TECHNICAL REPORT

APPROVED: 22 September 2016

Outcome of the consultation with Member States and EFSA on the basic substance application for *Millefolii herba* - Yarrow infusion for use in plant protection as fungicide and insecticide on various crops and to prevent freezing

European Food Safety Authority (EFSA)

Abstract

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context, EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Millefolii herba* - Yarrow infusion 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 *Millefolii herba* - Yarrow infusion as a basic substance for use in plant protection as fungicide and insecticide on various crops and to prevent freezing. The current report summarises the outcome of the consultation process organised by EFSA and presents EFSA's scientific views on the individual comments received.

Keywords: *Millefolii herba* - Yarrow infusion, basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: EFSA-Q-2016-00404

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Summary

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

In March 2013, the European Commission requested the European Food Safety Authority (EFSA) to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received from the European Commission in June 2016, EFSA was asked to organise a consultation on the basic substance application for *Millefolii herba* - Yarrow infusion, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table within three months of acceptance of the specific request.

A consultation on the basic substance application for *Millefolii herba* - Yarrow infusion, organised by EFSA, was conducted with Member States via a written procedure in March-May 2016. Subsequently, EFSA also provided comments and the applicant was invited to address all the comments received in the format of a reporting table and to provide an application update as appropriate, within a period of 30 days.

The current report summarises the outcome of the consultation process organised by EFSA on the basic substance application for *Millefolii herba* - Yarrow infusion and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

It has been clarified that only material meeting the specifications of European Pharmacopeia for the full aerial part of *Millefolii herba* is proposed to be used in the preparation of the infusion used as plant protection product.

Content of the active compounds in *Millefolii herba* - Yarrow infusion, resulting from a detailed recipe, is currently not available and would need to be clearly specified in order to perform an adequate risk assessment. Furthermore, methods to analyse these active compounds need to be provided. In particular, eugenol has been identified as one of the active components in *Millefolii herba* - Yarrow infusion. Eugenol has been approved as an active substance to be used in the formulation of plant protection products (Reg. (EU) No 546/2013)[1]. Further data has been required to be provided by the applicant of eugenol within two years after its approval in order to guarantee an adequate protection of workers, bystanders, residents, consumers (through groundwater) and the environment. Risk managers may need to consider whether equivalent provisions and information would be needed for *Millefolii herba* - Yarrow infusion with respect to its eugenol content. Similar considerations may need to be taken into account with respect to other active components in *Millefolii herba* - Yarrow infusion.

Insufficient scientifically documented data on efficacy and lack of phytotoxicity of *Millefolii herba* - Yarrow infusion with regard to the intended uses has been provided.

With regards to the impact on human and animal health, evidence of actual use of *Achillea millefolium*, *Millefolii herba* or yarrow as simple food or as aromatic herb has not been provided. The infusion contains chemicals of possible concern to human health when used in food and food supplements, such as alpha- and beta-thujone, camphor and 1,8-cineole (EFSA, 2012). Herbal tea uses are mainly related to traditional medicine. Concerns regarding possible adverse effects for pregnant women and on sperm parameters, as well as its endocrine disrupting potential have not been addressed. Based on human experience, the herbal preparation may need to be classified as a skin sensitiser.

[1] Commission Implementing Regulation (EU) No 546/2013 of 14 June 2013 approving the active substance eugenol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011 . OJ L 163, 15.6.2013, p. 17–20.

Since adverse effects have been reported on some constituent components of infusion of *Millefolii herba* and since no information has been provided on the possible residues resulting from the use of *Millefolii herba* - Yarrow infusion as plant protection product, a consumer risk assessment could not be completed.

There is no information pertaining to the environmental fate and behaviour of any components of the recipes in the applicant's submission. Acceptable supporting documents / primary research papers that might contain such information were not included in the submission.

No data were available in the area of ecotoxicology to perform a risk assessment to non-target organisms. Since the exposure to non-target organisms cannot be excluded for the proposed uses, and considering the mode of action of the substance, further data are considered necessary.

Table of contents

1. Introduction

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

Regulation (EC) No 1107/2009[2] (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.

Millefolii herba - Yarrow infusion is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Institut Technique de l'Agriculture Biologique (ITAB) for approval as a 'basic substance' for use in plant protection as fungicide on cucurbitaceae, corn, grapevine and tomato; as an insecticide on cabbage, turnip cauliflower, rape and horseradish and to prevent fruit trees from freezing.

The European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for *Millefolii herba* - Yarrow infusion, which was conducted via a written procedure in March-May 2016. The comments received, including EFSA's comments, were consolidated by EFSA in the format of a reporting table. Subsequently, the applicant was invited to address the comments in column 4 of the reporting table and to provide an application update as appropriate. The comments received and the response of the applicant thereon, together with the application update submitted by the applicant, were considered by EFSA in column 5 of the reporting table.

The current report aims to summarise the outcome of the consultation process organised by EFSA on the basic substance application for *Millefolii herba* - Yarrow infusion 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 *Millefolii herba* - Yarrow infusion as a 'basic substance' in the context of Article 23 of the Regulation, is a key supporting documentation, therefore it is considered as a background documentation to this report and will also be made publicly available, excluding its appendices (ITAB, 2015, 2016).

1.2. Interpretation of the Terms of Reference

On 6 March 2013 the European Commission requested EFSA to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. By a further specific request, received by EFSA on 22 June 2016, EFSA was asked to organise a consultation on the basic substance application for *Millefolii herba* - Yarrow infusion, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a reporting table.

To this end, a technical report containing the finalised reporting table is being prepared by EFSA. The agreed deadline for providing the finalised report is 22 September 2016.

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

[2] Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, p. 1-50.

2. Assessment

The comments received on the basic substance application for *Millefolii herba* - Yarrow infusion and the conclusions drawn by EFSA are presented in the format of a reporting table.

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

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

Documentation provided to EFSA

1. ITAB, 2015. Basic substance application on *Millefolii herba* - Yarrow infusion submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2015. Documentation made available to EFSA by the European Commission.

2. ITAB, 2016. Basic substance application update on *Millefolii herba* - Yarrow infusion submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July, 2016. Documentation made available to EFSA by the applicant.

References

EFSA, 2012. Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663

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

Abbreviations

a.s.	active substance
DAR	draft assessment report
DC	dispersible concentrate
EMA	European Medicines Agency
EU	European Union
GAP	good agricultural practice
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
PPP	Plant Protection Product
US NLM - Toxnet	United States National Library of Medicine – Toxicology data network

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Millefolii herba* - Yarrow infusion and the conclusions drawn by EFSA on the specific points raised

1. Purpose of the application

General					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
1(1)	General comment	ES: A title of the application with a more restrictive description as "*Achillea millefolium L.* (aerial parts)" would be more suitable.		*Millefolii herba* or Yarrow infusion was proposed. Applicant acknowledges position of ES M.S. as for *Equisetum*.	Addressed.
1(2)		NL: no comments			Noted
1(3)	General issue	DE: It is not agreed to approve *Millefolii herba – Yarrow infusion* as basic substance. The product contains a mixture of different active substances. The submitted data indicate that some of these substances are genotoxic, carcinogenic, neurotoxic, endocrine disrupting and/or toxic on reproduction. Therefore, further toxicological information is needed. The criteria for basic substances according to article 23 of Regulation (EC) No 1107/2009 are not fulfilled. It is proposed that the		Listed in French pharmacopeia "without risk" Arrêté 2008" and authorized as biostimulant as well. Is still at DE pharmacopeia: http://buecher.heilpflanzen-welt.de/BGA-Commission-E-Monographs/0380.htm Schafgarbe is alse biostimulant in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG so DE M.S. allows and legalize endocrine disruptor substance on its territory. Applicant applies the guidance document on botanical active substances	EFSA considers the fulfilment of criteria for basic substances according to article 23 of Regulation (EC) No 1107/2009 a risk management issue and do not expresses an opinion on them. With respect to the toxicological issues, see Section 5.

General					
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		application for approval of *Millefolii herba – Yarrow infusion* and the authorisation of plant protection products with *Millefolii herba – Yarrow infusion* should be based on the guidance document on botanical active substances (SANCO/11470/2012).		(SANCO/11470/2012) and especially Point §15.	

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

2.1. Identity and Physical and chemical properties of the substance and product to be used

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.1. Identity and physical chemical properties of the substance and product to be used	ES: It should be clarified the meaning of (f) and (g) in the table of the page 5.		Clarified; Legend added.	Addressed
2(2)	2.1.4. Description and specification of purity of the active substance and product	ES: *Millefolii herba* contains active substances used in crops protection (e.g. several terpenes), some of them even included in the Annex I (i.e. eugenol, thymol). Therefore, a maximum content of these active substances should be established.		This plant extract issued from natural plant does not have anything to do with synthetic chemicals. Content is described in tables found in Point §2.	Content of the active compounds in the infusion of *Millefolii herba,* resulting from a detailed recipe, need to be clearly specified in order to perform an adequate risk assessment.
2(3)	2.1.6. Methods of analysis	ES: Analytical methods for components of *Millefolii herba* included in the Annex I should be provided.		French Pharmacopiea added TLC scheme added.	Only qualitative analysis on the *Millefolii herba*, as described in the European pharmacopeia has been provided. Methods to analyse the individual active compounds in the infusion would need to be provided.
2(4)	2.1 Table page 5	NL: Eugenol should be included in the table (Eugenol is included in the tables on pages 6 and 7)		Eugenol is described in BSA p6 at Point 2.1.1.	Eugenol has been identified as one of the active components in the *Millefolii herba* infusion. Eugenol has been approved as an active substance to be used in the formulation of plant protection products (Reg. (EU)

2.1. Identity and Physical and chemical properties of the substance and product to be used					
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					No 546/2013). Further data has been required to be provided by the applicant of eugenol within two years after its approval in order to guarantee an adequate protection of workers, bystanders, residents, consumers (through groundwater) and the environment. Risk managers may need to consider whether equivalent provisions and information would be needed for *Millefolii herba* - Yarrow infusion with respect to its eugenol content. Conditions of use of other active components already authorized as active substances of plant protection products may also need to be considered with respect to *Millefolii herba* infusion.
2(5)	2.1.1 CAS number	EFSA: Is this CAS number referring to *Achillea millefolium* L. flower extract or just to *Achillea millefolium*, ext. or to both?		CAS number is referring to both, alternatively in literature, cosmetic and chemical database. ECHA consider Yarrow, *Achillea millefolium*, ext.	Addressed
2(6)	2.1.4 Specification	EFSA: is our understanding correct	Reference is made to the European	ECHA consider Yarrow, *Achillea*	Applicant clarified that the

2.1. Identity and Physical and chemical properties of the substance and product to be used

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	of the purity, p.8	that the submission is for *Millefolii herba*, i.e the aerial part of the plant and not for just the flowers?	Pharmacopeia 2005, where it seems that both or just one is also covered, and consequently, the composition would be different in the two cases. Clarification is needed.	*millefolium*, ext. for full aerial part of the plant. Applicant too.	application refers to the full aerial part of *Millefolii herba* not just the flowers.
2(7)	2.1.4 Specification of the purity, p.8	EFSA: the reference to the European Pharmacopeia would mean that this is the quality required, however in EMA/HMPC/290309/2009, also referenced it is stated that only about 50% of the samples met the standards of the European Pharmacopeia. Does this have any effect on the properties, efficacy of the product?		Reference Benedek 2008 added providing support for these results. No answer from applicant. Tested samples meet the Pharmacopeia specifications.	It is clarified that only material meeting the specifications of European Pharmacopeia is proposed to be used in the preparation of the infusion used as plant protection product.

2.2. Current Former and in case proposed trade names

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(8)		ES: No comments			Noted
2(9)		NL: no comments			Noted

2.3. Manufacturer of the substance/products					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(10)		ES: No comments			Noted
2(11)		NL: no comments			Noted

2.4. Type of preparation					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(12)		ES: No comments			Noted
2(13)		NL: no comments			Noted

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
2(14)	2.5. Description of the recipe for the product to be used	ES: Concentration of the infusion is dependent of the efficacy of the extraction. In this sense, it might be useful to provide an estimation of this parameter. Moreover, particle size, time and stirring could play an important role in the efficacy of the extraction. The use of pressure can also influence. Therefore, these parameters		Recipe is described as infusion (herbal tea) without pressure.	Recipe on the preparation of the "infusion" has not been given with enough detail and it is not prescriptive enough to guarantee consistent composition and therefore efficacy and safety properties of the applied product.

2.5. Description of the recipe for the product to be used					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		should also be described in more detail.			
2(15)	2.5. Description of the recipe for the product to be used	ES: Is the final concentration of the infusion tested? Otherwise, how is guaranteed a product with always similar properties, to be used according to the summary of intended uses (issue 3.4)?		Concentrations given in GAP Table are based on quantities before extraction.	See 2(14)
2(16)		NL: no comments			Noted
2(17)	2.5. Description of the recipe for the product to be used	EFSA: it is not clear how the different recipes described in this section correlate with the GAP table.	Explanation, harmonisation would be needed.	References for recipe are given for support. Unique recipe retrained for GAP Table is described in Point §2.5.	See 2(14)

3. Uses of the substance and its product

3.1. Field of use

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(1)		ES: Between the intended uses, the use for "*Sclerotinia Fuckelania*, the causal agent of strawberry grey mould" appears. This use is not included in the GAP table and the efficacy of the proposed basic substance on it is not demonstrated.		Line supressed in Point 3.1.	Addressed
3(2)		ES: Regarding the use against Small white butterfly *Pieris rapae*, all the intended crops (cabbage, cauliflower…), should be specified in the point 3.1		Corrected	Addressed
3(3)		ES: It should be included the use as Antifreeze action and the intended crops (Fruit trees) in the point 3.1 Field of use.		Corrected	Addressed
3(4)		DE: No specific data were provided which allow a detailed description of the cited GAPs.		Typical obstruction from DE M.S., not addressed	The opinion of some MS in relation of the lack of detailed description of the GAPs has not been properly addressed by the applicant.
3(5)		NL: 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(6)		ES: No comments			Noted
3(7)		NL: no comments			Noted
3(8)		DE: The literature cited and submitted does not provide the prediction of sufficient efficacy in the intended uses. The cited literature leaves the mode of action unclear. Overall, only limited effect in the uses described should be expected.	In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exist.	Efficacy or utility is one point, Mode of action (MOA) is another. Mode of action may be explain by components or the sum of the components without full explanation. Complexity of the mixture gives hard time to estimate unique and clear MOA.	Not enough scientifically documented data on efficacy of *Millefolii herba* infusion with regard to the intended uses has been provided.
3(9)	3.2.2.1 Mode of action against fungi 3.222 Mode of action against insects	EFSA: a trial was made to try to link the mode of action to certain compounds of the extract and also a minimum content of some components. As the composition of these compounds depends on many factors, is it possible to define a minimum specification assuring some efficacy?		Usual applications and proposed substances (chemical or not) intend to target one bioagressor specifically.	See 2(14)
3(10)	3.3.2 Usefulness against insects, p.17	EFSA: it does not seem that these studies demonstrate a proper efficacy of the extract against insects		If biocide properties are required for efficacy against insect EFSA is right, if repellence and non-biocide mode of action is intended Yarrow infusion is considered	See 3(8)

3.2. Effects on harmful organisms or on plants

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				as utile.	
3(11)	3.3.2 Usefulness against freeze, p.18	EFSA: it is strange to conclude on the usefulness of yarrow infusion against freeze when in the preceding paragraph it is stated that yarrow alone is inefficient		Regarding synergistic effect of plant extracts, and it is clearly observed in this case, we need both to get better efficacy.	See 3(8)

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
3(12)		ES: In the headline of the GAP table, the units of Application rate per treatment and Total rate are wrong (kg/ha and g/ha)		Corrected	Addressed
3(13)		ES: For cucurbitaceae, corn, grapevine and tomato, the application rate per treatment (kg/ha) is wrong taking into account the kg ai/hl and the water l/ha. Due to this, the Total rates for all these crops are also wrong.		Corrected	Addressed
3(14)		ES: In remarks, for some intended uses it is indicated "Mix with		Corrected	No scientifically documented data on the efficacy of the

3.3. Summary of intended uses

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		other basic substances for better efficiency". It should be specified what basic substances and in what proportion.			proposed mixture with other basic substances (like *Equisetum*) has been provided. See also 3(8)
3(15)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Please provide reasons for your opinion that no phytotoxicity must be expected.	Extract of yarrow (containing more than 60% water) at 10 to 25 g/L filtered and not intended for herbicide action used for decades by organic and biodynamic farmers may be accepted as non-phytotoxic…	No scientifically documented data on the lack of phytotoxicity of the proposed preparation of *Millefolii herba* has been provided.
3(16)		NL: no comments			Noted
3(17)	3.4 Summary of intended uses, p.19	EFSA: if the value for kg a.i/hl is correct, the kg/ha values should be verified taking into account the min. and max amount of water proposed.		Corrected	Addressed
3(18)	3.4 Summary of intended uses, p.19	EFSA: it is not clear from where the three "formulations" having different active ingredient content are coming? How are these correlated with the recipes described before?		Corrected	See 2(14)

4. Classification and labelling of the substance

Classification and labelling of the substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
4(1)		NL: no comments			Noted
4(2)	5.2 Acute toxicity, European Medicine Agency. 2010 Assessment report on Achillea millefolium L., herba. EMA/HMPC/290309/2009	EFSA: Chapter 5.1 and overall conclusion of the EMA assessment report on *Achillea millefolium* L. is that there is a possible risk of hypersensitivity. Cases of allergic contact dermatitis have been described since 1899; a 5-year follow-up (1985-1990) of Compositae-sensitive patients showed that more than 50% reacted when tested with an ether extract of yarrow. On this basis, classification of the herbal preparation as skin sensitiser may be required.	EFSA: based on human experience, the herbal preparation should be classified as a skin sensitiser.	Skin sensitizer Added in Point §4	Based on human experience, the herbal preparation may need to be classified as a skin sensitiser.

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No comments.

5.2. Acute toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	5.2 Acute toxicity, European Medicine Agency. 2010 Assessment report on Achillea millefolium L., herba. EMA/HMPC/290309/2009, p. 26	EFSA: Chapter 5.1 and overall conclusion of the EMA assessment report on *Achillea millefolium* L. is that there is a possible risk of hypersensitivity reaction that should be taken into consideration to draw patients' attention properly. This warning cannot be applied to its use as PPP.	EFSA: the skin sensitisation properties of the herbal preparation should be further addressed.	Listed in French pharmacopeia "without risk" Arrêté 2008" and authorized as biostimulant as well. Allowed also in DE M.S. as biostimulant. Is still at DE pharmacopeia: http://buecher.heilpflanzen-welt.de/BGA-Commission-E-Monographs/0380.htm Used as human treatment.	See 4(2)

5.3. Short-term toxicity

No comments.

5.4. Genotoxicity

No comments.

5.5. Long-term toxicity

No comments.

5.6. Reproductive toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(2)	section 5.6, page 28	NL: in the evaluation by the European Medicine Agency (2010) it is described that yarrow is contra-indicated for use in pregnancy. In addition, it is described that a significant increase in abnormal sperm was noted in Wistar rats. Effects on sperm parameters is also found in the paper by Takzare (2011) which concluded that A. millefolium causes antifertile activity in adult male animals. These concerns are not sufficiently addressed in the assessment report. It is noted that a basic substance should not have the inherent capacity to cause endocrine disrupting effects. In the EMA evaluation it is indicated that *A. millefolium* showed oestrogenic activity in MCF-7 cells and positive effects were also observed with compounds isolated for the extract (apigenin, luteolin). This suggests a possible endocrine	EFSA: Herbal tea uses are mainly related to traditional medicine. Concerns regarding possible adverse effects for pregnant women and on sperm parameters and endocrine disrupting potential should be addressed.	*A. millefolium* is considered as biostimulant in France (*Achillée millefeuille*) since April 2016 and linked to list of acceptable herbal teas intended for human consumption (Décret no 2008-841 du 22 août 2008 relatif à la vente au public des plantes médicinales inscrites à la Pharmacopée et modifiant l'article D. 4211-11 du code de la santé publique). *A. millefolium* is considered as biostimulant (Bio-Pflanzenspray mit Schafgarbe & Brennnessel) in Germany (Schafgarbe) since years (Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG) since 2014.	Herbal tea uses are mainly related to traditional medicine. Concerns regarding possible adverse effects for pregnant women and on sperm parameters, as well as its endocrine disrupting potential have not been addressed.

5.6. Reproductive toxicity

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

5.7. Neurotoxicity

No comments.

5.8. Toxicity studies on metabolites

No comments.

5.9. Medical Data: adverse effects reported in humans

No comments.

5.10. Additional Information related to therapeutic properties or health claims

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(3)	5.10 page 34	NL: according to the EMA report yarrow herb has estrogenic effects. According to Regulation (EU) 1107/2009 a substance cannot be approved as a basic substance when it has an inherent capacity to cause endocrine disruption.	EFSA: the endocrine disrupting potential of yarrow herb should be further addressed.	*A. millefolium* is considered as biostimulant in France (*Achillée millefeuille*) since April 2016 and linked to list of acceptable herbal teas intended for human consumption (Décret no 2008-841 du 22 août 2008 relatif à la vente au public des plantes médicinales inscrites à la Pharmacopée et modifiant	See 5(2)

5.10. Additional Information related to therapeutic properties or health claims					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
				l'article D. 4211-11 du code de la santé publique). *A. millefolium* is considered as biostimulant (Bio-Pflanzenspray mit Schafgarbe & Brennnessel) in Germany (Schafgarbe) since years (Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG) since 2014. Please inform those M.S. about this concern.	

5.11. Additional Information related to use as food					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
5(4)	5.11, page 35	EFSA: The use of *Achillea millefolium*, *Millefolii herba* or yarrow as simple food or as aromatic herb is not evident from the references given, including the EMA report, where only its medicinal use is analysed. The fact that substances present in the plant are also present in food items is not sufficient to	EFSA: further evidence of actual use as food should be provided.	See food status in Cummings 2010 with caution. Ref added. Yarrow (*A. millefolium*) is also feed additive. Toghyani et al 2011 Marcinčáková 2015 Georgieva 2015	The references added refer to medicinal uses for humans, and effects on growth performance of chicken, meat composition, fatty acid profile and oxidative stability when used as feed additive. Evidence of actual use of *Achillea millefolium*, *Millefolii herba* or yarrow as simple food or as aromatic herb has not been provided. The infusion

5.11. Additional Information related to use as food

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		consider the whole plant as a food item too. Additionally *Achillea millefolium* L. is listed in the "Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements" (EFSA Journal 2012;10(5):2663). The chemicals of concern are alpha- and beta-thujone, camphor and 1,8-cineole. This is confirmed in the references submitted (see chapter 5.2, 5.6 and 5.10)			contains chemicals of possible concern to human health when used in food and food supplements, such as alpha- and beta-thujone, camphor and 1,8-cineole.

5.12. Acceptable daily intake, acute reference dose, acceptable operator exposure level

No comments.

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(5)		EFSA: Please see chapters 4 and 5.11: lack of toxicological		See food status in Cummings 2010 with caution.	See 4(2), 5(2) and 5(4)

5.13. Impact on human and animal health arising from exposure to the substance or impurities contained in it					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		concerns regarding the food use of the herbal preparation has not been demonstrated, being the more prominent concern its skin sensitisation potential observed from human experience.		Ref added.	

6. Residues

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
6(1)		ES: No comments			Noted
6(2)	6 (page 39)	NL: On page 39 it is stated that 'the potential residues in crops and animal products resulting from application of it are considered as negligible', which implies that small quantities of residues could be present. However, in paragraph 2.1.6.3, it is stated that 'the use of the active substance in agriculture cannot produce residues on plants', which seems contradictory to what is stated in chapter 6. Furthermore, in the overall conclusion (chapter 9) it is stated that 'the amounts of yarrow compounds in crop protection are not such as to cause unwanted oestrogenic effects'. Altogether, it is not fully clear whether residues could be present and in which amounts. This is of importance, in particular because of possible oestrogenic activity.		If yarrow show unwanted oestrogenic effects please ask to remove allowance and sales as biostimulant in some EU M.S. If nobody does it then do not claim such risk evaluation as basic substance if allowed as "fertilizer".	Since adverse effects have been reported that have not been addressed (see Section 5), a consumer risk assessment related to the uses of infusion of *Millefolii herba* as a plant protection product cannot be completed.
6(3)		EFSA: No data were provided		See food status in Cummings	Based on the submitted

Residues					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
		considering that "Yarrow infusion is food stuff". However if toxicological concerns are identified in the section on toxicology, the potential of residues and their impact on the consumer safety would need to be addressed.		2010 with caution.	information, EFSA is of the opinion that evidence on actual use of *Achillea millefolium*, *Millefolii herba* or yarrow as simple food or as aromatic herb has not been provided

7. Fate and Behaviour in the environment

NL: no comments

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)		ES: No comments			Noted
7(2)		EFSA: This section of the application is essentially empty. No reference has been made to any EU evaluation. Primary scientific literature articles are not included in the application in relation to environmental fate and behaviour. There is only a review article for monoterpines, an abstract on a Chinese language paper indicating streptomycetes are able to biodegrade chlorogenic acid, that is probably not of direct relevance and entries for a number of components from the US NLM Toxnet database.	Primary research papers that are the source of the cited information included in the US NLM Toxnet data base or the pertinent papers cited in the review of Marmuller and Harder 2014 need to be included in the application if they are to be considered to support the application.	Yarrow infusion is allowed as fertilizer and biostimulant in some EU M.S. Why applicant as basic substance should provide risk evaluation if this is not requested for M.S.?	There is no information in the application on the fate and behaviour in the environment of the components that will be in the recipes that will be applied.

7.2 Estimation of the short and long-term exposure of relevant environmental media (soil, groundwater, surface water)					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
7(3)		ES: No comments			Noted

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
8(1)		ES: No comments			Noted
8(2)		NL: The possible ED effects in wildlife should be addressed as well (please refer to the section 5.6 above).			See 5(2)
8(3)	5.6 Reproductive toxicity	DE: Yarrow has traditionally been used as an abortifacient, emmenagogue, contraceptive, and for stimulating uterine contractions. In rats, a 2.8 g/kg b.w. daily dose of yarrow was associated with reduced fetal weight and increased placental weight. The total extract of *A. millefolium* L. exhibits temporary antifertile activity in adult male rats. The information on the effects of the intended uses (with a	Conduct a sound risk assessment for the effects of the intended uses on non-target terrestrial vertebrates.	Either Risk assessment was conducted for *A. millefolium* as Pflanzenstärkungsmittel and you may provide such evaluation to EFSA either *A. millefolium* was allowed as biostimulant without concern. Ref *A. millefolium* is considered as biostimulant (Bio-Pflanzenspray mit Schafgarbe & Brennnessel) in Germany (Schafgarbe) since years (Liste der	Since the exposure to non-target terrestrial vertebrates and in general to non-target organisms cannot be excluded for the proposed uses, and considering the mode of action of the substance, further effect data are considered necessary. In, particular, these data should be useful to perform a risk characterisation. According to point 7(2), it is noted that also exposure estimates were not available.

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		total application rate up to 52,5 kg as/ha) on non-target terrestrial vertebrates presented in the application is not sufficient.		Pflanzenstärkungsmittel gemäß § 45 PflSchG) since 2014.	Therefore, to perform a risk assessment, also data on exposure are considered necessary.
8(4)	8.1 effects on terrestrial vertebrates	EFSA: data provided were not suitable to understand the toxic effects and to derive toxicity endpoints. Considering that representative uses foresee application up to c. 52.5 kg/ha, the exposure in field to birds and wild mammals cannot be excluded. Further information on its relevance and on the risk assessment to birds and mammals should be provided.		Toxicity endpoints were not mentioned as this extract is allowed in many EU M.S. as biostimlulant. Applicant asks to remove all abusive and illegal fertilizer or biostimulant sales if risk is proven and if this basic substance application is rejected. Administered to chicken Marcinčáková 2011 Added ref: Toghyani et al 2011	See 8(3)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(5)		ES: No comments			Noted
8(6)	Section 8.2, Page 49	NL: There is no information on toxicity of the yarrow extract	The applicant might consider a literature search on either the	Although Yarrow is administrated to some fish,	See 8(3)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		to daphnids. Considering the use of the formulation as an insecticide, NL is of opinion that this point should be addressed.	toxicity of individual constituents of the extract to daphnids or a search on the toxicity of similar plants extracts and toxicity to daphnids. In the last case, if the constituents are known, a extrapolation to the current extract might be made.	some other results may show non-lethal effects on fish but sex ration modifications More ref added Shutler 2003	
8(7)	8.2. Effects on aquatic organisms - growth performance and blood biochemical parameters of rainbow trout	DE: Oral administration of 1 % of yarrow extract caused cytotoxicity and modifications in blood biochemical parameters of fish. The information on the effects of the intended uses on aquatic organisms presented in the application is not sufficient.	Conduct a sound risk assessment for the effects of the intended uses on aquatic organisms.	Attempt for LC50 for Daphnia is described. Ref added McBrayer 2015	See 8(3)
8(8)	8.2. Effects on aquatic organisms	EFSA: the information provided is not sufficient to draw a conclusion of the risk assessment to aquatic organisms. The exposure to aquatic organisms was not estimated and cannot be excluded. Furthermore, based the mode of action as insecticide, information on the level of toxicity on aquatic invertebrates should be reported.			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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(9)		ES: No comments			Noted
8(10)	8.3.1	NL: Considering the use of the product as an insecticide also on crops that are attractive to bees, NL is of opinion that information on oral and contact toxicity are more relevant as opposed to exposure via air. While NL does not contest the use of plant extract against the bee mites and as stimulators of bee health , in the view of considerable product application, NL is also of opinion that scientific publications addressing the toxicity of the plants extracts via relevant exposure routes should be provided.	Please refer to the suggestion provided for the aquatic organisms.	Regarding bees, A. millefolium extract are used in beehives. The plant macerates also have low toxicity to bees, acting like nutritive supplements in bee colony development. Ref added Mărghitaş 2011	See 8(3)
8(11)	8.3.2	NL: The information provided describes the attractiveness of plants, including the yarrow to insects. However, when deciding on concluding no effects to non-target arthropods the following should be considered:1) the product is a plant extract applied in high amounts in the		Not toxic to bees. Used in beehives Ref added Mărghitaş 2011	See 8(3)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		environment; 2) for applications in orchards, the maximum quantity is not even known, 3) the use of the product is as an insecticide; 4) according to the information provided under the mode of action, the product as repellent activity and reduction of F1 progeny in weevils, and antiffedant, toxic and reduction in metabolism in Preris rapae. In the study by Hashemina et al. the LC50 for 3rd instar larvae of P.rapae was at 4.19% plant extract. The current product contains 6.5% plant extract. Furthermore, adult emergence was affected at 2.5% plant extract and at concentrations of 0.625% there were anti-feeding effects. The authors also conclude that the yarrow extract can inhibit the growth of lepidopterans through various metabolic processes. Considering these, the NL is of opinion that the absence of non-harmful effects to non-			

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		target arthropods is not sufficiently addressed with the information currently provided. Furthermore, effects on beneficial insects used in the IPM should be discussed.			
8(12)	3.2.2.2 Mode of action against insects	DE: Low contact toxicity, but good repellency and reduction of F1 progeny was achieved by application of the leaf extract of *A. millefolium*. The insecticidal properties were indicated by their local use to repel or kill pests and based on their major constituents known to be biologically active against insects. This is contradictory to the statements in section 8.3 where it is stated that *A. millefolium* is attractive for bees and other arthropods.	Describe the risk of the intended uses of *A. millefolium* for non-target arthropods.	Applicant described this plant extract as candidate basic substance under PPP regulation, DE M.S. authorizes Shafgarbe / *A. millefolium* as biostimulant, bypassing the PPP regulation but at the same time expect full risk assessment for the corresponding basic substance. Somewhere there is a major antagonism in this request.	See 8(3)
8(13)		DE: No data were submitted for the assessment of the product with regard to risk for bees.	Please indicate in dossier.	Too toxic but not efficient, be consistent once.	See 8(3)
8(14)		DE: No experimental reports were submitted from which information about effects on beneficial organisms can be derived.	Please indicate in dossier.		See 8(3)

8.2. Effects on aquatic organisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(15)	8.3. effects on bees and other arthropods species	EFSA: the information provided is not sufficient to draw a conclusion of the risk assessment to non-target arthropods, including bees. The exposure was not estimated and cannot be excluded (i.e. high filed application rate). Furthermore, based the mode of action as insecticide, information on level of toxicity to non-target arthropods, including bees should be provided.		Applicant agrees, but how it is possible that EFSA and Commission tolerate illegal uses of Achillea millefolium in many M.S. as biostimulant with hidden PPP effect without evaluation?	See 8(3)

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(16)		ES: No comments			Noted
8(17)	8.4	NL: Effects on soil macro-organisms was not addressed.	Please perform a literature search on the effects of yarrow extract or the components therein on the Folsomia candida and Hypoaspis aculeifer.		See 8(3)
8(18)		DE: Robust experimental studies	Please indicate in the dossier.	Variable in	See 8(3)

8.4. Effects on earthworms and other soil macroorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		carried out with relevant soil macroorganisms (e.g. the standard test earthworm Eisenia fetida) were not submitted.		Pflanzenstärkungsmittel gemäß § 45 PflSchG Dossier ?	
8(19)	8.4.	EFSA: the information provided is not sufficient to draw a conclusion of the risk assessment to soil organisms. The exposure was not estimated and cannot be excluded (i.e. high filed application rate). Information on level of toxicity to soil organisms should be reported		Allowed as biostimulant and fertilizer in many M.S.	See 8(3)

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(20)		ES: No comments			Noted
8(21)	8.5	NL: the study included under 8.5 should be better placed under 8.4. The micro-organisms are seen here as the soil microbial activity, in terms of nitrogen transformation.	Please perform a literature search on the effects of yarrow extract or the components therein on the soil micro-organisms.		See 8(3)

8.5. Effects on soil microorganisms

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(22)	3.2.2.1 Mode of action against fungi	DE: *A. millefolium* shows antimicrobial activity and therefore is proposed as a fungicide. The information presented in the application on the fungitoxic action against soil microorganisms is not sufficient to assess the risk of the intended uses.	Describe the risk of the intended uses of *A. millefolium* for soil microorganisms.	Mode of action is not known	See 8(3)
8(23)		DE: No robust experimental reports were submitted from which information about effects on soil micro-organisms can be derived.	Please indicate in the dossier.		See 8(3)
8(24)		EFSA: see comment 8(21)			See 8(3)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(25)		ES: No comments			Noted
8(26)	8.6	NL: The NL wonders if all available information was included in this dossier. The applicant claims that the current extract does not have herbicidal activity. However, Alipour S. et al, European Journal of		No herbicidal activity is claimed. Application from Organic Sector for herbicides are not possible.	See 8(3)

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

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		Experimental Biology, 2012, 2 (6):2493-2498, state that with increasing concentrations of yarrow extract (1.25 to 20%) effects on seed germination and seedling growth of of Zea maize, Johnsongrass (Sorghum halepense), Common lambsquarter (Chenopodium album) and Redroot pigweed (Amaranthus retroflexus) are observed. Could the applicant extrapolate the effects of this research to the possible effects seen in off-crop non target terrestrial plants after the application of the current product?			

8.7. Effects on biological methods of sewage treatment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(27)		ES: No comments			Noted
8(28)		NL: no comments			Noted

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

Overall conclusions with respect of eligibility of the substance to be approved as basic substance					
No.	**Column 1** **Reference to Application Template**	**Column 2** **Comments from Member States / EFSA**	**Column 3** **Proposal by Member States/EFSA on how the application should be updated to address the comment**	**Column 4** **Follow up response from applicant**	**Column 5** **EFSA's scientific views on the specific points raised in the commenting phase conducted on the application**
9(1)	General comment	ES: The fulfilment of the criterion "(d) is not placed on the market as a plant protection product" is questionable, because *Millefolii herba* contains active substances included in the Annex I (i.e. eugenol, thymol) (please, see comments above for issue 2.1.4). This criterion should be guaranteed by establishing requirements that assurance the absence of these substances in the *Millefolii herba* infusion.		Sorry for ES M.S. responsible Annex I do not exist anymore since Implementing Regulation 540/2011[3]. Previously, Recital/Whereas (3) of Regulation 1107/2009 stated "In this context it is to be borne in mind that, as a consequence of Article 83 of Regulation (EC) No 1107/2009 having repealed Directive 91/414/EEC, the Directives which included the active substances in Annex I to Directive 91/414/EEC have become obsolete to the extent that they amend that Directive."	Thymol and eugenol are approved active substances under Regulation 1107/2009 (via Regulation (EU) 568/2013[4] and (EU) No 546/2013).
9(2)		NL: no comments			Noted
9(3)	9 Environment	DE: The risk assessment for several non-target organisms could not be finalised. Therefor no decision on the subject "substance of concern" is possible.	Conduct a sound risk assessment for the effects of the intended uses on non-target organisms.	Therefore how this substance is allowed in DE M.S. as biostimulant for years without evaluation?	See 7(2) and 8(3)

[3] Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances,OJ L 153, 11.6.2011, p. 1–186.

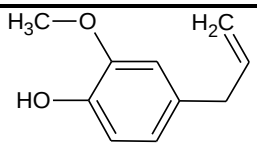
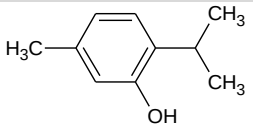
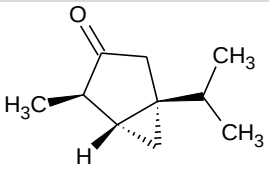
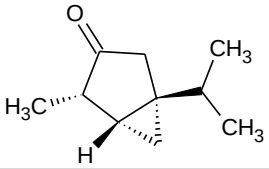
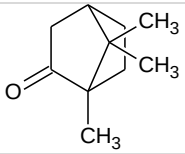
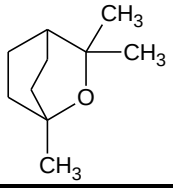
[4] Commission Implementing Regulation (EU) No 568/2013 of 18 June 2013 approving the active substance thymol, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011, OJ L 167, 19.6.2013, p. 33–36.

10. Other comments

Other comments

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
10(1)		ES: No comments			Noted
10(2)		NL: no comments			Noted
10(3)		DE: General comment on the efficacy evaluation in the dossier: the idea of the authorization of basic substances is that no product approval takes place after the final decision on the as.	Therefore, it should be made clear that neither sufficient efficacy nor side effects are well approved and may occur.	Again and repeatedly this application as usual is targeted with same antagonistic criticisms "toxic" but with "no efficacy"; "dangerous" and "allowed without evaluation" "no efficacy" but "phytotoxic"!	Insufficient scientifically documented data on efficacy and lack of phytotoxicity of *Millefolii herba* - Yarrow infusion with regard to the intended uses has been provided

Appendix B – Used compound codes

Code/trivial name[(a)]	Chemical name/SMILES notation	Structural formula
eugenol	4-allyl-2-methoxyphenol Oc1ccc(cc1OC)CC=C	
thymol	thymol CC(C)c1ccc(C)cc1O	
alpha-thujone	(1*S*,4*R*,5*R*)-1-isopropyl-4-methylbicyclo[3.1.0]hexan-3-one C[C@H]1C(=O)C[C@@]2(C[C@H]12)C(C)C	
beta-thujone	(1*S*,4*S*,5*R*)-1-isopropyl-4-methylbicyclo[3.1.0]hexan-3-one C[C@@H]1C(=O)C[C@@]2(C[C@H]12)C(C)C	
camphor	1,7,7-trimethylbicyclo[2.2.1]heptan-2-one CC2(C)C1CC(=O)C2(C)CC1	
1,8-cineole	1,3,3-trimethyl-2-oxabicyclo[2.2.2]octane CC2(C)OC1(C)CCC2CC1	

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

Appendix C – Identity and biological properties

Common name (ISO)	There is no ISO common name for this substance
Chemical name (IUPAC)	Not relevant, the substance is a complex mixture
Chemical name (CA)	Not relevant, the substance is a complex mixture
Common names	Yarrow infusion
CAS No	84082-83-7 (*Achillea millefolium* extract)
CIPAC No and EEC No	282-030-6 (EINECS)
FAO specification	Not available
Minimum purity	Not relevant Purity is depending on the origin
Relevant impurities	Open
Molecular mass and structural formula	Not relevant, the substance is a complex mixture
Mode of Use	Foliar or fruit spraying
Preparation to be used	Dispersible concentrate (DC)
Function of plant protection	Fungicide

Appendix D – List of uses

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Cucurbitaceae **For example Cucumber Cucumis sativus**	FR Not relevant	Extract of Achillea millefolium	FG	Cucumber leaf blight Pseudomonas marginalis	Dispersible Concentrate (DC)	12.5 of dry yarrow, which has been filtered	Foliar or fruit spraying	Until BBCH89 (fruits have typical fully ripe colour)	1 to 7	Depends on the pluvio-metry (P) 7 days if P <20mm	1.25	300 to 500	3.75 to 6.25	3.75 to 36.75	none	Treatment in the morning Mix with other basic substances for better efficiency like Equisetum
Corn *Zea mays*	FR Not relevant	Extract of Achillea millefolium	F	Northern leaf blight Excerohilum turcicum.	Dispersible Concentrate (DC)	12.5 of dry yarrow, which has been filtered	Foliar spraying	Until BBCH89 (fruits have typical fully ripe colour) Spring Summer	1 to 7	Depends on the pluvio-metry (P) 7 days if P <20mm	1.25	200 to 500	2.5 to 6.25	2.5 to 36.75	none	As above

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Grapevine ***Vitis vinifera***	FR Not relevant	Extract of Achillea millefolium	F	Downy mildew Plasmopara viticola	Dispersible Concentrate (DC)	12.5 of dry yarrow, which has been filtered	Foliar or fruit spraying	From 1st shoots to cluster tightening Spring	1 to 7	Depends on the pluvio-metry (P) 7 days if P <20mm	1.25	300 to 500	3.75 to 6.25	3.75 to 36.75	none	As above
Cucurbitaceae ***For example*** **Melon** ***Cucumis melo***	FR Not relevant	Extract of Achillea millefolium	F	Gummy stem blight Didymella Brionyae	Dispersible Concentrate (DC)	12.5 of dry yarrow, which has been filtered	Foliar or fruit spraying	From germination to BBCH89 (fruits have typical fully ripe colour) Spring Summer	1 to 7	Depends on the pluvio-metry (P) 7 days if P <20mm	1.25	400 to 600	5 to 7.5	5 to 52.5	none	As above

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Tomato *Solanum lycopersicum*	FR Not relevant	Extract of Achillea millefolium	FG	Early blight Alternaria solani, Tomato leaf mold Cladosporium fulvum, Septoria blight Septoria lycopersici	Dispersible Concentrate (DC)	12.5 of dry yarrow, which has been filtered	Foliar or fruit spraying	Until BBCH89 (fruits have typical fully ripe colour)	1 to 7	Depends on the pluvio-metry (P) 7 days if P <20mm	1.25	300 to 500	3.75 to 6.25	3.75 to 36.75	none	As above

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Cabbage *Brassica oleracea var. capitata,* **Turnip** *Brassica napus var. napobrassica,* **Cauliflower** *B. oleracea var. botrytis,* **Rape** *B. napus ssp. oleifera,* **Horseradish** *Armoracia rusticana*	France - All M.S.	*Extract of Achillea millefolium*	FG	Small white butterfly *Pieris rapae*	Dispersible concentrate (DC)	10 of dry yarrow, which has been filtered	Foliar spraying	Until BBCH49 (Typical size, form and firmness of heads reached)	1 to 5	Depends on the pluvio-metry (P) 7 days if P<20mm	1	300 to 500	3 to 5	3 to 25	None	Treatment in the morning

Crop and/or situation (a)	Member State or Country	Example product name as available on the market	FGI (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate per treatment			Total rate	PHI (days) (m)	Remarks (*,**)
					Type (d-f)	Conc Of a.i. g/L (i)	Method kind (f-h)	Growth stage and season (j)	Number min max (k)	Interval between applications (min)	kg a.i./hl min max (g/hl)	Water l/ha min max	kg a.i./ha min max (g/ha) (l)	kg a.i./ha min max (g/ha) (l)		
Grapevine *Vitis vinifera*	France - All M.S.	*Extract of Achillea millefolium*	F	*Antifreeze action*	Dispersible concentrate (DC)	25 of dry yarrow, which has been filtered	Foliar spraying	BBCH7 to BBCH16 (budding to six leaves)	Until freezing conditions subside	Every Second day	2.5	100 to 300	2.5 to 7.5	Depends on the number of springtime frosts	none	24h before freezing temperature Mix with Valerian infusion in proportions 50:50
Fruit trees Apple trees *Malus domestica Peer tree Pyrus communis* **Plum tree** *Prunus domestica* **Cherry tree** *Prunus cerasus*	France - All M.S.	*Extract of Achillea millefolium*	F	Antifreeze action	Dispersible concentrate (DC)	25 of dry yarrow, which has been filtered	Flower spraying	BBCH55 to BBCH67 (Flowers fading: majority of petals fallen) Spring	Until freezing conditions subside	Every Second day	2.5	200 to 400	5 to 10	Depends on the number of springtime frosts	none	24h before freezing temperature Mix with Valerian infusion in proportions 50:50.

* For uses where the column „Remarks. As above or other conditions to take into account
(a): For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b): Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c): e.g. pests as biting and suckling insects, soil born insects, foliar fungi, weeds or plant elicitor
(d): e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR) etc..
(e): GCPF Codes – GIFAP Technical Monograph N° 2, 1989
(f): All abbreviations used must be explained
(g): Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
(h): Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated
(i): g/kg or g/L. Normally the rate should be given for the active substance (according to ISO)
(j): Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k): Indicate the minimum and maximum number of application possible under practical conditions of use
(l): The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m): PHI - minimum pre-harvest interval