Commission Implementing Regulation (EU) 2017/2057 of 10 November 2017 concerning the non-approval of Achillea millefolium L. as a basic substance 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 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2017/2057

of 10 November 2017

concerning the non-approval of *Achillea millefolium* L. as a basic substance 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

(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 10 July 2015 an application from the Institut Technique de l'Agriculture Biologique (ITAB) for the approval of *Millefolii herba* as a basic substance. That application was accompanied by the information required under the second subparagraph of Article 23(3) of Regulation (EC) No 1107/2009.

(2) The Commission asked the European Food Safety Authority ('the Authority') for scientific assistance. The Authority provided the Commission with a Technical Report on the substance concerned on 29 September 2016[(2)]. The Commission presented the review report[(3)] and the draft of this Regulation on the non-approval of *Millefolii herba* to the Standing Committee on Plants, Animals, Food and Feed on 24 January 2017 and finalised them for the meeting of that Committee on 6 October 2017.

(3) During the consultation organised by the Authority, the applicant modified the basic substance name to *Achillea millefolium* L.

(4) The documentation provided by the applicant does not show that *Achillea millefolium* 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[(4)].

(5) Specific concerns were identified, in the Technical Report of the Authority, regarding exposure to the infusion and the components alpha- and beta-thujone, camphor and 1,8-cineole specifically through pesticide use. Concerns were identified regarding possible

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2017/2057. 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*

adverse effects for pregnant women and on sperm parameters as well as regarding the endocrine-disrupting potential. As a result, the assessment of the risk to operators, workers, bystanders, consumers and non-target organisms could not be finalised.

(6) The Commission invited the applicant to submit its comments on the Technical Report of the Authority and on the draft review report. The applicant submitted its comments, which have been carefully examined.

(7) However, despite the arguments put forward by the applicant, the concerns related to the substance cannot be eliminated.

(8) Consequently, as laid down in the Commission review report, it has not been established that the requirements laid down in Article 23 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate not to approve *Achillea millefolium* L. as a basic substance.

(9) This Regulation does not prejudice the submission of a further application for the approval of *Achillea millefolium* L. as a basic substance in accordance with Article 23(3) of Regulation (EC) No 1107/2009.

(10) 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

The substance *Achillea millefolium* L. is not approved as a basic substance.

Article 2

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, 10 November 2017.

For the Commission

The President

Jean-Claude JUNCKER