EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Safety of the Food Chain
Chemicals, contaminants, pesticides

COMMISSION STAFF WORKING DOCUMENT[1]

Basic Substance
Equisetum arvense L.

SANCO/12386/2013– rev. 5
20 March 2014

Final

Review report for the basic substance *Equisetum arvense* L.
Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on 20 March 2014
in view of the approval of *Equisetum arvense* L. as basic substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of *Equisetum arvense* L., made in the context of the assessment of the substance provided for in Article 23 of Regulation (EC) No 1107/2009[2] concerning the placing of plant protection products on the market, with a view to the possible approval of this substance as basic substance.

In accordance with the provisions of Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 28 December 2011 an application from the Task Force ITAB (Institut Technique de l'Agriculture Biologique), hereafter referred to as the applicant, for the approval of the substance *Equisetum arvense* L. as basic substance.

The application and attached information were distributed to the Member States and European Food Safety Authority (EFSA) for comments. The applicant was also allowed to address collated comments and provide further information to complete the application which was finalised in the new version of July 2012.

In accordance with the provisions of Article 23(4) of Regulation (EC) No 1107/2009 the Commission required scientific assistance on the evaluation of the application to the EFSA, who delivered its views on the specific points raised in the commenting phase.

1 Does not necessarily represent the views of the Commission.

2 OJ L 309, 24.11.2009, p. 1-50.

EFSA submitted to the Commission the results of its work in the form of a technical report for *Equisetum arvense* L. on 24 May 2013[3].

The Commission examined the application, the comments by Member States and EFSA and the EFSA technical report on the substance together with the additional information and comments provided on it by the applicant, before finalising the current draft review report, which was referred to the Standing Committee on the Food Chain and Animal Health, for examination. The draft review report was finalised in the meeting of the Standing Committee on 20 March 2014.

Given the importance of the EFSA technical report, the comments, additional information and clarifications submitted (background document C), all these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices thereto, has been developed in support of Commission Implementing **Regulation (EU) No 462/2014**[4] concerning the approval of *Equisetum arvense* L. as basic substance under Regulation (EC) No 1107/2009.

The review report will be made available for public consultation by any interested parties.

Without prejudice to the provisions of Regulation (EC) No 178/2002[5], in particular with respect to the responsibility of operators, following the approval of *Equisetum arvense* L. as basic substance, operators are responsible for using it for plant protection purposes in conformity with the legal provisions of Regulation (EC) No 1107/2009 and the conditions established in the sections 4, 5 and Appendices I and II of this review report.

EFSA will make available to public all background documents and the final Technical Report of EFSA as well as the application without the Appendices and excluding any information for which confidential treatment is justified in accordance with the provisions of Article 63 of Regulation (EC) No 1107/2009.

Products containing exclusively one or more basic substances do not require authorisation in line with the derogation set under Article 28 of Regulation (EC) No 1107/2009. As a consequence, no further assessment will be carried out on such products. However, the Commission may review the approval of a basic substance at any time in conformity with the provisions of Article 23(6) of Regulation (EC) No 1107/2009.

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[3] 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. 2013:EN-427.23.

[4] OJ L 134, 7.5.2014, p. 28-31.

[5] OJ L 31, 1.2.2002 p. 1-24 - Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion based on the application, including the results of the evaluation carried out with the scientific assistance of EFSA, and the comments and further additional information provided by the applicant to address the open points identified in the Technical report from EFSA, is that there are clear indications that it may be expected that *Equisetum arvense* L. fulfils the criteria of Article 23.

Equisetum arvense L. (Field horsetail) is a widespread pteridophyte distributed in the northern hemisphere.

The use of aerial sterile stems of *Equisetum arvense* L. is known in food supplements as ingredient in tea before 15 May 1997. Hence, a "qualified presumption of safety" approach can be applied in compliance with EFSA Guidance on Safety assessment of botanicals and botanicals preparations intended for use as ingredients in food supplements[6].

Moreover, the use of the substance is recognised in traditional medicine in several EU countries and a period of at least 30 years in medical use as requested by Directive 2004/24/EC on qualification as a traditional herbal medicinal product was recognised. However, EMEA could not conclude on the assessment as herbal medicine due to lack of data.

As mentioned in the Scientific report of EFSA "Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements"[7], *Equisetum arvense* L. is included in the Annex B which concerns "cases where some data were available, but the Scientific Committee could not identify substances of concern, or other reasons for the inclusion in the compendium".

The same report underlines that Annex B cannot be considered as a list of “safe botanicals” for use in food supplements, since the Compendium has identified possible hazards in a non-exhaustive way and no risk assessment had been performed. However, it is also stressed that both the compendium and Annex B are of particular use for Tier 1 of the safety assessment framework for specific botanical preparations, as described in the above-mentioned guidance.

In addition, *Equisetum arvense* L. was also examined within the context of Regulation (EC) No 1924/2006 on nutrition and health claims made on foods[8].

When used for plant protection, *Equisetum arvense* L. is produced from a decoction in water of dried edible aerial sterile stems of the native European widespread species of pteridophytes.

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[6] Guidance on Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements EFSA Scientific Committee EFSA Journal 2009; 7(9) :1249.

[7] European Food Safety Authority; Compendium of botanicals reported to contain naturally occurring substances of possible concern for human health when used in food and food supplements. EFSA Journal 2012;10(5):2663. [60 pp.] doi:10.2903/j.efsa.2012.2663. Available online: www.efsa.europa.eu/efsajournal.

[8] EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) EFSA Journal 2009; 7(9) : 1289 doi: 10.2903/j.efsa.2009.1289.

The rate of application and the conditions of use which are described in detail in Appendices I and II, would not lead to concerns for human health. Furthermore, no residues are expected and the conditions of use would not significantly increase the background level due to natural occurrence of the plant.

Hence, on the basis of the risk assessment approach described in the EFSA guidance on safety assessment of botanicals, and considering the use in plant protection and the level of exposure deriving from such use, it can be concluded that the information provided is sufficient to consider *Equisetum arvense* L. as basic substance.

Equisetum arvense L. is not a substance of concern, does not have an inherent capacity to cause endocrine disrupting, neurotoxic or immunotoxic effects and is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Finally, it is not placed on the market as a plant protection product.

It can be concluded that the substance has neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment when used in accordance with the supported uses as described in Appendix II.

In fact, these indications were reached within the framework of the uses which were supported by the applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this review report) and therefore, they are also subject to compliance with the particular conditions and restrictions in sections 4 and 5 of this report.

Extension of the use pattern beyond those described above will require an evaluation at Community level in order to establish whether the proposed extensions of use can still satisfy the requirements of Article 23 of Regulation (EC) No 1107/2009.

4. Identity and biological properties

The main properties of *Equisetum arvense* L. are given in Appendix I.

It has been established that for the *Equisetum arvense* L**.** as notified by the applicant none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

Specifications laid down in the European Pharmacopeia must be complied with.

Distinction must be made between *Equisetum arvense* L. and *Equisetum palustris* L. and other species, following visual identification see also EU Pharmacopeia and application documentation.

5. Particular conditions to be taken into account in relation to the uses as basic substance of *Equisetum arvense* L.

Equisetum arvense L. must be identified by given specifications in Appendix I and must be used in compliance with method of preparation and condition of use as reported in Appendices I and II.

The following conditions for use deriving from assessment of the application have to be respected by users:

- Only uses as basic substance being fungicide having an eliciting action on the crop's self-defence mechanisms are approved;
- Use of aerial sterile stems and extraction carried out with water via decoction in compliance with conditions specified and dilution explained in Appendices I and II.

On the basis of the proposed and supported uses (as listed in Appendix II), no particular issues have been identified.

The identification of *Equisetum arvense* L. as edible means that Regulation (EC) No 178/2002 on food safety applies and consequently this includes the respect to maximum permissible levels of chemical and biological contaminants legally set for this type of food supplement.

6. List of studies to be generated

No further studies were identified which were at this stage considered necessary.

7. Updating of this review report

The information in this report may require to be updated from time to time to take account of technical and scientific developments, as well as of the results of the examination of any information referred to the Commission in the framework of Article 23 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection, as appropriate, with any amendment of the approval conditions for *Equisetum arvense* L. in Part C of Annex of the Regulation (EC) No 540/2011 [9].

8. Recommended disclosure of this review report

Considering the importance of the respect of the approved conditions of use and the fact that a basic substance will be not placed on the market as plant protection product hence, no further assessment will have to be carried out on it, it is very important to inform not only applicants but also potential users of the substance on the existence of this review report.

It is therefore recommended that the competent authorities of Member States will make available such report to general public and operators by means of their national relevant websites and by any other appropriate form of communication to ensure that the information reaches potential users.

[9] OJ L 153, 11.6.2011, p. 1–186.

APPENDIX I

Identity and biological properties

EQUISETUM ARVENSE L.

Common name (ISO)	Not relevant
Chemical name (IUPAC)	Not relevant
Chemical Name. (CA)	Not relevant
Botanical classification	*Equisetum arvense* L. fam. Equisetaceae, it is a widespread pteridophyte distributed in the northern hemisphere.
Common names	Synonyms: Equiseti herba (European Pharmacopoeia); Field horsetail, Common horsetail; Prêle des champs (French); Schachtelhalm (German); Coda cavallina (Italian); Heermoes (Dutch).
Part used	Edible part: sterile aerial stems. Distinction must be made between *Equisetum arvense* L. and *Equisetum palustris* L. and other species following visual identification see also EU Pharmacopeia and application documentation.
CAS No	Not relevant
CIPAC No and EEC No	Not relevant
FAO SPECIFICATION	Not relevant
Purity	European Pharmacopeia
Molecular formula	Not relevant
Molecular mass and structural formula	Not relevant

Mode of Use	sterile aerial caules and leaves of *Equisetum arvense* L. are used as cut dried plant to prepare a water decoction.
Preparation to be used	The decoction is made of boiling water as follows: 200 g of the aerial part of *Equisetum arvense L.* dry plant are macerated in 10 litres of water for 30 minutes (soaking) and then boiled for 45 minutes. After cooling down, the decoction is filtrated with a fine sieve and then further diluted by 10 with water. Therefore, the theoretical concentration of aerial part dry plant present in the decoction is 20 g/L, which is then diluted by 10, hence 2 g/L in the final preparation applied on plants. The preparation so made has to be applied within maximum 24 hours, to avoid oxygenation and potential microbiological contamination which may occur during the storage. The solvent for extraction and preparation is water (spring water or rainwater) and the pH is 6.5.
Function of plant protection	Fungicide.

APPENDIX II

List of uses supported by available data

EQUISETUM ARVENSE L.

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**			**Total 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)	g a.i./ha min max (g/ha) (l)		
Fruit trees Apple fruit (Malus pumila, Malus domestica) Peach-tree *(Prunus persica)*	France	Homogenate of *Equisetum arvense* L.	F	Foliar fungi like scab disease:*Venturia inaequalis,* Powdery mildews: *Podosphaera leucotricha* Peach leaf curl *Taphrina deformans*	Dispersible Concentrate (DC)***	2	foliar application spraying	From green leaf tip (BBCH 53) to flowers fading (BBCH 67) Spring	2- 6	7 days	200	500 to 1000	1000 to 2000	2000 to 12000	None	plant homogenate extracted with hot water and filtered to be used 24 h after preparation (see Appendix I)

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**			**Total 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)	g a.i./ha min max (g/ha) (l)		
Grapevine *Vitis vinifera*	France	Homogenate of *Equisetum arvense* L.	F	Downy mildews: *Plasmopara viticola,* Powdery mildews *Erysiphe necator*	Dispersible Concentrate (DC)***	2	foliar application spraying	From 1st shoots (BCH10) to cluster tightening (BBCH57) Spring to summer	2- 6	7 days	200	100 to 300	200 to 600	400 to 3600	None	plant homogenate extracted with hot water and filtered to be used 24 h after preparation (see Appendix I)
Cucumber *roots* *Cucumis sativus*	France	Homogenate of *Equisetum arvense* L.	G	Powdery mildews: *Podosphaera xhantii* Root fungi Like common *root rot*, seedling *blight Pythium* spp.	Dispersible Concentrate (DC)***	2	Root feeding application and foliar application spraying	From (9th leaf unfolded on main stem – BBCH 19) to 9 or more primary side shoots visible (BBCH49)	2	3-4 days	200	300	600	1200	15 days	plant homogenate extracted with hot water and filtered to be used 24 h after preparation (see Appendix I)

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			Total 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)	g a.i./ha min max (g/ha) (l)		
Tomato *Lycopersicum esculentum*	France	Homogenate of *Equisetum arvense* L.	F	early blight: *Alternaria solani* Septoria blight *Septoria lycopsersici*	Dispersible Concentrate (DC)***	2	foliar application spraying	First inflorescence visible (BBCH 51) to BBCH 59 Summer	2	14 days	200	300	600	1200	15 days	plant homogenate extracted with hot water and filtered to be used 24 h after preparation (see Appendix I)

**** The product cannot be applied in case of hot temperature. It is used in case of rainy period**

***** The product is a plant homogenate extracted with hot water and filtered (decoction)**

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