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 *Equisetum arvense L.* and the conclusions drawn by EFSA on the specific points raised[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 *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. The current report summarises the outcome of the consultation process organised by the European Commission and presents EFSA's scientific views on the individual comments received.

KEY WORDS

Equisetum arvense L., extract, basic substance, application, consultation, plant protection, pesticide

[1] On request from the European Commission, Question No EFSA-Q-2013-00307, approved on 8 May 2013.

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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 the Task Force ITAB Institute (Institut Technique de l'Agriculture Biologique) 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.

A consultation on the basic substance application for *Equisetum arvense L.*, organised by the European Commission, was conducted with Member States and EFSA via a written procedure in June – July 2012. Subsequently the applicant was invited to address the comments received in the format of a Reporting Table.

In 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. 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 thereon, and to finalise the Reporting Table with its scientific views on the specific points raised in the commenting phase.

The current report therefore summarises the outcome of the consultation process organised by the European Commission and presents EFSA's scientific views on the individual comments received in the format of a Reporting Table.

There is no complete evaluation of *Equisetum arvense L.* in the EU, either as a food or as a medicine. The evaluation by the EMEA concluded the following: 'In summary the data on toxicity are insufficient. Therefore for horsetail a traditional monograph and no list entry are recommended.'

This substance does not meet the criteria as a basic substance. It does not comply with Article 23 (1)(c) because it is not the substance or a simple dilution of the substance that is applied to the crop. The *Equisetum arvense L.* dry plant is extracted with boiling water for 45 minutes. The extract is then cooled and diluted with water.

To address the efficacy some information from the open literature concerning the mode of action is available. It is stated that *Equisetum* would act through a desiccating effect, an elicitor effect and the presence of some fungistatic compounds. However, trials to confirm the effectiveness of *Equisetum* against apple and vineyard fungi are missing.

The data available in the mammalian toxicology section are not specifically relevant for *Equisetum* and, as such, do not allow a specific assessment. Furthermore, the composition of the extract following extraction of the dry plant with boiling water is unclear, also in consideration of the claimed presence of substances such as alkaloids, phytosterols, tannin, triterpenoids and phenolics, such as flavonoids, styrylpyrones and phenolic acids. Some of the data reported in a recent article raise concern over possible toxicological effects, which need to be addressed before a conclusion can be drawn.

Since the available data were not sufficient to conclude on the toxicity of *Equisetum arvense L.*, a consumer risk assessment could not be completed.

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* for plant protection is not possible.

The data provided in the area of ecotoxicology do not specifically address the toxicity of the substance to non-target organisms. However, they may be considered acceptable based on a weight of evidence approach to support the statement that no risk assessment is necessary for non-target organisms due to the natural occurrence of the substance. Therefore, pending on the definition of the exact identity of the compound *Equisetum*, the risk to non-target organisms can be considered as low.

TABLE OF CONTENTS

BACKGROUND AS PROVIDED BY THE EUROPEAN COMMISSION

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

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 the Task Force ITAB Institute (Institut Technique de l'Agriculture Biologique)[4] for approval as a "basic substance".

The European Commission organised a consultation with Member States and EFSA on the basic substance application for *Equisetum arvense L*, which was conducted via a written procedure in June – July 2012. The comments received were collated by the European Commission 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 European Commission 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 (France, 2011 and ITAB Institute, 2012).

TERMS OF REFERENCE AS PROVIDED BY THE EUROPEAN COMMISSION

On 6 March 2013 EFSA was requested to provide its scientific views on the specific points raised during the consultation process conducted on the basic substance application for *Equisetum arvense L.* To this end, a Technical Report containing the finalised Reporting Table is prepared by EFSA. 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 No L 309, 24.11.2009, p. 1-50.

[4] The Task Force also contains the FR competent authorities (ANSES - Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail)

EVALUATION

The comments received on the application for *Equisetum arvense L.* 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. France, 2011. *Equisetum arvense L.* Basic substance application submitted in the context of Article 23 of Regulation (EC) No 1107/2009. November 2011. Submitted by the Rapporteur Member State France. Documentation made available to EFSA by the European Commission.

2. ITAB Institute, 2012. *Equisetum arvense L.* Basic substance application update submitted in the context of Article 23 of Regulation (EC) No 1107/2009. July 2012. Submitted by ITAB Institute. Documentation made available to EFSA by the European Commission.

REFERENCES

Asgarpanah J., *et al.*, 2012. Phytochemistry and pharmacological properties of *Equisetum arvense* L. Journal of Medicinal Plants Research Vol. 6(21), pp. 3689-3693.

EMEA, HMPC (Committee on Herbal Medicinal Products), 2008. *Equisetum arvense* L., herba. Assessment report for the development of community monographs and for inclusion of herbal substance(s), preparation(s) or combinations thereof in the list. EMEA/HMPC/394895/2007, 3 July 2008.

APPENDIX

COLLATION OF COMMENTS FROM MEMBER STATES AND EFSA ON THE BASIC SUBSTANCE APPLICATION FOR *EQUISETUM ARVENSE L.* AND THE CONCLUSIONS DRAWN BY EFSA ON THE SPECIFIC POINTS RAISED

1. Purpose of the application

General				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	General	EFSA: This substance does not meet the criteria as a basic substance. It does not comply with Article 23 (1)(c) because it is not the substance or a simple dilution of the substance that is applied to the crop. It is also not a 'foodstuff as defined in Article 2 of Regulation (EC) No 178/2002. There are no relevant evaluations, carried out in accordance with other community legislation.	The *Equisetum arvense L.* dry plant is extracted with boiling water for 45 minutes. The extract is then cooled and diluted with water. It is then also not the case that the used substance is a foodstuff. What is eaten is the cooked stem the cooking water is drained away. *Equisetum arvense* is consume in Japan. Ref: The sporophyte of *Equisetum arvense L.* (tsukushi) is consumed as food in sweetened vinegar, cooked food, and chopped fish, while nutritive caulis (sugina) is well known as Sugina tea in Japan and is drunk as a health drink (Nagai et al., 2005). We found no other report than: - EMEA, 2007, *Equisetum arvense* L., Herba, ASSESSMENT REPORT EMEA /HMPC /394895/2007 - Efsa. Scientific opinion on the substantiation of health claims related to *Equisetum arvense L.* No	There is no complete evaluation of *Equisetum arvense* in the EU, either as a food or as a medicine. The evaluation by the EMEA (EMEA/HMPC/394895/2007) concluded the following: '*In summary the data on toxicity are insufficient. Therefore for horsetail a traditional monograph and no list entry are recommended*.' This substance does not comply with the definition for a basic substance as given in the legislation. This substance does not meet the criteria as a basic substance. It does not comply with Article 23 (1)(c) because it is not the substance or a simple dilution of the substance that

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
			1924/20061. EFSA Journal 2009; 7(9): 1289	is applied to the crop. The *Equisetum arvense L.* dry plant is extracted with boiling water for 45 minutes. The extract is then cooled and diluted with water.
2)	General	EFSA: There is no dossier for this substance.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provided.	Addressed: The dossier has been supplied (July 2012).
3)		DE: Study reports were not provided.	All references and studies are provided.	Addressed: The dossier with references has been supplied (July 2012).
4)		DE: Application and commenting table should be consistent in numbering and headlines. The commenting table should contain only relevant points and headlines. The application should be in order of the commenting table and should address all relevant points.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provided.	Addressed: This is just a format issue and not a scientific issue; the available information has been summarised appropriately so that it can be peer reviewed.
5)		DE: There are several repetitions in the report. For example, the identity of the active substance is described in level 1 and in level 2 and some of the data are identical. As this was a pilot project it is proposed for future reports to describe data comprehensively only once.	Corrections are done in Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 Comments are taking in account, see above.	Addressed: The repetition of the information in the original report has been corrected and now data/information have only been issued once.
6)	1.5.3 Summary of	EFSA: In the table with the summary of the	Corrections are done in the GAP Table of	Addressed:

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
	intended uses	intended uses it is not clear if "Lk a.i./ha" is intended to be "kg a.i./ha". Please clarify.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3.	In the original GAP table the rate per hectare was specified as 'Lk a.i./ha' and it was not clear what this meant. This has now been corrected to read 'g a.i./ha'.

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

No comments.

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

No comments.

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

No comments.

3. Uses of the substance and its product

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

No comments.

3.2. Effects on harmful organisms or on plants				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	1.5.2	DE: No information has been provided by the applicant with regard to efficacy and phytotoxicity. The applicant should list own or public available data (e.g. scientific publications) to inform about the experiences of practice with the basic substance as plant protection agent.	Data concerning fungicide potential of *Equisetum arvense* and silica are given. Field and Greenhouse experiments are given. All uses described in literature are constituting to our point of view an intrinsic a good proof of non phytotoxicity.	Some information from open literature concerning the mode of action is available. It is stated that *Equisetum* would act through a desiccating effect, an elicitor effect and the presence of some fungistatic compounds. However, trials to confirm the effectiveness of *Equisetum* against apple and vineyard fungi are missing.

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

No comments.

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
1)	General	EFSA: for the assessment of equisetum health effects no relevant EU evaluations are available (the EMA 2007 monograph includes limited details; the EFSA NDA Panel assessment of health claims is not relevant to the current purpose).	We believe that although evaluation in these documents is not similar to exposure in fields, it was permitted by this means to find Recommended Daily Intake in order to compare to exposure coming out from POEM-UK exposure calculation.	The available data are not specifically relevant for *Equisetum* and, as such, do not allow a specific assessment of *Equisetum* to be performed.
2)		EFSA: the identity of the compound equisetum has to be defined to further check its toxicological relevance in the frame of the definition of what a basic substance is.	Composition of Equisetum was described in few papers, furnished in our answer. We believe that in these documents it was permitted by this means to calculate POEM UK exposure for relevant compounds.	According to the paper by Asgarpanah *et al.*, 2012 (see section 2.2 of the revised application), *E. arvense* has been used for the treatment of various conditions, such as tuberculosis, haemostatic for profuse menstruation, nasal, pulmonary and gastric haemorrhages, for brittle fingernails and loss of hair, for rheumatic diseases, gout, poorly healing wounds and ulcers, swelling and fractures, and for frostbite. 'Horsetail' can produce toxic effects over its prolonged use: silicates produce digestive problems, especially when used for a long time; alkaloids, although not present in high concentrations, can accumulate in the organism, possibly facilitating premature childbirth, nervous disorders, headaches, loss of appetite,

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
				swallowing problems, etc. With regard to the chemical composition, it is indicated that the commonly known phytochemical compounds from *E. arvense* are alkaloids, phytosterols, tannin, triterpenoids and phenolics, such as flavonoids, styrylpyrones and phenolic acids. However, the available information does not allow to establish the identity of *Equisetum*. Overall, the available data are insufficient both qualitatively and quantitatively, and are not specifically relevant for *Equisetum* to allow a specific assessment to be undertaken.
3)		DE: On the basis of the report of the RMS there is at present no concern as to the approval of the active substance, horsetail extract, as a basic substance if - the watery extract and not the dried plant is approved as the active substance - taking into consideration the conditions for manufacturing and use envisaged by France.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides evidence that horsetail extract described in this application is a water extract. Furthermore, horsetail is available in all Europa at the same quality as describe in French provider Analyses certificates.	It is unclear what the composition of the decoction is, also in consideration of the claimed presence of substances, such as alkaloids, phytosterols, tannin, triterpenoids and phenolics, such as flavonoids, styrylpyrones and phenolic acids. Overall, the available data are insufficient both qualitatively and

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
				quantitatively, and are not specifically relevant for *Equisetum* to allow a specific assessment to be performed.
4)		DE: Since horsetail extract is a so-called decoction or a watery plant extract from which the PPP is manufactured through dilution, an evaluation of the active substance according to the draft "GUIDANCE DOCUMENT ON BOTANICALS USED IN PLANT PROTECTION PRODUCTS" (SANCO/xxxx/2012– rev. 0 of xx.xx. 2012) would be conceivable in this case. In doing so, a reduced data set could be used. From a toxicological point of view, the information stated is sufficient for a positive assessment according to the guidance document since corresponding data exist and present no evidence of acute toxicity, mutagenicity or critical effects following repeated dosage. From experience, health risks have not arisen through use in medical applications or as a dietary component either.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all data.	The data reported in the article by Asgarpanah *et al*, 2012, raise concern over possible toxicological effects (see column 4 at comment 5.1(2) above). Overall, the available data are insufficient both qualitatively and quantitatively, and are not specifically relevant for *Equisetum* to allow a specific assessment to be performed.
5)		DE: In order to avoid unequal treatment, a binding clarification is necessary as to whether plant extracts can be approved as basis substances or whether they must be assessed and decided on according to the	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all data.	Noted. This is an issue for risk managers.

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
		GUIDANCE DOCUMENT ON BOTANICALS USED IN PLANT PROTECTION PRODUCTS, which is at present under discussion and revision, before horsetail extract is officially approved as a basic substance.		

5.2. Toxicokinetics and metabolism in humans				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
6)	General	EFSA: toxicokinetic studies on flavonoid glycosides are summarised; however the relevance of these compounds to equisetum needs to be further addressed depending on the definition of equisetum identity (several compounds are mentioned to be present in equisetum).	We envisaged 3 main compounds for exposure calculation coming out from POEM-UK: nicotine, flavonoids and silica (although silica is amorphous in *Equisetum*).	According to the paper by Asgarpanah *et al.*, 2012, as regards the chemical composition, the commonly known phytochemical compounds from *E. arvense* are alkaloids, phytosterols, tannin, triterpenoids and phenolics such as flavonoids, styrylpyrones and phenolic acids. The available data are insufficient both qualitatively and quantitatively, and are not specifically relevant for *Equisetum* to allow a specific assessment to be performed.

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

No comments.

5.4. Short –term toxicity				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

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

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

No comments.

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

No comments.

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

No comments.

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

No comments.

5.14. Impact on human and animal health arising from exposure to the substance or impurities contained in it				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application

No comments.

6. Residues

No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
1)	1.11 Residue	EFSA: No risks to consumers envisaged, unless toxicological concerns are raised in the Phys-Chem or Tox. sections.	We envisaged 3 main compounds for exposure calculation coming out from POEM-UK: nicotine, flavonoids and silica (although silica is amorphous in *Equisetum*).	Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative consumer risk assessment is not possible. See also EFSA conclusion in comment 5.1(2).

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
1)	1.12. Fate and behaviour in the environment	EFSA: An EU evaluation relevant for environmental fate and behaviour assessment is not referred to so is probably not available. Therefore a derogation from Article 4 of the Regulation is not possible. Therefore 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.*'	Horsetail is constituted mainly of green matter, readily biodegradable, amorphous silica, and few lesser compounds (nicotine, flavonoids). Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all information possibly found in literature.	The available evaluations of *Equisetum arvense L.* in the dossier for basic substance application according to the guidance SANCO 10363/2012 v3[5] 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 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*

[5] 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

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
				distant from its use following long-range transport need to have been addressed in the application', as required by the Regulation.
2)	1.12 Fate and behaviour in soil	EFSA: Further information on the fate and behaviour of the active components (refer to comment in the tox section on the identity of the compound equisetum) of equisetum in soil is needed to provide a more refined surface water exposure assessment and to perform the ground water exposure assessment. It is envisaged that at least for some of these components more data will be available in the public scientific literature.	*Equisetum arvense* is a plant readily decomposed in basic constituents in environment. Water extraction does not concentrate active principles, which are mainly silica, present massively in soil.	Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* for plant protection is not possible. See also EFSA conclusion in comment 5.1(2).
3)	1.12 Fate and behaviour in water	EFSA: Further information on the fate and behaviour of the active components of equisetum (refer to comment in the tox section on the identity of the compound equisetum) in water and water/sediment systems is needed to refine the aquatic exposure assessment. It is envisaged that at least for some of these components more data will be available in the public scientific literature.	*Equisetum arvense* is a plant, the readily decomposed in basic constituents on environment. Water extraction does not concentrate active principles, which are mainly amorphous silica. As a part of a genus that some spp are growing in water, it is unobvious that leakage in water of small quantities of *E. arvense* plant extract will be of relevance.	Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* for plant protection is not possible. See also EFSA conclusion in comment 5.1(2).
4)	1.12 Fate and behaviour in air	EFSA: Further information on the fate and behaviour of the active components of equisetum (refer to comment in the tox	*Equisetum arvense* is a plant, the readily decomposed in basic constituents on environment. Water extraction does not	Because of the missing information on the exact identity of the compound Equisetum, a qualitative and a

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
		section on the identity of the compound equisetum) in air will be needed to address the potential for long-range transport.	concentrate active principles, which are mainly amorphous silica and green matter.	quantitative exposure assessment of the components introduced into the environment following the application of *Equisetum arvense* for plant protection is not possible. See also EFSA conclusion in comment 5.1(2).

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
1)	1.13 effect on non-target species	EFSA: An EU evaluation relevant for ecotoxicological risk assessment is not referred to so it is probably not available. Therefore derogation from Article 4 of the regulation is not possible. As highlighted in the toxicological section, the identity of the compound equisetum has to be defined to further check its toxicological relevance to non-target organisms. Some literature data were mentioned to support that no risk assessment is necessary for non-target organisms. However these data were not provided (there is no dossier for the substance). In particular data were mentioned for birds, fish, bees and soil macro-organisms while no data were referenced to for aquatic invertebrates, algae, non-target arthropods, earthworms, soil microorganisms.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references. References of the composition are here provided Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references.	Because of the missing information on the exact identity of the compound *Equisetum*, a qualitative and a quantitative risk assessment for non-target organisms cannot be performed (see EFSA conclusion in comment 5.1(2)). Some literature data were mentioned to support that no risk assessment is necessary for non-target organisms; in particular data were mentioned for birds, mammals, fish, bees, soil organisms (nematodes), non-target arthropods, and other non-target flora and fauna, while no data were referenced for aquatic invertebrates, algae and soil microorganisms. The data provided do not specifically address the toxicity of the substance. However, they may be considered acceptable based on a weight of evidence approach to support the statement that no risk assessment is necessary for non-target organisms due to the natural occurrence of the substance. Therefore, pending on the definition of the exact identity of the

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
				compound *Equisetum*, the risk to non-target organisms can be considered as low.
2)	1.13 effect on non-target species, birds and mammals	EFSA: the RMS concluded that no risk assessment was deemed necessary, because equisetum can be in the diet of birds and because it is not toxic to mammals. This statement could be considered acceptable, when the issues raised in the previous comment will be addressed.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references.	See EFSA conclusion in comment 8.1(1) above.

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
3)	1.13 effect on non-target species, aquatic organisms	EFSA: RMS said that Equisetum is a natural species in wetland and some species are consumed by fish. Based on this no risk assessment was deemed necessary for aquatics organisms. This statement could be considered acceptable, when the issues raised in the previous comment will be addressed.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references.	See EFSA conclusion in comment 8.1(1) above.

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
4)	1.13 effects on non-target species, bee and non-target arthropods	EFSA: some data were available on acute contact toxicity for bees within a project conducted in France. The mortality of bees never exceeded 4 %. Based on this no risk assessment was deemed necessary for bees and non-target arthropods. This statement could be considered acceptable, when the issues raised in the previous comment will be addressed.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references. We provide also previous dossier with references.	See EFSA conclusion in comment 8.1(1) above.
5)	1.13.2	DE: No information has been provided by the applicant with regard to effects on bees and other arthropods. It has not been reasoned that the substance is harmless for bees and other arthropods.	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references.	See EFSA conclusion in comment 8.1(1) above.

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
6)	1.13 effects on non-target species, earthworms	EFSA: a study on nematode population was mentioned, indicating no effects on abundance (number of species, biomass and number of individuals). The literature data referenced were not provided (there is no dossier for the substance). This statement could be considered acceptable, when the issues raised in the previous comment will	Dossier as BASIC SUBSTANCE APPLICATION TEMPLATE according to Sanco 10363/2012 v3 is provides all literature references. *E. arvense* is not considered as toxic for soil micro and macro organisms.	See EFSA conclusion in comment 8.1(1) above. Note: The study provided is on nematode population. Therefore it does not address the risk to earthworm populations, which may be more sensitive than the nematodes.

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
		be addressed. It is noted that this study will not address the risk to earthworms.		

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

No comments.

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
7)		EFSA: No data provided.	*Equisetum arvense* is a plant, the readily decomposed in basic constituents on environment. Water extraction does not concentrate active principles, which are mainly amorphous silica and green matter.	See EFSA conclusion in comment 8.1(1) above.

8.7. Effects on biological methods of sewage treatment				
No.	Column 1 Reference to Application Template	Column 2 Comments from Member States / EFSA	Column 3 Follow up response from applicant	Column 4 EFSA's scientific views on the specific points raised in the commenting phase conducted on the application
8)		EFSA: No data provided.	*Equisetum arvense* is a plant, the readily decomposed in basic constituents on environment. Water extraction does not concentrate active principles, which are mainly amorphous silica and green matter.	See EFSA conclusion in comment 8.1(1) above.

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
1)	1.15 Proposed decision concerning approbation in regulation (EC) N° 1107/2009	DE: It is proposed that the approval of *Equisetum arvense L.* should also be in compliance with European Pharmacopoeia.	All Equisetum extracts were issued from decoction of European Pharmacopoeia certified dry plants.	Addressed: It is clear that the starting material i.e. the dried plant will comply with the European Pharmacopoeia, but as this is not what is applied to the plant it does not change any of the outcomes.

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

No comments.

ABBREVIATIONS

µg	microgram
µm	micrometer (micron)
a.i.	active ingredient
a.s.	active substance
d	day
EMA	European Medicines Agency
EMEA	European Medicines Agency
EU	European Union
g	gram
GAP	Good Agricultural Practice
h	hour
ha	hectare
hl	hectolitre
HMPC	Committee for Herbal Medicinal Products (EMEA)
kg	kilogram
L	litre
mg	milligram
mL	millilitre
mm	millimetre
NDA	Panel on Dietetic Products, Nutrition and Allergies (EFSA)
POEM	predictive operator exposure model
PPP	plant protection product
RMS	Rapporteur Member State
SANCO	European Commission Directorate General Health and Consumers