European Food Safety Authority

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TECHNICAL REPORT

Outcome of the consultation with Member States and EFSA on the basic substance application for *Artemisia absinthium* for use in plant protection as fungicide in wheat and as nematicide and insecticide in vegetables[1]

European Food Safety Authority[2]

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

The European Food Safety Authority (EFSA) was asked by the European Commission to provide scientific assistance with respect to the evaluation of applications received by the European Commission concerning basic substances. In this context EFSA's scientific views on the specific points raised during the commenting phase conducted with Member States and EFSA on the basic substance application for *Artemisia absinthium* are presented. The context of the evaluation was that required by the European Commission in accordance with Article 23 of Regulation (EC) No 1107/2009 following the submission of an application for approval of *Artemisia absinthium* as a basic substance for use in plant protection as fungicide in wheat and as nematicide and insecticide in vegetables. The current report summarises the outcome of the consultation process organised by the EFSA and presents EFSA's scientific views on the individual comments received.

KEY WORDS

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

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[2] Correspondence: pesticides.peerreview@efsa.europa.eu

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SUMMARY

Artemisia absinthium 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 April 2014, EFSA was asked to organise a commenting on the basic substance application for *Artemisia absinthium*, to consult the applicant on the comments received, and to deliver its scientific views on the specific points raised in the format of a Reporting Table within 3 months of acceptance of the specific request.

A consultation on the basic substance application for *Artemisia absinthium*, 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 *Artemisia absinthium* and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

Artemisia absinthium is extracted from the aerial parts of the *Artemisia absinthium* L. (Wormwood) dry plant. The product is intended to be used as fungicide in wheat and as nematicide and insecticide in vegetables. 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 *Artemisia absinthium* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance is being prepared for these substances.

Artemisia absinthium contains several compounds whose toxicity potential cannot be adequately addressed based on the available data, which indicate several pharmacological/toxic effects; in addition the hazard of *Artemisia absintium* as such cannot be addressed either. Based on the available data, it cannot be concluded that *Artemisia absinthium* is a basic substance. A reliable risk assessment for operators, workers, bystanders and residents could not be performed.

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

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

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

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BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

Regulation (EC) No 1107/2009[3] (hereinafter referred to as 'the Regulation') introduced the new category of "basic substances", which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as "basic" and used for plant protection purposes.

Artemisia absinthium 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 in wheat and as nematicide and insecticide in vegetables.

The European Food Safety Authority (EFSA) organised a consultation with Member States and EFSA on the basic substance application for *Artemisia absinthium*, 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 application submitted by the applicant, were considered by EFSA in column 4 of the Reporting Table.

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

The application and, where relevant, any update thereof submitted by the applicant for approval of *Artemisia absinthium* 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); 2014a, 2014b).

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 April 2014, EFSA was asked to organise a commenting on the basic substance application for *Artemisia absinthium*, 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 *Artemisia absinthium* 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), 2014a. *Artemisia absinthium*. Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. February 2014. 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), 2014b. *Artemisia absinthium*. 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) Institut Technique de l'Agriculture Biologique (ITAB). Documentation made available to EFSA by the applicant.

REFERENCES

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *ARTEMISIA ABSINTHIUM* 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
	No comments.			

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
	No comments.			

2.2. Identity and Physical and chemical properties of the substance and product to be used				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
2(1)	2.2, identity	EFSA: There is no specification for this substance and no supporting data. No batch analysis or validated methods of analysis supplied. It is known that the composition of the plant varies considerably.	Corrected	Although the applicant has stated that this has been corrected this is not correct and no useful additional information has been provided. For this reason the issue remains. There is no specification for this substance and no supporting data. No batch analysis or validated methods of analysis were supplied. It is known that the composition of the plant varies considerably.
2(2)	General comment	ES: It might be useful to clarify the nature of basic substance. Oil, extract, dried plant, fresh plant, etc., are terms used along the report. Maybe the cover of the report should also include this information (e.g. Artemisia absinthium L. "extract").	Corrected	This is not a basic substance. What is being proposed is a hot water extract of the aerial parts of the plant.

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(3)	General comment 2.2.5. Description and specification of purity of the active substance and product	ES: Are the rates among the major components constant?	Not determined precisely, deductive conc. were made from literature.	The rates of the various components 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	The name in Spanish has been added.

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)	Description of the recipe for the product to be used	EFSA: The Regulation states the following. 'It is not predominantly used for plant protection purposes but nevertheless is useful in plant protection either directly or in a product consisting of the substance and a simple diluent.' This is not the case for this material as it is extracted by boiling or extracting with hot water and steeping for long periods of time. It is also proposed that the pH is corrected. This means that the *Artemisia absinthium* is being formulated and is not a basic substance. It is rather a plant extract and separate guidance has been 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 the *Artemisia absinthium* 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)	Description of the recipe for the product to be used	EFSA: What is known about the difference in composition of what is in the extract made with boiling water (use as fungicide and insecticide) and that made with 80°C water (use as nematicide). This difference in recipes gives indications, either that some components are undergoing a chemical transformation or that these differences in extraction conditions are changing the composition of the mixture that is used? This issue of their being different approaches to preparation depending on the use, reinforces EFSA's view that following the definition in the regulation, what will be applied to achieve plant protection is not a basic substance.	Budget to overcome full description of the difference in content between the 2 extractions is beyond the financial capabilities of a non-vendor applicant.	The financial capabilities of the applicant are not an issue for the risk assessment but is more a risk management issue. It is clear that the content of the extract is unknown and the content will vary greatly depending on the extraction method.
2(7)	Mode of preparation	DE: Two different concentrations are given. However, the first description does not explicitly state whether the weight portion refers to fresh or dried material. It should be made clear that the figure 0,03 refers to kg plant material / kg water, in terms of % (w/w) it should be 3% and resp. 0,1 kg plant material / kg water or 10 % (w/w).	Corrected in the BSA (2.5 Recipe) Corrected in the BSA (2.5 Recipe)	The recipe has been corrected by the applicant.
2(8)	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 when dry plants are used. Active substances are not completely known, therefore accuracy and efficacy of the extraction 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
3(1)		ES: It should be specified throughout the whole document that the substance is an extract.	Corrected in the BSA	This is correct and that is why it cannot be considered as a basic substance.

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(2)		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.	Wormwood (*Artemisia absintium* 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 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
3(3)		DE: No specific data were provided which allow the detailed description of GAPs. In the dossier it should be made clear that no experience on efficacy with regard to the intended uses exist.	Article 23 applications are submitted for substance with the characteristics of utility in agriculture, not for active substances with full biocide elucidated efficacy.	The efficacy of the extract is unknown.
3(4)		DE: No specific data were provided which allow the exclusion of potential phytotoxic effects.	Concentrations were established to give a decoction below phytotoxic effects	No data was provided on phytotoxic effects.
3(5)	GAP-Table, insecticidal uses, column crop and/or situation	DE: 'vegetable gardens, Ex: cabbage…'could be read as either 'example' or 'excluded', please clarify.	Corrected in the BSA (GAP Table)	The GAP table has been corrected.
3(6)	General comment	ES: It is not possible to define the purity of the active substance. The active substance is composed of the cut flowers and leaves of the plant. It is a complex mixture of natural compounds (see issue 2.2.5 of the report). Therefore, how the concentration of the active ingredient is fixed (Conc of a.i. g/kg)? See also above the comments to the issue "2.6. Description of the recipe for the product to be used"	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(7)	General comment	ES: Is the plant homogenate (extracted with hot water and filtered (decoction)), suitable for spray application after cooling? The solubility can change significantly.	After filtration with usual means (tights) solution is clear	After filtering the material, it would be sprayable.
3(8)		ES: The units of "Application rate for	Corrected according to recipe in g/L	It is not really clear what the GAP is

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
		treatment and Total rate" should be corrected (kg-g/hl; kg-g/ha) in the three tables.		as in the GAP table it is not clear if the rates are based on the dry plant material or the extract.
3(9)		ES: Nematicide uses - If there are two applications the interval between them should be specified (min).	Corrected	This has been clarified.
3(10)		ES: Insecticide uses - It should be included the column of "Total rate" as in the others.	Corrected	As mentioned above it not clear what the rates refer to.
3(11)		ES: In the footnote of the summary of intended uses, In fungicide uses: it is indicated "… *extracted with hot water*…" In nematicide uses: it is indicated "… *extracted with cold water*…" In insecticide uses: it is indicated "… *extracted with hot water***…"** All this should be reviewed because it is contrary to what it is included in the text; point 2.6 (Description of the recipe for the product to be used)	Suppressed	Neither uses are extracted with cold water. The extraction methods are either boiling or extracting at 80 degrees.

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
	No comments.			

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 (applicable to the whole chapter 5)	EFSA: *Artemisia absintium* contains several compounds whose toxicity potential cannot be adequately addressed based on the available data, which indicate several pharmacological/toxic effects; in addition the hazard of *Artemisia absintium* as such cannot be addressed either. Based on the available data, *Artemisia absintium* cannot be regarded as a basic substance.	More references and global consideration report is added at beginning of chapter §5 and §6 about decomposition with UV light	The information added does not solve the issues raised in the commenting phase. Based on the available data, *Artemisia absintium* cannot be regarded as a basic substance.
5(2)	5.1 General comment p. 21	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 to amendment of the report.	idem	See 5(1)

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(3)	5.2.1 thujone p. 26	DE: Please check whether the abstract of Fraisse et al. 2011 is relevant for *Artemisia absinthium* as it is related to Tansy. The abstract is cited under a heading related to "Tansy" which should probably read "Artemisia".	Corrected	Addressed

5.3. Acute toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(4)	5.3 Acute Toxicity, p. 28	DE : Acute toxicity data on the extract or on Artemisia extracts in general should be added e.g. 1 mg/kg intraperitoneally (i.p.) in rats. As information on unspecified extracts is available, it should be added as it might be relevant for classification purposes. If such data does not apply to the decoction used a justification should be added.	Corrected reference added	Addressed

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
	No comments.			

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(5)	5.6.1 Thujone, p. 33	DE: Please correct the sentence: "*The ADI (Acceptable Daily Intake) is so estimated to be 11 mg/kg bw/day; …".* Probably the $BMDL_{10}$ is meant by 11 mg/kg as calculated by Lachenmaier and Uebelacker (2010) from the dose response modelling of the chronic NTP study data using clonic seizures as a BMD response.	Sentence corrected in the BSA	Addressed

5(6)	5.8.2 absinthin and anabsinthin , p. 36	DE: Please check the citation under the heading 5.8.2 which is probably displaced. The citation: - EMA/HMPC/732886/2010 Rev.1 – refers the thujon and should be placed under the heading above (5.8.1 thujone).	Sentence transferred in the BSA (5.8.1 thujone) References corrected	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. 35	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 it should be clearly pointed out which concentrations are to be expected or else the content of thujone should be limited. 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).	This toxicological point was taken in account when allowance of wermut in this light category of biorational plant strengthener in Germany, no significant toxicity should be envisaged. All details should be available in the application of Absinth (Artemisia extracts) as plant strengthener listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: bellaflora biogarten Rainfarn und Wermut FSC 31.07.2013. If necessary, EFSA can request complete evaluation of corresponding sold product.	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. 39	DE: The allergic potential of *Artemisia absinthium* extract should be addressed and evaluated. It is mentioned that a substance (curcumene) with low allergenic potential is part of the plant. Members of the *Asteraceae* family may have an allergenic potential which should be addressed. Available information should be described and evaluated. If there is no such information than that should be mentioned as well.	Although *Artemisia* spp are known for generating allergy, this is conveyed by proteins (Art v 1, Art v 3, Art v 60 kDa), which should be transformed by the heating process part of the recipe.	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(9)		EFSA: some reference values are proposed based on single compounds present in *Artemisia absintium*. However, also in consideration of the lack of a clear specification and of a detailed assessment of the toxicological potential of all single compounds and of *Artemisia absintium* as such, they are not considered sufficient to perform a reliable risk assessment.	Risk assessment is provided in Dossier bellaflora biogarten Rainfarn und Wermut by FSC available upon request from EFSA in plant strengthener listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014.	See 5(1). Based on the lack of a specification and of a detailed assessment of the toxicological potential of all single compounds and of *Artemisia absintium* as such, it is not possible to perform a reliable risk assessment.
5(10)	5.13, p. 47	DE: Product application is intended for low crops (wheat and vegetables). Thus, exposure calculations should be made for tractor mounted/trailed boom sprayers with hydraulic nozzles and hand-held sprayers (low level target) instead of tractor mounted /trailed air-assisted sprayers. The assumed concentrations of thujone and absinthin in the water extract are based on a decoction made of 300 g plant material in 10 litres water. However, the decoction for nematicide uses is made of 1 kg plant material in 10 litres water. This could give higher concentrations of both compounds. Please consider.	Corresponding POEMUK values generated Values for thujone and absinthin x 3 are still below ADI	See 5(1). The values of UK POEM have been generated only for some of the compounds contained in *Artemisia absintium* however all the input parameters have not been clearly described (e.g. the specific dermal absorption values used and the rationale behind). Based on the limited toxicological data package, the specific reference values (or a general one for *Artemisia absintium*) could not be established so no risk assessment was possible.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(11)	5.14, p. 48	DE: A statement on the risk for workers, bystanders and residents from exposure during/after application of the preparation should be given. A risk assessment was only made for the operator.	POEMUK .XLSX files provided	See 5(10)

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)	6 - Residues	EFSA: Uses are envisaged on a large number of crops (wheat, vegetables) and therefore, consumer exposure to thujone resulting the applications of *Artemisia absintium* should be estimated.	ECHA classification added	Since the available data are not sufficient to conclude on the toxicity of *Artemisia absinthium* and since information related to the residues has not been provided, a consumer risk assessment could not be completed.
6(2)	p. 50	DE: A general statement on residues background exposure should be provided.	More references added	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 in the environment page 50	EFSA: The information presented is considered inadequate to make any assessment. Though it is agreed that it can be expected 'that these different natural substances are degraded in the environment in accordance with the known metabolic pathways of' 'organic matter.' No information on the rate of degradation of the different constituents that might be present in the extract has been presented. No information on their soil mobility has been presented. No information on levels of occurrence, natural as well as after the use of *Artemisia absintium*, are provided. Such information is required as a minimum, for estimation of possible effects on the environment.	Conclusive sentence added	Even after the addition of a couple of literature references in the updated application the information presented is considered inadequate to make any assessment. Though it is agreed that it can be expected that these different natural substances are degraded in the environment in accordance with the known metabolic pathways of organic matter, no information on the rate of degradation of the different constituents that might be present in the extract has been presented. No information on their soil mobility has been presented. No information on levels of occurrence, natural as well as after the use of *Artemisia absintium*, are provided. Such information is required as a minimum, for estimation of possible effects on the environment.

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	EFSA: in the application, it is stated that it is not clear whether *Artemisia absintium* has toxic effects to birds, as they avoid it. Therefore adverse effects on birds after exposure to *Artemisia absintium* need to be further addressed.	See bibliographic part For example Lans and Turner Journal of Ethnobiology and Ethnomedicine 2011	The available information is not considered adequate to conclude a low risk to non-target organisms. It has also to be considered that the information on the exposure is considered inadequate for a proper characterization.
8(2)	8.1.2 Mammals	EFSA: Effects on mammals cannot be excluded based on the available information (see comments in section 5). Moreover, the exposure of wild mammals to *Artemisia absintium* also needs further consideration (see comments 7.1)	See bibliographic part For example Lans and Turner Journal of Ethnobiology and Ethnomedicine 2011	See 8(1)
8(3)	8.1.1 Birds	DE: Uses in "folk botanic" are not sufficient to describe the risk of the application of *A. absinthium* for birds. Sound evidence of the repellent effect and/or the innocuousness of *Artemisia absintium* on birds have to be given in the application.	See bibliographic part One example added	See 8(1)
8(4)	8.1.2 Mammals	DE: The submitted studies are not suitable to describe the risk of the application of *Artemisia absintium* for mammals. There are acute toxic effects on mammals caused by ferulic acid, alpha- and beta-thujone. The consequences of an application of *Artemisia absintium* for mammals are not described in the application.	See bibliographic part For example Lans and Turner Journal of Ethnobiology and Ethnomedicine 2011	See 8(1)

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
		In the application it is stated that *Artemisia absintium* shows a long-term toxicity that cannot be neglected. Anti-implantation and abortifacient effects in rats are described in the application as well as vaginal bleeding of pregnant rats and a reduction of the number of born pups per rat. An unacceptable risk for mammals cannot be excluded based on the application.		

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(5)	8.2 Effects on aquatic organisms	EFSA: the information presented may not be adequate to exclude adverse effects of *Artemisia absintium* to aquatic organisms. It is also noted that information on the exposure is not considered adequate, see also comment 7(1).		See 8(1)
8(6)		DE: The study submitted is not suitable to describe the risk of the application of *Artemisia absintium* for aquatic organisms.		See 8(1)

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(7)	8.3.1 Oral Toxicity	EFSA: The study submitted seems to show effects on bees 4 days after the exposure. Moreover, it is also stated that no effects on bee colonies are expected since the substance rapidly decline after the treatment. However, as there is no information on the time period for the components in the extract to degrade, more data are needed to confirm that bees are not exposed and risk assessment may therefore deemed necessary.	Since degradation occurs with UV light and contact toxicity is clearly low, only ingestion toxicity is showing effect after 4 days. The absence of persistence in lighted environment.	See 8(1)
8(8)	8.3.2 Effects on other arthropods	EFSA: As *Artemisia absintium* is traditionally used as miticide, therefore adverse effects on non target arthropods cannot be excluded. Additional information is needed. It is also noted that information on the exposure is not considered adequate, see also comment 7(1).	Evaluation of Wormwood (*Artemisia absintium* L.) listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: is available from FSC company (as asbellaflora biogarten Rainfarn und Wermut Product)	See 8(1)
8(9)		DE: No data were submitted for the assessment of the product with regard to risk for bees.	Guillet 2012 both toxicity oral and contact are determined.	See 8(1)
8(10)	8.3.2 Effects on other arthropods	DE: *Artemisia absintium* is used as an insecticide. Effects on non-target arthropods are not unlikely. These effects have to be described in the application; an	Evaluation of Wormwood (*Artemisia absintium* L.) listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: is avalable	See 8(1)

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
		unacceptable risk for non-target arthropods cannot be excluded based on the application.	from FSC company (as asbellaflora biogarten Rainfarn und Wermut Product)	

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(11)	8.4.2 Effects on earthworms	EFSA: As *Artemisia absintium* is also used as vermifuge, therefore adverse effects on earthworms cannot be excluded. Additional information is needed. It is also noted that information on the exposure is not considered adequate, see also comment 7(1).	Evaluation of Wormwood (*Artemisia absintium* L.) listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: is available from FSC company (as asbellaflora biogarten Rainfarn und Wermut Product)	See 8(1)
8(12)	8.4.1	DE: *Artemisia absintium* is used as a vermifuge. An unacceptable risk for earthworms cannot be excluded based on the application, since robust experimental studies carried out with relevant soil macroorganisms (e.g. the standard test earthworm Eisenia fetida) were not submitted. The applicant states that use of the substance "could lead to activity against worms".	Evaluation of Wormwood (*Artemisia absintium* L.) listed in Liste der Pflanzenstärkungsmittel gemäß § 45 PflSchG Stand: 8. Juli 2014: is available from FSC company (as asbellaflora biogarten Rainfarn und Wermut Product)	See 8(1)

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(13)	8.5 Effects on soil micro-organisms	EFSA: the available information is not considered enough to exclude effects on soil micro-organisms when *Artemisia absintium* extract is applied for the intended uses. It is also noted that information on the exposure is not considered adequate, see also comment 7(1).		See 8(1)
8(14)		DE: No information has been provided by the applicant regarding the effects of *Artemisia absintium* on soil micro-organisms.		See 8(1)

8.6. Effects on other non target organisms (flora and fauna)				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 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(15)	8.6 Effects on other non target organisms	EFSA: It is not possible from the available data to exclude effects on non target terrestrial plants.		See 8(1)

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
	No comments.			

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: It would be advisable to include some study regarding the efficacy of this substance on several cultures (wheat, vegetable gardening…)	More references are given in § 3	The efficacy of the extract is unknown.

ABBREVIATIONS

µg	microgram
ADI	acceptable daily intake
a.i.	active ingredient
BMD	Benchmark dose
$BMDL_{10}$	Lower 95 % confidence limit for a benchmark response at 10 % extra risk
bw	body weight
ECHA	European Chemical Agency
EEC	European Economic Community
EFSA	European Food Safety Authority
EU	European Union
g	gram
GAP	good agricultural practice
ha	hectare
hl	hectolitre
kg	kilogram
L	litre
mg	milligram
NTP	US National Toxicology Programme
w/w	weight per weight
µg	microgram
pH	pH-value
UKPOEM	UK Predictive Operator Exposure Model