

COMMISSION IMPLEMENTING REGULATION (EU) 2022/2305**of 24 November 2022****renewing the approval of the low-risk active substance Fish oil 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 Fish oil 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 Fish oil, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 August 2023.
- (4) An application for the renewal of the approval of the active substance Fish oil was submitted to the Czech Republic, the rapporteur Member State, in accordance with Article 1 of Commission Implementing Regulation (EU) No 844/2012 ⁽⁵⁾ and 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 admissible by the rapporteur Member State.
- (6) The Czech Republic prepared a draft renewal assessment report in consultation with France, the co-rapporteur Member State, and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 10 September 2020. In its draft renewal assessment report the Czech Republic proposed to renew the approval of Fish oil as a low-risk substance.

⁽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). This Regulation was replaced by Regulation (EU) 2020/1740, however, it shall continue to apply to the procedure for the renewal of the approval of active substances: (1) whose approval period ends before 27 March 2024; (2) for which a Regulation, adopted in accordance with Article 17 of Regulation (EC) No 1107/2009 on or after 27 March 2021, extends the approval period to 27 March 2024 or a later date.

- (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. On 16 December 2021, the Authority communicated to the Commission its conclusion ⁽⁶⁾ which indicated that Fish oil can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009. The Commission presented a renewal report and a draft of this Regulation regarding Fish oil to the Standing Committee on Plants, Animals, Food and Feed on 30 March 2022 and on 17 May 2022, respectively.
- (8) 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 and taken into consideration where appropriate.
- (9) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance Fish oil that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (10) The Commission further considers that Fish oil is a low-risk active substance pursuant to Article 22 of Regulation (EC) No 1107/2009. Fish oil 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 renew the approval of Fish oil as a low-risk substance.
- (12) 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 set a minimum purity of the active substance as manufactured in order to underpin the safety of the active substance to be used in plant protection products.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2022/708 ⁽⁷⁾ extended the approval period of Fish oil to 31 August 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 shall apply as soon as possible.
- (15) 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 Fish oil, as specified in Annex I to this Regulation, is renewed subject to the conditions laid down in that Annex.

⁽⁶⁾ *EFSA Journal* 2022;20(1):10600, 39 pp. doi:10.2903/j.efsa.2022.10600 Available online: www.efsa.europa.eu

⁽⁷⁾ Commission Implementing Regulation (EU) 2022/708 of 5 May 2022 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, aclonifen, aluminium ammonium sulphate, aluminium phosphide, aluminium silicate, beflubutamid, benthiavalicarb, boscalid, calcium carbide, captan, cymoxanil, dimethomorph, dodemorph, ethephon, ethylene, extract from tea tree, fat distillation residues, fatty acids C7 to C20, fluoxastrobin, flurochloridone, folpet, formetanate, gibberellic acid, gibberellins, hydrolysed proteins, iron sulphate, magnesium phosphide, metam, metamitron, metazachlor, metribuzin, milbemectin, phenmedipham, pirimiphos-methyl, plant oils/clove oil, plant oils/rape seed oil, plant oils/spear mint oil, propamocarb, proquinazid, prothioconazole, pyrethrins, quartz sand, fish oil, repellents by smell of animal or plant origin/sheep fat, S-metolachlor, Straight Chain Lepidopteran Pheromones, sulcotrione, tebuconazole and urea (OJ L 133, 10.5.2022, p. 1).

*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, 24 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
Fish oil CAS No: 8016-13-5 CIPAC No: 918	Not applicable	<p>Minimum purity of the active substance as manufactured: Fish oil 100 %.</p> <p>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured:</p> <p>Maximum levels according to Commission Directive 2002/32/EC ⁽²⁾ for the following impurities, proportionate to a fish oil with a moisture content of 12 %:</p> <p>5 ng/kg of sum of polychlorinated dibenzo-paradioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) ⁽³⁾</p> <p>20 ng/kg of sum of polychlorinated dibenzo-paradioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin like polychlorinated biphenyls (PCBs) ⁽⁴⁾</p> <p>0,5 mg/kg of mercury</p> <p>2 mg/kg of cadmium</p> <p>10 mg/kg of lead</p> <p>175 µg/kg of non-dioxin-like PCBs</p>	1 March 2023	28 February 2038	<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 fish oil, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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

⁽²⁾ Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed (OJ L 140, 30.5.2002, p. 10).

⁽³⁾ Expressed in World Health Organisation (WHO) toxic equivalents.

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ANNEX II

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

- (1) in Part A, entry 248 on fish oil 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
'41	Fish oil CAS No: 8016-13-5 CIPAC No: 918	Not applicable	<p>Minimum purity of the active substance as manufactured: Fish oil 100 %</p> <p>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured:</p> <p>Maximum levels according to Commission Directive 2002/32/EC ⁽²⁾ for the following impurities, proportionate to a fish oil with a moisture content of 12 %:</p> <p>5 ng/kg of sum of polychlorinated dibenzo-pardioxins (PCDDs) and polychlorinated dibenzofurans (PCDFs) ⁽³⁾</p> <p>20 ng/kg of sum of polychlorinated dibenzo-paradioxins (PCDDs), polychlorinated dibenzofurans (PCDFs) and dioxin like polychlorinated biphenyls (PCBs) ⁽⁴⁾</p> <p>0,5 mg/kg of mercury</p> <p>2 mg/kg of cadmium</p> <p>10 mg/kg of lead</p> <p>175 µg/kg of non-dioxin-like PCBs</p>	1 March 2023	28 February 2038	<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 fish oil, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p>

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