Commission Implementing Regulation (EU) 2015/2082 of 18 November 2015 concerning the non-approval of Arctium lappa L. (aerial parts) 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) 2015/2082

of 18 November 2015

concerning the non-approval of *Arctium lappa* L. (aerial parts) 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 3 June 2014 an application from the Institut Technique de l`Agriculture Biologique (ITAB) for the approval of *Arctium lappa* L. as basic substance. That application was accompanied by the information required under 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 27 November 2014[(2)]. The Commission presented the review report[(3)] and the draft of this Regulation on the non-approval of *Arctium lappa* L. (aerial parts) to the Standing Committee on Plants, Animals, Food and Feed on 26 May 2015.

(3) The documentation provided by the applicant shows that not all aerial parts of *Arctium lappa* L. fulfil 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)].

(4) Specific concerns were identified, in the Technical Report of the Authority, regarding exposure to arctigenin, chlorogenic and caffeic acids and, as a result, the assessment of the risk to operators, workers, bystanders, consumers and non-target organisms could not be finalised.

Changes to legislation: There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2015/2082. 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

(5) 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.

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

(7) 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 *Arctium lappa* L. (aerial parts) as basic substance.

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

(9) 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

Non-approval as basic substance

The substance *Arctium lappa* L. (aerial parts) is not approved as basic substance.

Article 2

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.

Done at Brussels, 18 November 2015.

For the Commission

The President

Jean-Claude JUNCKER