TECHNICAL REPORT

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Outcome of the consultation with Member States and EFSA on the basic substance application for approval of *Equisetum arvense* L. for the extension of use in plant protection against fungal diseases on horticulture and vegetable crops

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 an extension of use for *Equisetum arvense* L. 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 *Equisetum arvense* L. as a basic substance for an extension of use in plant protection against fungal diseases on horticulture and vegetable crops. 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: *Equisetum Arvense* L., basic substance, application, consultation, plant protection, pesticide

Requestor: European Commission

Question number: Q-2020-00185

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Summary

Equisetum arvense L. 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 Biovitis 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. In particular, EFSA was asked to consider the comments received on the basic substance application for *Equisetum arvense* L. and the response of the applicant Task Force ITAB Institute (Institut Technique de l'Agriculture Biologique) thereon, and to finalise the Reporting Table with its scientific views on the specific points raised in the commenting phase.

A Technical Report containing the finalised reporting table was issued by EFSA on 03 June 2013.

Equisetum arvense L. was approved on 01 July 2014 by Commission Implementing Regulation (EU) No 462/2014, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use as a fungicide.

By a further specific request, received from the European Commission on 26 February 2020, EFSA was asked to organise a consultation on the basic substance application for *Equisetum arvense* L., 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 the extension of use of *Equisetum arvense* L., organised by EFSA, was conducted with Member States via a written procedure in February-March 2020. 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 *Equisetum arvense* L. and presents EFSA's scientific views on the individual comments received in the format of a reporting table.

Equisetum arvense L. (Equisetaceae, subgenus *Equisetum*), is a well-known and widespread pteridophyte distributed in the northern hemisphere. Its sterile stems are used as medicines in various countries, constituting "Equiseti herba" of European Pharmacopoeias. The active substance is composed of the cut dried aerial parts, sterile stems of the plant. It consists of fragments of grooved stems and linear leaves, light green to greenish-grey. It is a complex mixture of natural compounds, the purity of the active substance cannot be defined.

Equisetum arvense L. is intended to be used as a dispersible concentrate by foliar spray applications on grapevine, wheat, vegetables, pome fruit, stone fruit, small fruits and ornamental plants against various fungal diseases.

In the mammalian toxicology section, data submitted from the open literature are not sufficient to address the hazard identification and exposure assessment of *Equisetum arvense* L. A full evaluation of the compound as food or medicine has not been provided at the EU level. In the view of the available data and the lack of identity assessment, a data gap is set regarding the toxicity risk assessment of *Equisetum arvense* L.

In the absence of a new assessment of the identity and toxicity of *Equisetum*, the previous conclusion that a qualitative and a quantitative consumer risk assessment is not possible because of the missing information on the exact identity of the compound *Equisetum* is maintained.

The available information in the environmental fate and behaviour section does not contain any assessment of the potential exposure of the environment to *Equisetum arvense* L. Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and quantitative

exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* L. for plant protection is not possible.

Since the exact identity of the *Equisetum* compound is not clearly described it is not possible to determine its influence on non-target organisms.

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1. Introduction

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

Regulation (EC) No 1107/2009[1] (hereinafter referred to as 'the Regulation') introduced the new category of 'basic substances', which are described, among others, as active substances, not predominantly used as plant protection products but which may be of value for plant protection and for which the economic interest of applying for approval may be limited. Article 23 of the Regulation lays down specific provisions to identify a substance as a basic substance with a view to ensure that such active substances that do not have an immediate or delayed harmful effect on human and animal health nor an unacceptable effect on the environment can be approved as 'basic' and used for plant protection purposes.

Equisetum arvense L. is an active substance for which, in accordance with Article 23(3) of the Regulation, the European Commission received an application from Biovitis for approval as a 'basic substance' to be used in plant protection against fungal diseases on horticulture and vegetable crops.

On 06 March 2013 the European Food Safety Authority (EFSA) was requested by European Commission to organise a consultation on the basic substance application submitted, 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. A Technical Report containing the finalised reporting table was issued by EFSA on 03 June 2013 (EFSA, 2013).

Equisetum arvense L. was approved on 01 July 2014 by Commission Implementing Regulation (EU) No 462/2014, in accordance with Article 23 of Regulation (EC) No 1107/2009, for the use as a fungicide.

In June 2019, the European Commission received a further application from Biovitis for the extension of use of the basic substance *Equisetum arvense* L., consisting of a spray application for the use in plant protection against fungal diseases on horticulture and vegetable crops.

Following a specific mandate received on 26 February 2020, the European Food Safety Authority (EFSA) organised a consultation with Member States on the basic substance application for the extension of use of *Equisetum arvense* L., which was conducted via a written procedure in February-March 2020. 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 the extension of use of *Equisetum arvense* L. 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 *Equisetum arvense* L. 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 (Biovitis, 2019, 2020).

1.2. Interpretation of the Terms of Reference

On 06 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 26 February 2020, EFSA was asked to organise a consultation on the basic substance application for *Equisetum arvense* L., 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 26 May 2020.

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

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. Assessment

The comments received on the basic substance application for *Equisetum arvense* L. 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 B and C, respectively.

Documentation provided to EFSA

1. Biovitis, 2019. Basic substance application on *Equisetum arvense* L. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. June 2019. Documentation made available to EFSA by the European Commission.

2. Biovitis, 2020 Basic substance application update on *Equisetum arvense* L. submitted in the context of Article 23 of Regulation (EC) No 1107/2009. March 2020. Documentation made available to EFSA by the applicant.

References

EFSA (European Food Safety Authority), 2013. Technical report on the outcome of the consultation with Member States and EFSA on the basic substance application for *Equisetum arvense* L. and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-427

Abbreviations

a.s.	active substance
DAR	draft assessment report
GAP	good agricultural practice
LC_{50}	lethal concentration, median
LD_{50}	lethal dose, median; dosis letalis media
MRL	maximum residue level
MS	Member State
NESTI	national estimated short-term intake
OSR	oilseed rape
PBI	plant-back interval
PEC	predicted environmental concentration
PEC_{sed}	predicted environmental concentration in sediment
PEC_{soil}	predicted environmental concentration in soil
PEC_{sw}	predicted environmental concentration in surface water
PRIMo	Pesticide Residue Intake Model
RMS	rapporteur Member State
TMDI	theoretical maximum daily intake

Appendix A – Collation of comments from Member States and EFSA on the basic substance application for *Equisetum arvense* L. (extension of use) 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

No comments

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)	2.1.6 Identity	EFSA agrees that the *Equisetum arvense* L., as basic substance should meet the requirements of the European Pharmacopoeia.		No comment from applicant. Compulsory since the initial application.	Addressed: *Equisetum arvense* L., as basic substance should meet the requirements of the European Pharmacopoeia.

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

No comments

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

No comments

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

No comments

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(2)	2.5 Description of the recipe	EFSA: 225 g in 10 l (assuming 10 kg) is not 0.225 %	After the 10 times dilution (and not 10th) it becomes 0.225%, but in this case the heading is not correct as it talks about mother extraction.	§2.6 corrected	Addressed: The description of the recipe has been corrected in the updated submission.
2(3)	2.5 Description of the recipe, p.12	EFSA: mode of application is not mentioned	From the GAP table the mode of application seems to be spraying, but probably would be helpful to mention what kind of spray equipment can be used and if there is a need for filtration of the extract before application.	Filtration described since the original application in the recipe.	Addressed: It is mentioned in the GAP that the extract must be filtered before use. Information on the spray equipment to be used was not included.

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)	3.4	DE: The intended uses on crop plants (vegetables, pome fruit, stone fruit, small fruit, ornamental plants) and pests (fungal diseases, powdery mildews, D. rosae, Botrytis) are very unspecific. E.g., it would be very difficult to proof efficiency for all fungal diseases on all vegetables.	Please be more specific with crop plants and pests for the description of intended uses.	GAP corrected, OEPP codes + latin names of crops and diseases added	Addressed: The GAP table was updated in the revised submission.
3(2)	3.3. Usefulness in the framework of plant protection, p.17	EFSA: it seems that there aren't literature/experimental data showing efficacy of the product for the extension of use.		More reference added in §3	Addressed: Three new bibliographic references were added, not really addressing the usefulness for the extension of use.

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(3)	3.2.1.2 Mode of action	EFSA: it is not clear what are the Si-based fertilisers and if their effects have any relation with the application of the *Equisetum* extract		Mode of action is fungicidal activity (FU), but antisporulant properties are also described. Elicitor (EL) effect may be found for components of Equisetum including silicon based natural substances. More references added.	Addressed: Additional information was added to the revised submission.

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

No comments

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**

No comments

5. Impact on Human and Animal Health

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
5(1)	General	EFSA: There is no complete evaluation of *Equisetum arvense* L. in the EU, either as food or medicine. In regard to the health effects the EFSA NDA Panel assessment is not relevant. The evaluation by EMA (EMA/HMPC/278089/2015 of the February 2nd 2016) indicates the following: "No data from investigations of single- and repeat- dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity, local tolerance or other special studies of preparations from Equiseti herba in animals, according to current state-of-		All references prove the multiple safe uses of *Equisetum arvense*, including medicinal uses. More references as medicinal uses are added in the updated BSA. Citation: „EA meets the requisites for having well-defined medical applications with proven efficacy and acceptable safety"	EFSA: The additional references in the updated BSA are not considered sufficient to address hazard identification and exposure assessment of the compound. Regarding the medicinal use of the compound, the most recent assessment at the EU level was conducted by EMA in February 2016 (EMA/HMPC/278091/2015) and is taken into account. *Equisetum arvense* L. has not been evaluated as a well-established medicine and "no data from investigations of single- and repeat-dose toxicity, genotoxicity, carcinogenicity, reproductive

5.1. Toxicokinetics and metabolism in humans

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
		the-art standards are available".			and developmental toxicity, local tolerance or other special studies of preparations from Equiseti herba in animals, according to current state-of–the-art standards are available". In view of the evaluations at EU level (EFSA NDA panel, EMA) and the absence of new assessment of the identity, the previous EFSA conclusion is maintained and a data gap is set
5(2)	General	EFSA: in this use extension the identity of the compound equisetum is still doubtful and therefore its toxicological relevance remains unclarified.		Using Equisetum and toxicity search for 2018-2020 references only positive references were found.	See also 5(1)

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

No comments

5.3. Short-term toxicity

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA		Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments

5.4. Genotoxicity

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

No comments

5.5. Long-term toxicity

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

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

No comments

5.7. Neurotoxicity

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

No comments

5.8. Toxicity studies on metabolites

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

No comments

5.9. Medical Data: adverse effects reported in humans

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

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

No comments

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

No comments

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

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

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

No comments

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
3(1)	6 Residues	EFSA: In the absence of a new assessment of the identity and toxicity of *Equisetum* the previous conclusion that because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative consumer risk assessment is not possible will be maintained. See also: European Food Safety Authority, 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for *Equisetum arvense* L. and the conclusions drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-427. 42 pp.		Safe for medicinal product and herbal tea but with dangerous residues?	EFSA: In the absence of a new assessment of the identity and toxicity of *Equisetum* the previous conclusion that because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative consumer risk assessment is not possible are maintained. See also: European Food Safety Authority, 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for *Equisetum arvense* L. and the conclusions

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
					drawn by EFSA on the specific points raised. EFSA supporting publication 2013:EN-427. 33 pp.

7. Fate and Behaviour in the environment

7.1 Fate and Behaviour in the environment

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
7(1)		EFSA: In the absence of a new assessment of the identity of *Equisetum*, neither a qualitative nor a quantitative exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* for plant protection is possible. See also: European Food Safety Authority, 2013; Outcome of the consultation with Member States and EFSA on the basic substance application for *Equisetum arvense* L. and the conclusions drawn by EFSA on the specific points raised. EFSA	Should a better characterisation of the major components of *Equisetum arvense* be made available, then scientific literature on the fate and behaviour in soil and water of these components could be scrutinised and this information be included in an updated application.	Composition is described in the Pharmacopeia. More description is provided in the updated BSA about the composition. Reference added.	The available evaluations of *Equisetum arvense* L. in the dossier for basic substance application according to the guidance SANCO 10363/2012 v3[2] do not make any reference to information from open scientific literature for the fate and behaviour in the environment, and the mentioned EMEA evaluation (EMEA/HMPC/394895/2007) does not contain any assessment of the potential exposure of the environment to *Equisetum arvense* L. and corresponding environmental risk assessment relevant to the proposed uses for plant

[2] European Commission, DRAFT Guidance on the procedure for application of basic substances to be approved in compliance with Article 23 of Regulation 1107/2009, SANCO/10363/2012, rev 3, 13 July 2012

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
		supporting publication 2013:EN-427. 42 pp.			protection. Therefore derogation from Article 4 of the Regulation (EC) No 1107/2009 is not possible with respect to environmental assessment. Information on '*its fate and distribution in the environment, particularly contamination of surface waters, including estuarine and coastal waters, groundwater, air and soil taking into account locations distant from its use following long-range transport need to have been addressed in the application*', as required by the Regulation. Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a

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
					quantitative exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* for plant protection is not possible.

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

No comments

8. Effects on non-target species

8.1. Effects on terrestrial vertebrates

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(1)	8.1. Effects on terrestrial vertebrates	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to birds and mammals. Nevertheless, in terms of the proposed change of approval, it is not anticipated that the change will notably increase the risks to birds and mammals. However, it should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha), as indicated in the GAP table included in the application of July 2012. The GAP included in the current application is a		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: Since identity and toxicity of *Equisetum* presented in this application is not clear (see 6(1)) it was not possible to estimate its influence on non-target organisms and it is considered a data gap.

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
		much higher rate of 6 applications of 2000 g/ha).			

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(2)	8.2. Effects on aquatic organisms	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to aquatic organisms. It should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: See 8(1)

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
		application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).			

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(3)		DE: The reference (CASDAR 2009) is not adequate to proof that there are no harmful effects on bees.	Please provide studies that meet scientific standards, preferably in peer-reviewed independent scientific journals.	Bibliography updated, no negative reference was found since initial approval.	EFSA: See 8(1)
8(4)	8.3.1. Effects on bees	EFSA: Insufficient information is available to perform a		Maximum rate already allowed as basic substance is 12.000	EFSA: 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 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
		quantitative assessment of the risks to bees. It should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).		g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	
8(5)	8.3.2. Effects on other arthropods	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to non-target arthropods. Nevertheless, in terms of the proposed change of approval, it is not anticipated that the change will notably increase the risks to non-target arthropods. However, it		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: 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 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 be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).			

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(6)	8.4. Effects on earthworms and other soil macroorganisms	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to soil organisms. It should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: See 8(1)

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(7)	8.5. Effects on soil micro-organisms	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to soil microorganisms. It should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: 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 Proposal by Member States/EFSA on how the application should be updated to address the comment	Column 4 Follow up response from applicant	Column 5 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8(8)	8.6. Effects on other non-target organisms (flora and fauna)	EFSA: Insufficient information is available to perform a quantitative assessment of the risks to non-target terrestrial plants (NTTP). Nevertheless, in terms of the proposed change of approval, it is not anticipated that the change will notably increase the risks NTTP. However, It should be noted that the previous assessment of EFSA (EFSA supporting publication 2013:EN-427) was performed for a much smaller application rate (maximum of 6 application of 1.5 g a.s./ha). The GAP included in the current application is a much higher rate of 6 applications of 2000 g/ha).		Maximum rate already allowed as basic substance is 12.000 g/ha in SANCO/12386/2013–rev. 7 of 20 July 2017	EFSA: 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 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

No comments

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

No comments

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

No comments

Appendix B – Identity and biological properties

Common name (ISO)	*Equisetum arvense* L. (not ISO)
Chemical name (IUPAC)	not applicable
Chemical name (CA)	not applicable
Common names	Field horsetail, Common horsetail
CAS No	71011-23-9
CIPAC No and EEC No	275-123-8
FAO specification	not applicable
Minimum purity	n.a. (complex mixture of chemical substances) European Pharmacopoeia 2008, Equisetum Stem, Equiseti Herba. European Pharmacopoeia 6.0., 01/2008:1825
Relevant impurities	European Pharmacopoeia 6.2., 07/2008:20813
Molecular mass and structural formula	n.a. (complex mixture of chemical substances)
Mode of Use	foliar spraying
Preparation to be used	Dispersible concentrate (DC) (decoction)
Function of plant protection	fungicide

Appendix C – List of extension of uses

Crop and/ or situation (a)	Member State or Country	Example product of *Equisetum arvense* L. as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks*
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha)(l)		
Grapevine *Vitis vinifera* VITVI	All MS	Homogenate of *Equisetum arvense* L.	F	Downy mildews: *Plasmopara viticola,* PLASVI Powdery mildews *Erysiphe necator* UNCINE	Dispersible concentrate (DC)	2	Foliar application spraying	From 1st shoots (BCH10) to cluster tightening **(BBCH 85)** Spring to summer	2 to 6	7 days	200	100 to 300	200 to 600	None	plant homogenate extracted with hot water and filtered to be used within 24 h after preparation
Wheat *Triticum turgidum* ssp durum *Triticum aestivum* *Triticum sativum* *Triticum vulgare* TRZAX			F	*Fusarium* spp. FUSASC				From BBCH10 to BBCH89		5 to 15 days					

Crop and/ or situation (a)	Member State or Country	Example product of *Equisetum arvense* L. as available on the market	F G or I (b)	Pests or group of pests controlled (c)	Formulation		Application				Application rate			PHI (days) (m)	Remarks*
					Type (d-f)	Conc of a.i. g/kg (i)	Method kind (f-h)	Growth stage & season (j)	No. of application min/max (k)	Interval between applications (min)	g a.i./hl min max (g/hl)	Water l/ha min max	Total rate each application g a.i./ha min max (g/ha)(l)		
Vegetables 3VEGC	All MS	Homogenate of *Equisetum arvense* L.	F + G	Fungal diseases	Dispersible concentrate (DC)	2	foliar application spraying	all stages	1 to 6	1 day	200	200 to 1000	400 to 2.000	None	plant homogenate extracted with hot water and filtered to be used within 24 h after preparation
Pome fruit 3PMFC stone fruit 3STFC and small fruit 3SMFC			F					Whole vegetation period BBCH 19 - 69	2 to 6	5 days	200	500 to 1000	1000 to 2000	7 days	
ornamental plants like Rosa 1ROSG			F	Powdery Mildews Rose black spot disease *Diplocarpon rosae* DIPCRO *Botrytis* spp BOTRSP				BBCH 19 - 59	6	7 days	200	1000	2000	None	
			G												

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(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.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(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) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(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