TECHNICAL REPORT

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

European Food Safety Authority[2]

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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 *Tanacetum vulgare* 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 *Tanacetum vulgare* as a basic substance for use in plant protection as repellent on orchards, vineyards, vegetables and ornamentals. 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

Tanacetum vulgare, basic substance, application, consultation, plant protection, pesticide

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SUMMARY

Tanacetum vulgare 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 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 in May 2014, EFSA was asked to organise a commenting on the basic substance application for *Tanacetum vulgare*, 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 *Tanacetum vulgare*, organised by the EFSA, was conducted with Member States and EFSA via a written procedure in May 2014-July 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 *Tanacetum vulgare* and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Tanacetum vulgare is extracted from the aerial parts of the plant *Tanacetum vulgare* L. The product is intended to be used as repellent on orchards, vineyards, vegetables and ornamentals. However, neither specification nor other supporting data regarding composition have been provided.

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 or extracting with hot water and steeping for long periods of time. It is also proposed that the pH is corrected. This means that *Tanacetum vulgare* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance is being prepared for these substances.

The limited available toxicological data show that *Tanacetum vulgare* compounds can cause different toxicological effects of concern, that cannot be fully quantified based on the information reported in the application. Therefore *Tanacetum vulgare* cannot be considered a basic substance. A reliable risk assessment for operators, worker, bystanders and residents could not be performed.

Since the toxicological profile of *Tanacetum vulgare* could not be fully quantified, a reliable consumer risk assessment could not be performed.

An environmental exposure assessment is not available, this would be necessary to complete a reliable environmental risk assessment and groundwater exposure assessment for this substance where different toxicological effects of concern have the potential to be caused.

A reliable risk assessment to non-target organisms could not be performed.

TABLE OF CONTENTS

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.

Tanacetum vulgare L. 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 repellent on orchards, vineyards, vegetables and ornamentals.

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for *Tanacetum vulgare*, which was conducted via a written procedure in May 2014-July 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 updated 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 *Tanacetum vulgare* 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 *Tanacetum vulgare* 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); 2013, 2014).

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 in May 2014, EFSA was asked to organise a commenting on the basic substance application for *Tanacetum vulgare*, 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 24 October 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 *Tanacetum vulgare* 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), 2013. *Tanacetum vulgare*. 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), 2014. *Tanacetum vulgare*. Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. August 2014. Submitted by Institut Technique de l'Agriculture Biologique (ITAB) . Documentation made available to EFSA by the applicant.

REFERENCES

EFSA (European Food Safety Authority) 2012. Compendium of botanicals reported to contain naturally occuring 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.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *TANACETUM VULGARE* 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)	Application of *Tanacetum vulgare* as basic substance in the Parliament and Council Regulation (EC) 1107/2009.	EFSA: *Tanacetum vulgare* L. is listed by EFSA Scientific committee as a botanical reported to contain substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663. Therefore, *Tanacetum vulgare* should be considered to be and/or contain substances of concern and is not eligible to be approved as a basic substance.	See global consideration report at chapter §9	No additional data could be found and therefore the original comment is still correct. *Tanacetum vulgare, L.* is listed by EFSA Scientific committee as a botanical reported to contain substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663. Therefore, *Tanacetum vulgare* should be considered to be and/or contain substances of concern and is not eligible to be approved as a basic substance.

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)	2.2.1, identity of the basic substance	EFSA: From the information provided it seems that the chemical nature of the plant is very complex and there are large variations in composition from region to region and from country to country. There is no proposed specification and no supporting data for a specification.	*Tanacetum vulgare* L. extract is registered in EU as cosmetic for perfuming, with **CAS #** 84961-64-8 INCI name: *TANACETUM VULGARE*	The essential oil is not allowed to be used as a food additive because of its toxicity. The original statement still stands. From the information provided it seems that the chemical nature of the plant is very complex and there are large variations in composition from region to region and from country to country. There is no proposed specification and no supporting data for a specification.

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)	General comment	ES: It might be useful to clarify the nature of basic substance. Oil, extract, dried flowering herb, etc., are terms used along the report. Maybe the cover of the report should also include this information (e.g. *Tanacetum vulgare* L. "extract").	*Tanacetum vulgare* L. extract "adopted as title	This is not a basic substance. What is being proposed is a hot water extract of the aerial parts of the plant.
2(3)	General comment	ES: Are the rates among the major	Tanacetum is not analysed itself,	The rates of the various components

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
	2.2.5. Description and specification of purity of the active substance and product	components constant?	chemotypes are defined by the content of volatiles or essential oil.	are likely to vary considerably. No data have been provided on this issue.
2(4)	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 in the BSA	The Spanish name has been included.

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
	No comments.			

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
	No comments.			

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
	No comments.			

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(5)	2.6, recipe	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. This means that it is being formulated and is not a basic substance. It is rather a plant extract and separate guidance is being prepared for these substances.	Not relevant, EC Implementing Regulation 462/2014 refers to a plant extract. Dilution occurs after extraction Botanicals 2.0 guideline do not exclude "basic substance" as approval opportunity.	The reply from the applicant in column three does not change the fact as detailed below. 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 or extracting with hot water and steeping for long periods of time. It is also proposed that the pH is corrected. This means that *Tanacetum vulgare* 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(6)	General comment	ES: Is not necessary to 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? And its accuracy?	Corrected in the BSA Maceration is needed in order to soak water into plant especially when dry plant are used. Active substances are not completely known, therefore accuracy and efficacy of the decoction is not known	It is not clear if maceration is required. The description of the process is not correct as macerate is being used in the wrong sense. The efficacy of the extracts is unknown.

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
	No comments.			

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
	No comments.			

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.	Tansy (*Tanacetum vulgare* L.) is listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: bellaflora biogarten Rainfarn und Wermut FSC 31.07.2013 It is therefore not significantly considered as toxic.	The efficacy of the extracts is unknown.

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(2)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses.	More literature is provided	The efficacy of the extract is unknown.

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
		The cited literature speculates on the mode of action. It remains unclear. Overall, only limited effect in some uses described should be expected.		
3(3)		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.	Article 23 of Regulation 1107/2009 is mentioning "utility", not efficacy. Finally, repellence is most likely the main effect of *Tanacetum vulgare* L. extract	The efficacy of the extract is unknown.
3(4)	General comment	ES: It is not possible to define the purity of the active substance. The active substance is the dried flowering herb. 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"	No It is calculated as if all plant is soluble (extrapolation worst case)	The concentration of the active substance(s) is unknown. The only measurement possible is the weight of the dried plant material.
3(5)		ES: In the footnote of the summary of intended uses, it is indicated "… *extracted with hot water*…" but in the point 2.6 (Description of the recipe for the product to be used) it is specified in another way. Please, clarify.	Description added in the recipe	The recipe has been provided for the extraction procedure which according to the legislation means this is not a basic substance.

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(6)		ES: In the "Remarks" the following should be included: "*The preparation has to be used in the 24 hours after the preparation because the water extract is sensible to oxygen and or avoiding the potential contamination and multiplication of microorganisms during the storage*."	Corrected	This has been included in the remarks.

4. 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)			Hazard Statement Code(s) added in BSA corresponding to § 10 question	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)	General comment	EFSA: the available toxicological data (limited only to few *Tanacetum vulgare* L. compounds) show that they can cause different toxicological effects of concern. Therefore *Tanacetum vulgare* L cannot be considered a basic substance.	See global consideration report at chapter §9	The limited available toxicological data show that *Tanacetum vulgare* L compounds can cause different toxicological effects of concern, that cannot be fully quantified based on the information reported in the application. Therefore *Tanacetum vulgare* L cannot be considered a basic substance.
5(2)	5.1 General comment p17ff!	DE: All endpoints concerning human health should be addressed by a brief description of possible effects followed by an evaluation whether these effects are relevant for the extract applied for. Some endpoints are only addressed by citation of abstracts derived from publications. We suggest the amendment of the report.	$ see global consideration report at chapter §9	See 5(1)
5(3)	5.1.1 Camphor, p 17	DE: Please check whether the text concerning thujone ("*Thujon is present in food with ingredients…")* is displaced under the heading 5.1.1. Camphor. The text and citation concerning thujone is probably displaced and should be described under "5.1.2 Thujone".	Corrected	Addressed

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(4)	5.2 Toxicokinetics, p18	DE: Please add information on the metabolism and kinetics of 1,8-cineole and camphor. There is a limited number of studies available in the open literature concerning kinetics including dermal absorption and metabolism of 1,8-cineole and camphor. As these compounds are very well absorbed (dermally and orally) but are expected to be present only in low concentrations in the tansy water extract kinetic data should be included in the overall risk assessment.	All details should be available in the aplication of Tansy (*Tanacetum vulgare* L.) as plant strengthener listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: bellaflora biogarten Rainfarn und Wermut FSC 31.07.2013 As it was allowed in this light category of plant strengthener, no significant toxicity should be envisaged.	See 5(1)

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
	No comments.			

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

No comments.

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(5)	5.5.2 Thujone	DE: Please add description of the results performed by NTP 2011 on thujone. NTP investigated the genotoxic potential of thujone in mice and rats. The results were published in 2011, Report No. 570, and should be added.	Complete Report No. 570 added in bibliography	Addressed

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(6)	5.6 Long-term toxicity, p. 21	DE: Please add description of the results performed by NTP 2011 on thujone. NTP investigated the carcinogenic potential of thujone in mice and rats. The results were published in 2011, Report No. 570, and should be added.	Complete Report No. 570 added in bibliography	Addressed

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
	No comments.			

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(7)	5.8 Neurotoxicity, p 23	DE: General proposal concerning neurotoxicity (genotoxicity, carcinogenicity) of thujone: Article 23 of Reg (EC) No 1107/2009 clearly states that a basic substance must not have inherent capacity to cause neurotoxic effects. As thujone is clearly neurotoxic but is expected to be present in low concentrations in the decoction calculation of thujone (e.g. as performed at pp 17-18) should be included in the risk assessment. This is also relevant as genotoxic effects were observed in female mice and some evidence of carcinogenic activity were identified in male rats in the NTP study (2011, both concerning α,β-thujone).	All details should be available in the aplication of Tansy (*Tanacetum vulgare* L.) as plant strengthener listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: bellaflora biogarten Rainfarn und Wermut FSC 31.07.2013 As it was allowed in this light category of plant strengthener, no significant toxicity should be envisaged. See global consideration report at chapter §9	See 5(1)

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
	No comments.			

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(8)	5.10 Medical Data, p. 24	DE: The allergic potential of tansy extract should be evaluated. Skin allergy has been mentioned very briefly only. More available information should be described and evaluated.	See global consideration report at chapter §9	See 5(1)
5(9)	5.10 Medical Data, p. 25	DE: Cases of accidental poisoning with camphor should be included in the risk assessment using calculation. Intoxication from camphor ingestion and dermal application is reported in the literature. On the other hand, camphor is expected to be present in low concentrations in the decoction. Calculation of camphor concentration in the extract (e.g. as performed on pp 17-18) should be included in the risk assessment.	See global consideration report at chapter §9	See 5(1)

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
	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
	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(10)		EFSA: the available toxicological data do not allow setting reliable reference values.	See global consideration report at chapter §9	See 5(1) A reliable risk assessment cannot be performed

5(11)	5.13, p. 27	DE: The calculation of operator exposure is not comprehensible. Please make clear, how the thujone concentration in the preparation was derived. The exposure estimate of 1.46 mg/day (=0.02 mg/kg bw) exceeds the TMDI for thujone of 0.01 mg/kg bw. Please comment on this.	See global consideration report at chapter §9	See 5(1) A reliable risk assessment cannot be performed
5(12)	5.13 Acceptable daily intake… p 27	DE: Please derive the AOEL and describe the basis for its derivation. Only values for a NOAEL/LOAEL are given without derivation of the AOEL. The basis for these values should be mentioned (again).	See global consideration report at chapter §9	See 5(1) A reliable risk assessment cannot be performed
5(13)	5.13 Acceptable daily intake… p 27	DE: Please rephrase the text concerning the Acute Reference Dose (*LD_{50} between 5 and 15 g/kg is non-toxic in humans*). An LD_{50} cannot be non-toxic. Furthermore, derivation of ARfD (or non-derivation) should be described in a more comprehensive way. The same applies for the ADI – ADI for thujone should be added here (displaced from above) and the basis for its derivation should be given. (Lachenmaier and Uebelacker 2010). In general, derivation of reference values should be performed in a comprehensive way. Justification should be given if derivation is considered not required.	See global consideration report at chapter §9	See 5(1) A reliable risk assessment cannot be performed

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
	No comments.			

6. 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)		EFSA: A statement on residues should be provided. Moreover, if toxicological concerns are indentified in the Phys-Chem or Tox. sections, the possible impact on the consumers safety should be addressed.	See global consideration report at chapter §9	Since the toxicological profile of *Tanacetum vulgare* could not be fully quantified (see point 5(1)), a reliable consumer risk assessment cannot be performed.
6(2)	p.28	DE: A general statement on residues background exposure should be provided.	See global consideration report at chapter §9	See point 6(1)

7. 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)	7. Fate and behaviour into the environment. General	EFSA: no data and no exposure assessment is provided. Taking into account the various adverse effects reported to be caused by *Tanacetum vulgare* and / or some of its identified components to human health and animal health data, on the persistence and mobility of *Tanacetum vulgare* in the different environmental compartments and assessment of the exposure to them under the proposed conditions of use would need to be presented and assessed.	See global consideration report at chapter §9	No data and no exposure assessment is provided. Taking into account the various adverse effects reported to be caused by *Tanacetum vulgare* and / or some of its identified components to human health and animal health, data on the persistence and mobility of *Tanacetum vulgare* in the different environmental compartments and assessment of the exposure to them under the proposed conditions of use would need to be presented and assessed. PEC in surface water and sediment need to be calculated for those components present in *Tanacetum vulgare* known to cause adverse effects to aquatic organisms. Potential contamination of ground water above regulatory limits and / or level of concern by components in *Tanacetum vulgare* that are reported to be toxic and neurotoxic organic substances need to be assessed. Therefore *Tanacetum vulgare* cannot be considered a basic substance.
7(2)	7. Fate and behaviour into the environment.	EFSA: Under 8.2 it is stated that *Tanacetum vulgare* is very toxic to aquatic	See global consideration report at chapter §9	See 7(1)

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
	Aquatic environment.	organisms and may cause long term adverse effects in the aquatic environment. PEC in surface water and sediment need to be calculated for those components present in *Tanacetum vulgare* known to cause adverse effects to aquatic organisms.		
7(3)	7. Fate and behaviour into the environment. Ground water.	EFSA: A number of components in *Tanacetum vulgare* are reported to be toxic and neurotoxic organic substances. Potential contamination of ground water above regulatory limits and / or level of concern with respect to human health need to be assessed.	See global consideration report at chapter §9	See 7(1)

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)	8.1.1 Birds	DE: No information has been provided by the applicant regarding the effects of *Tanacetum vulgare* on birds.	See global consideration report at chapter §9	No data on effects on birds were provided. The exposure to birds following the uses proposed in the GAP could not be excluded but no exposure estimations were provided. A risk assessment cannot be performed.
8(2)	8.1.2 Mammals	DE: The information submitted in the application is not sufficient to describe the risk of an application of *T. vulgare* for mammals. *Tanacetum vulgare* L is known to possibly cause damages in liver and kidney of mammals and irritation of mucous membranes.	See global consideration report at chapter §9	The information available is not sufficient for the hazard characterisation to mammals (see point 5(1)). The exposure to mammals following the uses proposed in the GAP could not be excluded but no exposure estimations were provided. A risk assessment cannot be performed.

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(3)		DE: According to the application *Tanacetum vulgare* is very toxic to aquatic	See global consideration report at chapter §9	No data on effects on aquatic organisms were provided. *Tanacetum*

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
		organisms and can cause long-term adverse effects in the aquatic environment. Unacceptable risks for non-target organisms caused by the application of *Tanacetum vulgare* cannot be tolerated. Effects on organisms in ground, surface or underground water have to be described more detailed.		*vulgare* is classified as toxic to aquatic environment with long lasting effects. The exposure to the aquatic environment following the uses proposed in the GAP could not be excluded but no exposure estimations were provided. A risk assessment cannot be performed.
8(4)		ES: As it is indicated, "According to the New Directions Aromatics, *Tanacetum vulgare* is very toxic to aquatic organism may cause long-term adverse effects in the aquatic environment. Avoid any pollution of ground, surface or underground water". Because of this we consider that it should be included a risk assessment of the effects on aquatic organisms.	See global consideration report at chapter §9	See 8(3)

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(5)		DE: No data were submitted for the assessment of the product with regard to risk	See global consideration report at chapter §9	Based on the information provided (acute LD_{50}>40µg a.s./bee) a high risk

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
		for bees.		to bees could not be excluded for the representative uses.
8(6)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	See global consideration report at chapter §9	No data on effects on non-target arthropods were provided. The exposure to non-target arthropods could not be excluded for the representative uses but no exposure estimations were provided. A risk assessment cannot be performed.
8(7)	8.3.2 Effects on other arthropods	DE: Because of the insecticidal effect of *Tanacetum vulgare* an unacceptable risk for non-target arthropods cannot be excluded. The submitted information is not suitable to describe the risk for non-target arthropods.	See global consideration report at chapter §9	See 8(6)

8.4. Effects on earthworms and other soil macro-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(8)		DE: *Tanacetum vulgare* is used as a vermifuge. The possible effects on earthworms and other soil macro-organisms are not described sufficiently in the application and robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm *Eisenia fetida*) were not submitted. Negative effects on earthworms and other soil macroorganisms cannot be excluded.	See global consideration report at chapter §9	Adverse effects and exposure on soil organisms could not be excluded for the representative uses. A reliable risk assessment cannot be performed.

8.5. Effects on soil micro-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(9)		DE: *Tanacetum vulgare* has antimicrobial effects. No experimental reports were submitted from which information about effects on soil micro-organisms can be derived. With the information given in the application an unacceptable risk for soil micro-organisms cannot be excluded.	See global consideration report at chapter §9	See 8(8)

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
	No comments.			

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
	No comments.			

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

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
9(1)	9 (a) is not a substance of concern	EFSA: *Tanacetum vulgare* is listed by EFSA Scientific committee as a botanical reported to contain substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663. Therefore, *Tanacetum vulgare* should be considered to be and/or contain substances of concern and is not eligible to be approved as a basic substance.	Summarizing toxicological reviews on this Tanacetum BSA, EFSA and some member states point to this application is not admissible as basic substance for such toxicological concerns. Two possible ending issues are: 1. Either Tanacetum is not acceptable, and MS have therefore to remove corresponding products sold and advertised as plant strengtheners in their own countries. Example of Products : bellaflora biogarten Rainfarn und Wermut; Bio-Vitalspray mit Rainfarn und Wermut and Rainfarn für Pflanzen sold by F. Schacht GmbH & Co. KG Bültenweg 48, D-38106 Braunschweig. and all corresponding products from the **Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG** http://www.bvl.bund.de/DE/04_Pflanzenschutzmittel/01_Aufgaben/04_Pflanzenstaerkungsmittel/psm_Pflanzenstaerkungsmittel_node.html 2. Or Tanacetum, sold as plant strengthener in many European countries is not of concern and this application is a regularization of field practices in accordance with "utility" claimed in article 23 and whereas (18).	See 1(1)

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
9(2)		ES: From our point of view and taking into account that *Tanacetum vulgare* is very toxic to aquatic organism and it may cause long-term adverse effects in the aquatic environment, we consider that this should be clarified in order to affirm that this substance fulfil the criteria of "*is not a substance of concern"*		See 1(1), 8(3), 10(1)

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: In the point 4: **Classification and labelling of the substance**. Here it should be specified that the substance is very toxic to aquatic organism and it may cause long-term adverse effects in the aquatic environment. Avoid any pollution of ground, surface or underground water.	Hazard Statement Code(s) added in BSA § 4 corresponding this question	See 4(1).

ABBREVIATIONS

µg	microgram
ADI	acceptable daily intake
a.i.	active ingredient
AOEL	acceptable operator exposure level
ARfD	acute reference dose
a.s.	active substance
bw	body weight
CAS	Chemical Abstracts Service
EU	European Union
g	gram
INCI	International Nomenclature of Cosmetic Ingredients
kg	kilogram
LD_{50}	lethal dose, median; dosis letalis media
LOAEL	lowest observable adverse effect level
mg	milligram
NOAEL	no observed adverse effect level
NTP	US National Toxicology Programme
PEC	predicted environmental concentration
pH	pH-value
TMDI	theoretical maximum daily intake