

COMMISSION IMPLEMENTING REGULATION (EU) 2020/1018**of 13 July 2020****approving ferric pyrophosphate as low-risk active 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 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009, BROS Sp. z o.o. Sp.k. submitted to Poland on 28 December 2015 an application for the approval of the active substance ferric pyrophosphate.
- (2) In accordance with Article 9(3) of that Regulation, Poland, 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 24 June 2016.
- (3) On 21 August 2018, 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 Regulation (EC) No 1107/2009, 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 on 9 August 2019.
- (5) On 17 December 2019, the Authority communicated to the applicant, the Member States and the Commission its conclusion ⁽²⁾ on whether the active substance ferric pyrophosphate 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 23 and 24 March 2020, the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for ferric pyrophosphate and on 19 May 2020, the draft of this Regulation providing that ferric pyrophosphate 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 ferric pyrophosphate is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. In fact, ferric pyrophosphate is not a substance of concern and it fulfils the conditions set out in point 5 of Annex II to Regulation (EC) No 1107/2009, including the second subparagraph of point 5.1.2. More specifically, even though ferric pyrophosphate is considered persistent, it eventually dissociates into ions which are a natural constituent of the human diet, that are ubiquitous in the environment, and essential for animal and plant functions. Consequently, the additional exposure of humans, animals and the environment by the uses approved under Regulation (EC) No 1107/2009 is expected to be negligible compared to exposure expected through realistic natural situations

⁽¹⁾ OJL 309, 24.11.2009, p. 1.

⁽²⁾ EFSA (European Food Safety Authority), 2020. Conclusion on the peer review of the pesticide risk assessment of the active substance ferric pyrophosphate. *EFSA Journal* 2020;18(1):5986, 25 pp. doi:10.2903/j.efsa.2020.5986.

- (10) It is therefore appropriate to approve ferric pyrophosphate as a low-risk substance.
- (11) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, Commission Implementing Regulation (EU) No 540/2011 ⁽³⁾ should be amended accordingly.
- (12) 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 the active substance

The active substance ferric pyrophosphate, 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.

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, 13 July 2020.

For the Commission
The President
Ursula VON DER LEYEN

⁽³⁾ Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances (OJ L 153, 11.6.2011, p. 1).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
Ferric pyrophosphate CAS No: 10058-44-3 CIPAC No: —	iron(3+) diphosphate	<p>≥ 802 g/kg</p> <p>The following impurities are of toxicological and environmental concern and must not exceed the following levels in the technical material:</p> <ul style="list-style-type: none"> — Lead: 3 mg/kg — Mercury: 0,1 mg/kg — Cadmium: 1 mg/kg 	3.8.2020	3.8.2035	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric pyrophosphate, and in particular Appendices I and II thereto, shall be taken into account.

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.

ANNEX II

In Part D of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
'20	Ferric pyrophosphate CAS No: 10058-44-3 CIPAC No: —	iron(3+) diphosphate	≥ 802 g/kg The following impurities are of toxicological and environmental concern and must not exceed the following levels in the technical material: — Lead: 3 mg/kg — Mercury: 0,1 mg/kg — Cadmium: 1 mg/kg	3.8.2020	3.8.2035	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on ferric pyrophosphate, and in particular Appendices I and II thereto, shall be taken into account.'

⁽¹⁾ Further details on identity and specification of active substance are provided in the review report.