COMMISSION IMPLEMENTING REGULATION (EU) 2022/2315

of 25 November 2022

renewing the approval of the low-risk active substance heptamaloxyloglucan 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 2010/14/EU ([2]) included heptamaloxyloglucan 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 heptamaloxyloglucan, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 May 2023.

(4) An application for the renewal of the approval of the active substance heptamaloxyloglucan was submitted to the rapporteur Member State 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 to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority'). 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 Authority and the Commission on 29 September 2020.

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

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

([2]) Commission Directive 2010/14/EU of 3 March 2010 amending Council Directive 91/414/EEC to include heptamaloxyloglucan as active substance (OJ L 53, 4.3.2010, p. 7).

([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 2 March 2022, the Authority communicated to the Commission its conclusion [6] on whether heptamaloxyloglucan can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

(9) As regards the criteria to identify endocrine disrupting properties set out in points 3.6.5 and 3.8.2 of Annex II to Regulation (EC) No 1107/2009, the conclusion of the Authority indicated that, based on the scientific evidence, it is highly unlikely that heptamaloxyloglucan is an endocrine disrupter via the estrogenic, androgenic, thyroidogenic and steroidogenic modalities.

(10) The Commission presented a renewal report and a draft Regulation regarding heptamaloxyloglucan to the Standing Committee on Plants, Animals, Food and Feed on 30 March 2022 and 13 October 2022 respectively.

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

(12) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance heptamaloxyloglucan that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It has also been established that heptamaloxyloglucan is not to be considered as having endocrine disrupting properties.

(13) The risk assessment for the renewal of the approval of the active substance heptamaloxyloglucan is based on a limited number of representative uses, which however do not restrict the uses for which plant protection products containing heptamaloxyloglucan may be authorised. It is therefore appropriate not to maintain the restriction to use as a growth regulator.

(14) The Commission further considers that heptamaloxyloglucan is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Heptamaloxyloglucan is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009. Furthermore, heptamaloxyloglucan is present naturally as a component of plants and soil. 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. It is therefore appropriate to renew the approval of heptamaloxyloglucan as a low risk active substance.

(15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

(16) Commission Implementing Regulation (EU) 2022/814 [7] extended the approval period of heptamaloxyloglucan to 31 May 2023 in order to allow the renewal process to be completed before the expiry of the approval period of that active substance. However, given that a decision on renewal has been taken ahead of that extended expiry date, this Regulation should 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 heptamaloxyloglucan is renewed as set out in Annex I.

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(6) EFSA Journal 2022;20(3):7210. Available online: https://doi.org/10.2903/j.efsa.2022.7210.

(7) Commission Implementing Regulation (EU) 2022/814 of 20 May 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval period of the active substance heptamaloxyloglucan (OJ L 146, 25.5.2022, p. 6).

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 March 2023.

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

Done at Brussels, 25 November 2022.

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
Heptamaloxyloglucan CAS No: 870721-81-6 CIPAC No: 851	α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→2)-α-D-xylopyranosyl-(1→6)-[α-D-xylopyranosyl-(1→6)-β-D-glucopyranosyl-(1→4)]-β-D-glucopyranosyl-(1→4)-D-glucitol	≥ 780 g/kg The following impurity is of toxicological and enviromental concern and must not exceed the following levels in the technical material: — Patulin, max. 50 μg/kg	1 March 2023	28 February 2038	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 heptamaloxyloglucan, and in particular Appendices I and II thereto, shall be taken into account.

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

ANNEX II

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

(1) in Part A, entry 298 on heptamaloxyloglucan is deleted;

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

No.	Common Name, Identification Numbers	IUPAC Name	Purity ([1])	Date of approval	Expiration of approval	Specific provisions
‘40	Heptamaloxyloglucan CAS No: 870721-81-6 CIPAC No: 851	α-L-fucopyranosyl-(1→2)-β-D-galactopyranosyl-(1→2)-α-D-xylopyranosyl-(1→6)-[α-D-xylopyranosyl-(1→6)-β-D-glucopyranosyl-(1→4)]-β-D-glucopyranosyl-(1→4)-D-glucitol	≥ 780 g/kg The following impurity is of toxicological and enviromental concern and must not exceed the following levels in the technical material: - Patulin, max. 50 μg/kg	1 March 2023	28 February 2038	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 heptamaloxyloglucan, and in particular Appendices I and II thereto, shall be taken into account.’

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