COMMISSION IMPLEMENTING REGULATION (EU) 2021/413

of 8 March 2021

renewing the approval of the low-risk active substance blood meal 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 the Annex to 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 20(1) in conjunction with Article 22(1) thereof,

Whereas:

(1) Commission Directive 2008/127/EC ([2]) included blood meal as an active substance in Annex I to Council Directive 91/414/EEC ([3]).

(2) Active substances included in Annex I to Directive 91/414/EEC are deemed to have been approved under Regulation (EC) No 1107/2009 and are listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011 ([4]).

(3) The approval of the active substance blood meal, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011 expires on 31 August 2021.

(4) An application for the renewal of the approval of the active substance blood meal was submitted in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ([5]) within the time period provided for in that Article.

(5) The applicant submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be complete by the rapporteur Member State.

(6) The rapporteur Member State prepared a draft renewal assessment report in consultation with the co-rapporteur Member State and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 18 February 2019.

(7) The Authority communicated the draft renewal assessment report to the applicant and to the Member States for comments and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to the public.

([1]) OJ L 309, 24.11.2009, p. 1.

([2]) Commission Directive 2008/127/EC of 18 December 2008 amending Council Directive 91/414/EEC to include several active substances (OJ L 344, 20.12.2008, p. 89).

([3]) Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (OJ L 230, 19.8.1991, p. 1).

([4]) 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).

([5]) Commission Implementing Regulation (EU) No 844/2012 of 18 September 2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (OJ L 252, 19.9.2012, p. 26).

(8) On 31 January 2020, the Authority communicated to the Commission its conclusion ([6]) on whether blood meal can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented an initial renewal report and the draft Regulation regarding blood meal to the Standing Committee on Plants, Animals, Food and Feed on 16 July 2020.

(9) The Commission invited the applicant to submit its comments on the conclusion of the Authority and, in accordance with the third paragraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, on the renewal report. The applicant submitted its comments, which have been carefully examined.

(10) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance blood meal that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to renew the approval of blood meal.

(11) The risk assessment for the renewal of the approval of the active substance blood meal is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing blood meal may be authorised.

(12) Following the assessment by the Rapporteur Member State and the Authority, and taking into account the intended uses, no critical area of concern was identified.

(13) As regards the criteria to identify endocrine disrupting properties set out in point 3.6.5 and point 3.8.2 of Annex II to Regulation (EC) No 1107/2009„ the conclusion of the Authority indicates that it is highly unlikely that blood meal is an endocrine disruptor. Thus, the Commission concludes that blood meal is not to be considered as having endocrine disrupting properties.

(14) The Commission further considers that blood meal is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009, given that blood meal is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Moreover, blood is a component of animal body and normally present in human diet.

(15) In accordance with Article 20(3) of Regulation (EC) No 1107/2009, in conjunction with Article 13(4) thereof, Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(16) Commission Implementing Regulation (EU) 2020/1160 ([7]) extended the approval period of blood meal to 31 August 2021 in order to allow the renewal process to be completed before the expiry of that period. However, given that a decision on renewal is being taken ahead of the expiry of that extended approval period, this Regulation should start to apply earlier than that date.

(17) 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

Renewal of the approval of the active substance

The approval of the active substance blood meal, as specified in Annex I, is renewed subject to the conditions laid down in that Annex.

([6]) EFSA Journal 18(2):6006, doi: 10.2903/j.efsa.2020.6006. Available online: https://www.efsa.europa.eu/fr/efsajournal/pub/6006

([7]) Commission Implementing Regulation (EU) 2020/1160 of 5 August 2020 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances aluminium ammonium sulphate, aluminium silicate, blood meal, calcium carbonate, carbon dioxide, extract from tea tree, fat distillation residues, fatty acids C7 to C20, garlic extract, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, kieselgur (diatomaceous earth), plant oils/rape seed oil, potassium hydrogen carbonate, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, Straight Chain Lepidopteran Pheromones, tebuconazole and urea (OJ L 257, 6.8.2020, p. 29).

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 and date of application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from 1 April 2021.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 8 March 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity (1)	Date of approval	Expiration of approval	Specific provisions
Blood meal 90989-74-5 909	Not applicable	100 % blood meal haemoglobin content: min 80 %.	*1 April 2021*	*31 March 2036*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on blood meal, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention: — to the protection of fish and aquatic invertebrates when less targeted spraying techniques are used, and — on the need of blood meal-containing plant protection products to be swirled before use to wet the product.

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

ANNEX II

The Annex to Commission Implementing Regulation (EU) No 540/2011 is amended as follows:

(1) in Part A, entry 222 on blood meal is deleted;

(2) in Part D, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity *	Date of approval	Expiration of approval	Specific provisions
'26	Blood meal 90989-74-5 909	Not applicable	100 % blood meal haemoglobin content: min 80 %.	*1 April 2021*	*31 March 2036*	For the implementation of the uniform principles, as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the renewal report on blood meal, and in particular Appendices I and II thereto, shall be taken into account. Member States shall pay particular attention: — to the protection of fish and aquatic invertebrates when less targeted spraying techniques are used, and — on the need of blood meal-containing plant protection products to be swirled before use to wet the product.

* Further details on the identity and the specification of the active substance are provided in the renewal report.'