



2025/845

6.5.2025

**COMMISSION IMPLEMENTING REGULATION (EU) 2025/845**

**of 5 May 2025**

**approving the active substance elemental iron as a low-risk active substance in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and amending Commission Implementing Regulation (EU) No 540/2011**

**(Text with EEA relevance)**

THE EUROPEAN COMMISSION,

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 <sup>(1)</sup>, and in particular Article 13(2) in conjunction with Article 22(1) thereof,

Whereas:

- (1) On 28 June 2018, Austria, as rapporteur Member State, received an application pursuant to Article 7(1) of Regulation (EC) No 1107/2009 from ADAMA Agriculture B.V. for the approval of the active substance elemental iron.
- (2) On 9 August 2018, in accordance with Article 9(3) of Regulation (EC) No 1107/2009, the 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.
- (3) On 2 July 2021, the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether elemental iron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (4) The Authority circulated the draft assessment report received from the rapporteur Member State to the applicant and the other Member States, in accordance with Article 12(1) of Regulation (EC) No 1107/2009.
- (5) In accordance with Article 12(3) of Regulation (EC) No 1107/2009, the Authority requested the applicant to 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 form of an updated draft assessment report on 25 April 2022.
- (6) On 2 October 2024, the Authority communicated to the applicant, the Member States and the Commission its conclusion <sup>(2)</sup> on whether the active substance elemental iron 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.
- (7) The Commission presented a review report and a draft Regulation regarding elemental iron to the Standing Committee on Plants, Animals, Food and Feed on 4 December 2024 and 11 March 2025, respectively.
- (8) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with Article 13(1) of Regulation (EC) No 1107/2009, on the review report. The applicant submitted its comments, which have been carefully examined.
- (9) 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.

<sup>(1)</sup> OJ L 309, 24.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1107/oj>.

<sup>(2)</sup> Conclusion on the peer review of the pesticide risk assessment of the active substance elemental iron, *EFSA Journal* 2024; 22: e9056, <https://doi.org/10.2903/j.efsa.2024.9056>.

- (10) The Commission further considers that elemental iron is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Elemental iron is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.
- (11) It is therefore appropriate to approve elemental iron as a low-risk active substance.
- (12) In accordance with Article 13(4) of Regulation (EC) No 1107/2009 in conjunction with Article 22(2) thereof, Commission Implementing Regulation (EU) No 540/2011 <sup>(3)</sup> 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 the active substance**

The active substance elemental iron, 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**

The Annex to 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, 5 May 2025.

*For the Commission*

*The President*

Ursula VON DER LEYEN

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<sup>(3)</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2011/540/oj](http://data.europa.eu/eli/reg_impl/2011/540/oj)).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
Elemental iron CAS No: 7439-89-6 CIPAC No: -	Iron	≥ 989 g/kg of total iron  The following impurities are of toxicological concern and shall not exceed the following levels in the technical material:  Arsenic: Max 0,003 g/kg Mercury: Max 0,001 g/kg Lead: Max 0,01 g/kg	26.5.2025	26.5.2040	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 elemental iron, and in particular Appendices I and II thereto, shall be taken into account.  Conditions of use shall include risk mitigation measures, where appropriate.

<sup>(1)</sup> 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 <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'52	Elemental iron CAS No: 7439-89-6 CIPAC No: -	Iron	≥ 989 g/kg of total iron  The following impurities are of toxicological concern and shall not exceed the following levels in the technical material:  Arsenic: Max 0,003 g/kg Mercury: Max 0,001 g/kg Lead: Max 0,01 g/kg	26.5.2025	26.5.2040	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 elemental iron, and in particular Appendices I and II thereto, shall be taken into account.  Conditions of use shall include risk mitigation measures, where appropriate.

<sup>(1)</sup> Further details on identity and specification of active substance are provided in the review report.'