Commission Implementing Regulation (EU) 2020/1263 of 10 September 2020 approving the active substance sodium hydrogen carbonate as a low-risk 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, and amending Commission Implementing Regulation (EU) No 540/2011 (Text with EEA relevance)

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1263

of 10 September 2020

approving the active substance sodium hydrogen carbonate as a low-risk 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, and amending 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 22(1) in conjunction with Article 13(2) thereof,

Whereas:

(1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 Austria received on 18 March 2016 an application from BIOFA AG for the approval of the active substance sodium hydrogen carbonate. On 21 January 2020, the Commission was informed of the transfer of the applicant holder rights from Biofa AG to SCC Legal GmbH.

(2) In accordance with Article 9(3) of Regulation (EC) No 1107/2009, Austria, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (‘the Authority’) of the admissibility of the application on 26 April 2016.

(3) On 7 September 2017 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(4) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of that Regulation, it requested that the applicant supply additional information to the Member States, the Commission and the Authority. The assessment of the additional information by the rapporteur Member State was submitted to the Authority in the format of an updated draft assessment report in June 2018.

Changes to legislation: *There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/1263. 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) On 17 August 2018 the Authority communicated to the applicant, the Member States and the Commission its conclusion[(2)] on whether the active substance sodium hydrogen carbonate can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Authority made its conclusion available to the public.

(6) On 24-25 January 2019 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for sodium hydrogen carbonate providing that sodium hydrogen carbonate is approved.

(7) The applicant was given the possibility to submit comments on the review report.

(8) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.

(9) The Commission further considers that sodium hydrogen carbonate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Sodium hydrogen carbonate is not a substance of concern and fulfils the conditions set in Annex II point 5 to Regulation (EC) No 1107/2009.

(10) It is therefore appropriate to approve sodium hydrogen carbonate as a low-risk substance.

(11) 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.

(12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011[(3)] should be amended accordingly.

(13) 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 active substance

The active substance sodium hydrogen carbonate, 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

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

***Changes to legislation:** There are outstanding changes not yet made to Commission Implementing Regulation (EU) 2020/1263. 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*

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.

Done at Brussels, 10 September 2020.

For the Commission

The President

Ursula VON DER LEYEN