REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) No 462/2014

of 5 May 2014

approving the basic substance *Equisetum arvense* L., in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending Implementing Regulation (EU) No 540/2011

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ([1]), and in particular Article 23(5) in conjunction with Article 13(2) and Article 78(2) thereof,

Whereas:

(1) In accordance with Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 28 December 2011 an application from Institut Technique de l'Agriculture Biologique (ITAB) for the approval of *Equisetum arvense* L. as basic substance. That application was accompanied by the information required by the second subparagraph of Article 23(3).

(2) The Commission asked the European Food Safety Authority (hereinafter 'the Authority') for scientific assistance. The Authority presented to the Commission a Technical report on the substance concerned on 24 May 2013 ([2]). The Commission presented the review report and this draft regulation on the approval of *Equisetum arvense* L. to the Standing Committee on the Food Chain and Animal Health on 20 March 2014.

(3) The documentation provided by the applicant and the results of examination carried out by the Authority ([3]) in accordance with Regulation (EC) No 1924/2006 of the European Parliament and of the Council ([4]) show that *Equisetum arvense* L. fulfils the criteria of a foodstuff as defined in Article 2 of Regulation (EC) No 178/2002 of the European Parliament and of the Council ([5]). Moreover, it is not predominantly used for plant protection purposes but nevertheless is useful in plant protection in a product consisting of the substance and water. Consequently, it is to be considered as a basic substance.

(4) As the basic substance concerned is a foodstuff not requiring a specific authorisation under Regulation (EC) No 178/2002, it is deemed to be evaluated as having neither an immediate or delayed harmful effect on human or animal health nor an unacceptable effect on the environment.

(5) It has appeared from the examinations made that *Equisetum arvense* L. may be expected to satisfy, in general, the requirements laid down in Article 23 of Regulation (EC) No 1107/2009, in particular with regard to the uses which were examined and detailed in the Commission review report. In accordance with Article 13(2) of Regulation (EC) No 1107/2009 in conjunction with Article 6 thereof and in the light of current scientific and technical knowledge, it is necessary to include certain conditions for the approval which are detailed in Annex I to this Regulation.

([1]) OJ L 309, 24.11.2009, p. 1.
([2]) 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 pp.
([3]) EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA) EFSA Journal 2009; 7(9): 1289 doi: 10.2903/j.efsa.2009.1289.
([4]) Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods (OJ L 404, 30.12.2006, p. 9.).
([5]) 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 (OJ L 31, 1.2.2002, p. 1).

(6) In accordance with Article 23(5) of Regulation (EC) No 1107/2009, basic substances are to be listed separately in the Regulation referred to in Article 13(4) of Regulation (EC) No 1107/2009. It is therefore appropriate to add a Part C in the Annex to Commission Implementing Regulation (EU) No 540/2011 ([1]). That Regulation should therefore be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of a basic substance

The basic substance *Equisetum arvense* L., as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

(1) In Article 1 of Regulation (EU) No 540/2011 the second paragraph is replaced by the following two paragraphs:

'The active substances approved under Regulation (EC) No 1107/2009 are as set out in Part B of the Annex to this Regulation. The basic substances approved under Regulation (EC) No 1107/2009 are as set out in Part C of the Annex to this Regulation.'

(2) The Annex to Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 5 May 2014.

For the Commission
The President
José Manuel BARROSO

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

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Specific provisions
Equisetum arvense L. CAS No: not allocated CIPAC No: not allocated	Not applicable	European Pharmacopeia	1 July 2014	*Equisetum arvense* L. may be used in accordance with the specific conditions included in the conclusions of the review report on *Equisetum arvense* L. (SANCO/12386/2013) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.

(1) Further details on identity, specification and manner of use of basic substance are provided in the review report.

ANNEX II

The Annex to Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) The title of the Annex is replaced by the following:

'ANNEX ACTIVE SUBSTANCES'

(2) The following Part C is added:

'PART C

Basic Substances

General provisions applying to all substances listed in this Part: the Commission shall keep available all review reports (except for confidential information within the meaning of Article 63 of Regulation (EC) No 1107/2009) for consultation by any interested parties or shall make them available to them on specific request.

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Specific provisions
1	*Equisetum arvense* L. CAS No: not allocated CIPAC No: not allocated	Not applicable	European Pharmacopeia	1 July 2014	*Equisetum arvense* L. may be used in accordance with the specific conditions included in the conclusions of the review report on *Equisetum arvense* L. (SANCO/12386/2013) and in particular Appendices I and II thereof, as finalised in the Standing Committee on the Food Chain and Animal Health on 20 March 2014.

(*) Further details on identity, specification and manner of use of basic substance are provided in the review report.'