Commission Implementing Regulation (EU) 2020/643 of 12 May 2020 concerning the non-approval of Saponaria officinalis L. roots 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) 2020/643

of 12 May 2020

concerning the non-approval of *Saponaria officinalis* L. roots 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 13(2) in conjunction with Article 23(5) thereof,

Whereas:

(1) On 9 October 2015, the Commission received an application from the Crop Research Institute (Czech Republic) for the approval of *Saponaria officinalis* L. roots 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 *Saponaria officinalis* L. roots on 19 June 2017[(2)]. The Commission presented the review report[(3)] and a draft Regulation on the non-approval of *Saponaria officinalis* L. roots to the Standing Committee on Plants, Animals, Food and Feed on 6 December 2017.

(3) The documentation provided by the applicant shows that *Saponaria officinalis* L. roots 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)], being used as a traditional emulsifier.

(4) However, the technical report of the Authority identified specific concerns regarding the presence of substances of concern (e.g. triterpenoid saponins, saporin) in extracts of *Saponaria officinalis* L. roots when used for plant protection purposes. Insufficient information was available to establish a safe level of intake for consumers and the consumer risk assessment could not be completed for the uses of *Saponaria officinalis* L. roots in cucumber, tomato and hops. Furthermore, there was insufficient information to reach a conclusion regarding the risk to non-target organisms.

Changes to legislation: *Commission Implementing Regulation (EU) 2020/643 is up to date with all changes known to be in force on or before 19 March 2022. There are changes that may be brought into force at a future date. Changes that have been made appear in the content and are referenced with annotations. (See end of Document for details) View outstanding changes*

(5) No other, relevant evaluation, carried out in accordance with other Union legislation as referred to in Article 23(2) of Regulation (EC) No 1107/2009, was available.

(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) 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 *Saponaria officinalis* L. roots as a basic substance.

(8) This Regulation does not prejudice the submission of a further application for the approval of *Saponaria officinalis* L. roots as a 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

The substance *Saponaria officinalis* L. roots 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, 12 May 2020.

For the Commission

The President

Ursula VON DER LEYEN