Commission Implementing Regulation (EU) 2015/1107 of 8 July 2015 approving the basic substance Salix spp. cortex, 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 the Annex to Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1107

of 8 July 2015

approving the basic substance *Salix* spp. cortex, 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 the Annex to Commission 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) thereof,

Whereas:

(1) In accordance with Article 23(3) of Regulation (EC) No 1107/2009, the Commission received on 26 April 2013 an application from the Institut Technique de l'Agriculture Biologique (ITAB) for the approval of *Salix alba* bark 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 3 June 2014[(2)]. The Commission presented the review report[(3)] and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 14 November 2014 and finalised them for the meeting of that Committee of 29 May 2015.

(3) The documentation provided by the applicant and the results of examination carried out by the European Medicine Agency[(4)] in accordance with Directive 2001/83/EC of the European Parliament and of the Council[(5)] show that *Salix* cortex fulfils the criteria of a traditional herbal medicine. It was therefore considered appropriate to extend the scope of the application from *Salix alba* bark to *Salix* spp. cortex. 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.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1107. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(4) The Commission considers that *Salix* spp. cortex is a basic substance pursuant to Article 23 of Regulation (EC) No 1107/2009. *Salix* spp. cortex is part of a plant and is ubiquitous in the environment. The additional exposure of humans, animals and the environment by the uses as detailed in the review report is expected to be negligible compared to exposure expected through realistic natural situations.

(5) Therefore, *Salix* spp. cortex 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. It is therefore appropriate to approve *Salix* spp. cortex as a basic substance.

(6) 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, however, necessary to include certain conditions for the approval which are detailed in Annex I to this Regulation.

(7) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011[(6)] should be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

Approval of a basic substance

The substance *Salix* spp. cortex as specified in Annex I is approved as basic substance subject to the conditions laid down in that Annex.

Article 2

Amendments to Implementing Regulation (EU) No 540/2011

Part C of the Annex to Implementing Regulation (EU) No 540/2011 is amended in accordance with Annex II to this Regulation.

Article 3

Entry into force

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.

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/1107. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

Done at Brussels, 8 July 2015.

For the Commission

The President

Jean-Claude JUNCKER