*, 1-30 November 2012; Sciforum Electronic Conference Series, Vol. 16, 2012	See section 2.6
3(4)	General comment	ES: Is the plant homogenate (extracted with hot water and filtered (decoction)), suitable for foliar spraying after cooling? The solubility can change significantly.	Yes, after filtration, details included in recipe (§2.6).	Addressed: The recipe is given.
3(5)	*3.3*	ES: In the summary of intended uses (GAP table) some units should be corrected. In "application rate" and "total rate" columns it should say "Kg a.i./ha min max (kg/ha)"	Corrected	Addressed.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
4(1)		NL: no comments	-	Noted

5. Impact on Human and Animal Health

5.1. Effects having relevance to human and animal health arising from exposure to the substance/its products or to impurities				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: the literature submitted for the review of the application indicates several health effects (in some case claimed for therapeutic used) which are not sufficiently investigated, both qualitatively and quantitatively. For some of the components of *Artemisia vulgaris* (it is noted the overall composition cannot be given in detail) reference values are proposed. Based on the above, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.	Many examples are cited for medicinal uses of *Artemisia vulgaris*. A new, and more recent one, not ignoring presence of thuyone, is added Adams James David, Garcia Cecilia, Garg Garima 2012 Mugwort (*Artemisia vulgaris*, *Artemisia douglasiana*, *Artemisia argyi*) in the Treatment of Menopause, Premenstrual Syndrome, Dysmenorrhea and Attention Deficit Hyperactivity Disorder *Chinese Medicine*, 3, pp 116-123 http://dx.doi.org/10.4236/cm.2012.33019	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Precautions and adverse reactions	DE: It is at least questionable if a plant that may cause allergic reactions (see also 5.3.) and should be applied with gloves, therefore (see recommendation under 9., General conclusion), and that must not be used during pregnancy should be in fact considered a "basic substance" for which all toxicological tests may be waived.	Use of gloves is frequently recommended for dish washing or cleaning, however, this recommendation does not proved dish washing or house cleaning to be adverse. Usual safety recommendations are not systematically synonyms to mitigation procedure. USEPA, 2010 A Brief Guide to Mold, Moisture, and Your Home, Indoor Air Quality (IAQ) United States Environmental Protection Agency *EPA 402-K-02-003 (Reprinted 09/2010)*	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: basic information only is given on the toxicokinetics of some components of *A. vulgaris*, not sufficient to reliably conclude.	More references added.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Information on ingredients	DE: It seems that some of the known ingredients such as eucalyptol, camphor or (and in particular) thujone may exhibit adverse health effects. However, there is no reliable information on a possible dose response. In particular, the information is not sufficient to allow proper risk assessment by comparing no- or low-effect doses to an expected exposure due to use of *A. vulgaris* in plant protection (that is apparently also not known yet). Another possibility might be the calculation of usual dietary intake of these substances in Europe and consideration of the additional exposure by the intended use in plant protection. For this purpose, the content of these substances in the PPP must be determined. All this information will not be submitted if *A. vulgaris* is considered a "basic substance".	Proposed ADI for tujone is 0.11 mg/kg bw/day, which would not be reachable even for consumers of high-levels of thujone-containing foods (including absinthe and sage). Walch et al.: 2011 Determination of the biologically active flavour substances thujone and camphor in foods and medicines containing sage (*Salvia officinalis* L.). *Chemistry Central Journal* 5:44, pp 1-10	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: *A. vulgaris* is a sensitiser agent.	Sun B, Zheng P, Wei N, Huang H, Zeng G (2014) Co-Sensitization to Silkworm Moth (Bombyx mori) and 9 Inhalant Allergens among Allergic Patients in Guangzhou, Southern China. PLoS ONE 9(5): e94776. Agreement, like some other foodstuff used as PPP (canola/rape seed oil) Lettuce is similarly reported as allergenic Vila, SÁnchez, Sanz, DIÉguez, MartÍnez, Palacios and MartÍnez (1998), Study of a case of hypersensitivity to lettuce (*Lactuca sativa*) . Clinical & Experimental Allergy, 28: 1031–1035.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, **A. vulgaris** cannot be considered a basic substance.
5(2)	5.3 Acute toxicity	NL: minor comment. The acute toxicity of camphor is listed twice (5.3.1 and 5.3.4).	Corrected	Noted
5(3)	Information on ingredients	DE: See our comment above! The LD_{50} of some ingredients are higher than those of many synthetic active ingredients in pesticides. Very often, it is erroneously assumed that substance of natural origin would be less toxic than anthropogenic compounds but this is simply not true.	No statement in our BSA mention such assertion. Submission of this BSA attempt, is clearly a WILL from our part to proceed to an evaluation, instead of clamming harmlessness without data. If such toxicity was clear, EMEA would have forbidden such mutworg tea extracts for humans, but it is not the case.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: some published studies are summarised	Main papers are referring to the essential oil	Based on the limited available data,

5.4. Short–term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		indicating for some specific components of *A. vulgaris* health effects of concern, which are not sufficiently investigated, neither qualitatively nor quantitatively.	concentrate not to a decoction.	indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Information on ingredients	DE: Although the database is poor, it becomes apparent that toxicity of camphor or thujone must not be ignored. If a (provisional) reference value (such as 0.01 mg/kg bw for thujone) has been established, it should be compared to dietary intake and expected (additional) exposure. The provided information is not sufficient.	Proposed ADI for tujone is 0.11 mg/kg bw/day. Walch et al.: 2011 Determination of the biologically active flavour substances thujone and camphor in foods and medicines containing sage (*Salvia officinalis* L.). *Chemistry Central Journal* 5:44, pp 1-10	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: based on the available information it is not possible to reliably conclude on the genotoxocity potential of *A. vulgaris*.	Genotoxicity: No relevant genotoxicity data were available for thujone. Scientific Committee on Food 2002 Opinion of the Scientific Committee on Food on Eucalyptol SCF/CS/FLAV/FLAVOUR/22 ADD2 Final. Scientific Committee on Food 2003 Opinion of the Scientific Committee on Food on Thujone SCF/CS/FLAV/FLAVOUR/23 ADD2 Final.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Camphor and thujone	DE: For a complex mixture, it is not sufficient to refer to data obtained with two ingredients to	Zeiger E. Tice R. 1998 Chlorogenic Acid [327-97-9] and Caffeic Acid [331-39-5] Review of	Based on the limited available data, indicating health effects of potential

5.5. Genotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		exclude genotoxicity.	Toxicological Literature *Prepared for* National Institute of Environmental Health Sciences, pp1-120 Reference to chlorogenic acid added	concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: some published studies are summarised indicating for some specific components of A. Vulgaris health effects of concern, which are not sufficiently investigated, neither qualitatively nor quantitatively.	Main papers are referring to the essential oil concentrate not to a decoction.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	5.6 Long-term toxicity, page 23	NL: the last section "However test on…" seems be intended as an argument against the sentence that "a long term toxicity cannot be neglected". However, looking at the studies mentioned in that section they do not really seems to support that. A consumption of 0.812 g *Artemisia absinthium* L/kg/day (containing 5 mg/kg thujone) equals 48.72 g/day for 60 kg person. This equals 0.2436 mg thujone/day. This is well below the ADI of 6.6 mg/day. Therefore, it is not surprising that no effect were observed in the human studies.	No comment	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(3)	NTP studies, human data	DE: The long-term studies in rats suggest a possible toxicity that should not be expected	Interesting point of view since « Wermut für Pflanzen » (*Artemisia absinthium*) containing	Based on the limited available data, indicating health effects of potential

5.6. Long-term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		if a substance is considered a "basic" one. More information from these studies as well as from the human data is urgently needed.	more thujone is sold as **Pflanzenstärkungsmittel.** Again, mutworg is also sold as this type of « substance »"See « Schacht Kräutermischung Beifuß und Eichenrinde ist eine Kräutermischung und dient als Pflanzenstärkungsmittel »	concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: some of the claimed effects of *A. vulgaris* (e.g. against dismenorrhea, or as abort inducer) are not sufficiently investigated, though they are not confirmed by the available data on camphor and thujone.	Added Adams James David, Garcia Cecilia, Garg Garima 2012 Mugwort (*Artemisia vulgaris*, *Artemisia douglasiana*, *Artemisia argyi*) in the Treatment of Menopause, Premenstrual Syndrome, Dysmenorrhea and Attention Deficit Hyperactivity Disorder *Chinese Medicine*, 3, pp 116-123 http://dx.doi.org/10.4236/cm.2012.33019 Lee S-J.et al. 1998 Estrogenic Flavonoids from *Artemisia vulgaris* L. *J. Agric. Food Chem.*, *46*, 3325-3329	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Reproductive effects	DE: The available information resembles the situation with neem extracts for which some reproductive toxicity was also suspected. Accordingly, studies were performed before application in plant protection became possible. It is not understood why another	Situation is quite different, A. vulgaris is used as medicinal treatment for menopause and Premenstrual Syndrome, not as abortive, and Neem extract is approved as PPP and forbidden in some EU M.S..	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.7. Reproductive toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		approach should be taken for *A. vulgaris*.		

5.8. Neurotoxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: some of the components of *A. vulgaris* clearly show neurotoxic potential (e.g. camphor).	Web of Science give no record for *A. vulgaris* and Neurotoxicity	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Neurotoxicity	DE: The scarce information suggests a need for experimental studies so far it cannot be shown that exposure is negligible (e.g., as compared to daily dietary intake).	Answer should be find in Dossier « Schacht Kräutermischung Beifuß und Eichenrinde ist eine Kräutermischung und dient als Pflanzenstärkungsmittel »	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.9. Toxicity studies on metabolites				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

EFSA: No comments.
DE: No comment

5.10. Medical Data adverse effects reported in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)		EFSA: the submitted publications indicate health effects of concern, which are not sufficiently investigated, neither qualitatively nor quantitatively.	Web of Science give no significant record for *A. vulgaris* and adverse effect.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.
5(2)	Poisoning incidents	DE: The occurrence of intoxications suggests that some toxicological testing should be performed before the mixture can be approved as a PPP.	Intoxication are cited by M.S. but without citation. Web of Science give no record for *A. vulgaris* and Intoxication.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

5.11. 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 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(1)	Use in medicine	DE: The fact that a medicinal plant has been used for long does not necessarily mean that it is safe. Side effects must be considered. Again, the situation is comparable to neem extracts.	*A. vulgaris* does not have clear abortive effect as Neem extract approved as a;s; in PPP and forbidden in some EU countries.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

EFSA: No comments.

5.12. Additional information related to use as food				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(1)	Former and current use	DE: This information does not contribute much to health evaluation as a PPP.	Annex II of Directive 88/388/EEC (EEC, 1988) on flavourings sets the following maximum levels for thujone (and) in foodstuffs and beverages to which flavourings or other food ingredients with flavouring properties have been added: 0.5 mg/kg in foodstuffs and beverages with the exception of 5 mg/kg in alcoholic beverages with not more than 25% volume of alcohol 10 mg/kg in alcoholic beverages with more than 25% volume of alcohol 25 mg/kg in foodstuffs containing preparations based on sage 35 mg/kg in bitters.	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance.

EFSA: No comments.

5.13. 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 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(1)		EFSA: the proposed TMDI of 0,01 mg/kg bw for thujone cannot be considered per se for *A. vulgaris* as its composition is unclear as well as if there are effects due to the exposure to the mixture and not to the single compounds only.	TMDI for eucalyptol added	Based on the limited available data, indicating health effects of potential concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance. In addition, data do not allow setting of reference values
5(2)	Reference values	DE: There is a temporary ADI given for thujone but for all other ingredients and the plant	ADI for Eucalyptol added	Based on the limited available data, indicating health effects of potential

5.13. 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		mixture itself, information is not available. Usually, this issue is addressed as the outcome of appropriate toxicological testing.		concern, and considering the relevant regulation, *A. vulgaris* cannot be considered a basic substance. In addition, data do not allow setting of reference values.

5.14. 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 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(1)	Study by Natifidad et al. (2011)	DE: Allocation of this information to this template point is not clear.	Subject Artemisia vulgaris, animal health	Noted
5(2)	5.14., p. 31	DE: A statement on the risk for operators, workers, bystanders and residents during/after application of *Artemisia vulgaris* as repellent should be given.	POEM-UK attempt is made in §6 Residues	The assessment provided is not acceptable for the risk assessment (lack of reliable reference values).

EFSA: No comments.

6. Residues

Residues				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6(1)	Page 32	DE: At least a general statement on residues evaluation should have been provided.	Eine Antwort finden Sie in Dossier « Schacht Kräutermischung Beifuß » als Pflanzenstärkungsmittel	Since the available data are not sufficient to conclude on the toxicity of *Artemisia vulgaris* extracts and since information related to the residues has not been provided, a consumer risk assessment could not be completed.
6(2)	Page 32	EFSA: A statement on residues should be provided. Moreover, if toxicological concerns are indentified in the Phys-Chem or Tox. sections, they should be addressed in the residues section.	POEM-UK attempt is made in §6 Residues	See point 6(1)

7. Fate and Behaviour in the environment

Fate and Behaviour in the environment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)		ES: No comments	-	Noted
7(2)	7	NL: no information was provided other than it is a natural occurring substance. The same for the constituents. No information on levels of occurrence, natural as well as after the use of Artemisia, are provided. This is required as a minimum for estimation of possible effects on the environment.	Although we manage new search, no data found on negative impact regarding Artemisia spilling, smashing or transfer into rivers.	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
7(3)	7. Fate and behaviour in the environment page 32	EFSA: The statement regarding the fact that the extract is biodegradable is not very helpful. Nearly all organic materials are biodegradable. Over what time period do the components in the extract degrade. Evidence from OECD ready biodegradability tests would give some indication of the speed of biodegradation.	No adverse effect data found.	The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
7(4)	7. Fate and behaviour in the environment page 32	EFSA: The statement that thujone and camphor are naturally present in the environment is not supported by any information. How do these natural levels compare to the amount that will be added via the use being proposed. Information is probable also necessary for 1,8-cineole in addition to thujone and camphor?	Regarding the point of view of the recipe (decoction), no concentration factor of the present compounds is made by this means	The information provided in relation to the components thujone, camphor and 1,8-cineole is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
7(5)	7. Fate and behaviour in the environment page 32	EFSA: The information presented is considered inadequate to make any assessment.		The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: no comments	-	Noted
8(2)		ES: No comments	-	Noted
8(3)		EFSA: Effects on mammals cannot be excluded based on the available information (see comments in section 5). Moreover, the exposure of wild mammals to *A. vulgaris* also needs further consideration (see comments 7.3, 7.4 and 7.5)	More References added.	The available information is not considered adequate to conclude a low risk to wild mammals. It has also to be considered that the information on the exposure is considered inadequate for a proper characterization.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.2 effects on aquatic organisms	NL: the included information does not reflect the outcome of the study. Though to NL experts opinion some information is compiled in a strange way in the article, it seems there is some toxicity to fish in the study. This result should have been reported.	Although some A. vulgaris contained compounds can be toxic for fishes at certain doses, conclusion in Noor El Deen et al, 2009, garlic and Artemisia vulgaris can be used as an alternatives to chemicals to treat *Trichodina and Aeromonus* sp. infections in tilapia in laboratory trials.	Based on the limited available data, indicating potential effects on fish it is not possible to conclude a low risk on aquatic organisms. See also section 7.
8(2)		ES: No comments	-	Noted
8(3)	8.2 effects on aquatic organisms	EFSA: Based on the available information, the exposure of aquatic organisms cannot be excluded See comments 7.3, 7.4 and 7.5. Moreover, some of the plant extract ingredients seem to be very toxic.	Although some A. vulgaris contained compounds can be toxic for fishes at certain doses, conclusion in Noor El Deen et al, 2009, garlic and Artemisia vulgaris can be used as an alternatives to chemicals to treat *Trichodina and Aeromonus* sp.	Based on the limited available data, indicating potential effects on fish it is not possible to conclude a low risk to aquatic organisms. See also section 7.

8.2. Effects on aquatic organisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Therefore, as it is unclear from the submitted study whether there are adverse effects on fish, additional data are needed to conclude on a low risk.	infections in tilapia in laboratory trials.	

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.3.1.1 contact toxicity	NL: the information provided is too limited. As the original study is in French a more extended summary in English is requested. NL expert cannot reproduce the conclusion as reported from the figure that is presented. It is unclear to us what is the control an what is the toxic reference both from the study as from the summary presented. With limited knowledge of the French language NL expert thinks that effects were reported in the study mainly depending on the number of applications. Please provide more detailed information.	Reference Test : CEB Méthode n°230 : Méthode d'évaluation des effets des préparations phytopharmaceutiques sur l'abeille domestique *Apis mellifera* L. Same as for regular PPP ICPBR GIFFARD Hervé / Testapi –Vergnet Christine / Anses(F) Comparison between French and EPPO field test guidelines	The available information is not considered adequate to conclude a low risk to bees. It has also to be considered that the information on the exposure is considered inadequate for a proper characterization.
8(2)	8.3.1.2 Oral Toxicity	EFSA: The study submitted seems to show effects on bees at all the tested concentration but the highest one. Moreover, it is also stated that no effects on bee colonies are expected since the substance rapidly decline after the treatment. However, as there is no information on the time period for the	Reference Test : CEB Méthode n°230 : Méthode d'évaluation des effets des préparations phytopharmaceutiques sur l'abeille domestique *Apis mellifera* L. Same as for regular PPP ICPBR GIFFARD Hervé / Testapi –Vergnet Christine / Anses(F) Comparison between French and EPPO field test guidelines	The available information is not considered adequate to conclude a low risk to bees. It has also to be considered that the information on the exposure is considered inadequate for a proper characterization.

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		components in the extract to degrade, more data are needed to confirm that bees are not exposed.		
8(3)		DE: No data were submitted for the assessment of the product with regard to risk for bees.	GUILLET Bertrand 2012 Evaluation de l'INNOCUITE DE substances d'origine végétale SUR *APIS MELLIFERA*, in CASDAR Evaluation des caractéristiques et de l'intérêt agronomique de préparations simples de plantes, pour des productions fruitières, légumières et viticoles économes en intrants. AAP CAS DAR 2009, n° 9046. Reference Test : CEB Méthode n°230 : Méthode d'évaluation des effets des préparations phytopharmaceutiques sur l'abeille domestique *Apis mellifera* L. Same as for regular PPP	Addressed.
8(4)		DE: Experimental reports from which information about effects on beneficial organisms can be derived. were not submitted and would be helpful for the assessment of sustainability in the integrated pest management.	Reference added - *Artemisia vulgaris* as of 2014 Invasive Plants of Asian Origin Established in the US and Their Natural Enemies pp 21-27	Addressed

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		DE : Robust experimental studies carried out with relevant soil macro-organisms (e.g. the standard test earthworm Eisenia fetida) were not submitted and would be necessary for the	Eine Antwort finden Sie in Dossier « Schacht Kräutermischung Beifuß » als Pflanzenstärkungsmittel	The provided information is not considered adequate to conclude a low risk to earthworms and other soil macro-organisms. It has also to be noted that the

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		assessment of sustainability in the integrated pest management. Otherwise negative effects in regard to sustainability cannot be excluded.		information on the exposure is considered inadequate for a proper characterization
8(2)	8.4 effects on earthworms and soil macro organisms	NL: the information provided is about the use of Artemisia as a biopesticide against soil pathogens (nematodes) no information about soil non-target macro organisms is provided. Furthermore, there is no information on relevant exposure (see section 7). More information with regard to this should be provided.	1 Reference added	The provided information is not considered adequate to conclude a low risk to earthworms and other soil macro-organisms. It has also to be noted that the information on the exposure is considered inadequate for a proper characterization
8(3)		ES: No comments	-	Noted

8.5. Effects on soil microorganisms				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: no comments	-	Noted
8(2)		ES: No comments	-	Noted

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: no comments	-	Noted
8(2)		ES: No comments	-	Noted

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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)		NL: no comments	-	Noted
8(2)		ES: 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 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
9(1)	9 Overall conclusions	NL: According to the applicant no exposure assessment is required. In section 5.13 a general daily dosage of 0.5-2 g, 3 times daily is given. Since *Artemesia vulgaris* can produce toxic systems at high doses it would be useful to known how the exposure due to the use for plant protection purposes relates to the recommended daily dosage.	Attempt for better characterisation of impact, although Artemisia vulgaris is foodstuff in different countries, thus since is an intrinsic basic substance.	See section 5.13
9(2)	9 Overall conclusions	NL: no environmental exposure is considered due to the fact the plant is naturally occurring in the Northern hemisphere. However, a comparison in exposure route and level is not presented.		The information provided is insufficient to address fate and behaviour in the environment and characterise environmental exposure.
9(3)		ES: No comments	-	Noted

10. Other comments

Other comments				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		ES: No comments	-	Noted

ABBREVIATIONS

µg	microgram
ADI	acceptable daily intake
bw	body weight
CAS	Chemical Abstracts Service
DG SANCO	European Commission Directorate General Health and Consumers
EEC	European Economic Community
EFSA	European Food Safety Authority
EU	European Union
g	gram
GAP	good agricultural practice
ha	hectare
kg	kilogram
mg	milligram
PPP	plant protection product
TMDI	theoretical maximum daily intake
w/w	weight per weight