



2024/821

11.3.2024

**COMMISSION IMPLEMENTING REGULATION (EU) 2024/821**

**of 8 March 2024**

**renewing the approval of the low-risk active substance hydrolysed proteins 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 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 <sup>(1)</sup>, and in particular Article 20(1) in conjunction with Article 22(1) thereof,

Whereas:

- (1) Commission Directive 2009/153/EC <sup>(2)</sup> included hydrolysed proteins as an active substance in Annex I to Council Directive 91/414/EEC <sup>(3)</sup>.
- (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 <sup>(4)</sup>.
- (3) The approval of the active substance hydrolysed proteins, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 April 2025.
- (4) An application for the renewal of the approval of the active substance hydrolysed proteins was submitted to Spain, the rapporteur Member State, and Greece, the co-rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 <sup>(5)</sup> and within the time period provided for in that Article.
- (5) The applicants submitted the supplementary dossiers required to the rapporteur Member State, the co-rapporteur Member State, the Commission and the European Food Safety Authority ('the Authority') in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The application was found to be admissible 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 24 June 2020. In its draft renewal assessment report the rapporteur Member State proposed to renew the approval of hydrolysed proteins.
- (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.

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

<sup>(2)</sup> Commission Directive 2009/153/EC of 30 November 2009 amending Annex I to Council Directive 91/414/EEC as regards the common name and the purity of the active substance hydrolysed proteins (OJ L 314, 1.12.2009, p. 67, ELI: <http://data.europa.eu/eli/dir/2009/153/oj>).

<sup>(3)</sup> 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, ELI: <http://data.europa.eu/eli/dir/1991/414/oj>).

<sup>(4)</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)).

<sup>(5)</sup> 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, ELI: [http://data.europa.eu/eli/reg\\_impl/2012/844/oj](http://data.europa.eu/eli/reg_impl/2012/844/oj)).

- (8) On 30 May 2023, the Authority communicated to the Commission its conclusion<sup>(6)</sup> which indicated that hydrolysed proteins can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) The Commission presented a renewal report and a draft of this Regulation to the Standing Committee on Plants, Animals, Food and Feed on 12 July 2023 and 11 December 2023 respectively.
- (10) 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 and taken into consideration.
- (11) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance hydrolysed proteins that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (12) The Commission further considers that hydrolysed proteins is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009, given that hydrolysed proteins is not a substance of concern and fulfils the conditions set in point 5 of Annex II to Regulation (EC) No 1107/2009.
- (13) It is therefore appropriate to renew the approval of hydrolysed proteins as a low-risk substance.
- (14) In accordance with Article 14(1) of Regulation (EC) No 1107/2009, in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge, it is, however, necessary to provide for certain conditions. It is, in particular, appropriate to set maximum limits for toxicologically relevant impurities in the technical material.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (16) Commission Implementing Regulation (EU) 2023/1446<sup>(7)</sup> extended the approval period of hydrolysed proteins to 15 April 2025 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 hydrolysed proteins, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

<sup>(6)</sup> EFSA Journal 10.2903/j.efsa.2023.8079. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu).

<sup>(7)</sup> Commission Implementing Regulation (EU) 2023/1446 of 12 July 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances 2,5-dichlorobenzoic acid methylester, acetic acid, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, calcium carbide, cymoxanil, dodemorph, ethylene, extract from tea tree, fat distillation residues, fatty acids C7-C20, flonicamid (IKI-220), gibberellic acid, gibberellins, halosulfuron-methyl, hydrolysed proteins, iron sulphate, magnesium phosphide, maltodextrin, metamitron, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, pyrethrins, sulcotrione, tebuconazole and urea (OJ L 178, 13.7.2023, p. 1, ELI: [http://data.europa.eu/eli/reg\\_impl/2023/1446/oj](http://data.europa.eu/eli/reg_impl/2023/1446/oj)).

*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 May 2024.

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

Done at Brussels, 8 March 2024.

*For the Commission*  
*The President*  
Ursula VON DER LEYEN

## ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
Hydrolysed proteins CAS No: Not applicable CIPAC No: 901	Not available	<p>Hydrolysed proteins. <i>Animal tissues hydrolysate excluding ruminants hides and skins</i> (no ISO common name):</p> <p>— 708 g/kg on a dry weight basis [range in TK (technical concentrate) 400-434 g/kg].</p> <p>Hydrolysed proteins. <i>Urea enriched beet molasses, hydrolysed</i> (no ISO common name):</p> <p>— 110 g/kg on a dry weight basis [range in TK (technical concentrate) 90-110 g/kg].</p> <p>Hydrolysed Proteins. <i>Collagen protein Hydrolysate</i> (no ISO common name):</p> <p>— 582 g/kg on a dry weight basis [range in TK (technical concentrate) 249-262 g/kg].</p> <p>Lead, cadmium, arsenic, mercury and biuret in accordance with Regulation (EU) 2019/1009 on fertilising products.</p> <p>Formaldehyde below 1 g/kg.</p>	1 May 2024	30 April 2039	<p>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 hydrolysed proteins, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <p>— the specification of the technical material for 'hydrolysed proteins-urea enriched beet molasses, hydrolysed' as commercially manufactured on the basis of an analysis of at least five representative batches.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

<sup>(1)</sup> Further details on the identity and 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 234 on hydrolysed proteins is deleted;
- (2) in Part D, the following entry is added:

No	Common Name, Identification Numbers	IUPAC Name	Purity <sup>(1)</sup>	Date of approval	Expiration of approval	Specific provisions
'47	Hydrolysed proteins CAS No: Not applicable CIPAC No: 901	Not available	<p>Hydrolysed proteins. <i>Animal tissues hydrolysate excluding ruminants hides and skins</i> (no ISO common name):</p> <ul style="list-style-type: none"> <li>— 708 g/kg on a dry weight basis [range in TK (technical concentrate) 400-434 g/kg].</li> </ul> <p>Hydrolysed proteins. <i>Urea enriched beet molasses, hydrolysed</i> (no ISO common name):</p> <ul style="list-style-type: none"> <li>— 110 g/kg on a dry weight basis [range in TK (technical concentrate) 90-110 g/kg].</li> </ul> <p>Hydrolysed Proteins. <i>Collagen protein Hydrolysate</i> (no ISO common name):</p> <ul style="list-style-type: none"> <li>— 582 g/kg on a dry weight basis [range in TK (technical concentrate) 249-262 g/kg].</li> </ul> <p>Lead, cadmium, arsenic, mercury and biuret in accordance with Regulation (EU) 2019/1009 on fertilising products.</p> <p>Formaldehyde below 1 g/kg.</p>	1 May 2024	30 April 2039	<p>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 hydrolysed proteins, and in particular Appendices I and II thereto, shall be taken into account.</p> <p>In this overall assessment Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> <li>— the specification of the technical material for “<i>hydrolysed proteins-urea enriched beet molasses, hydrolysed</i>” as commercially manufactured on the basis of an analysis of at least five representative batches.</li> </ul> <p>Conditions of use shall include risk mitigation measures, where appropriate.’</p>

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