

Official Journal of the European Union

L 7



English edition

Legislation

Volume 63

13 January 2020

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⁽¹⁾ Text with EEA relevance.

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

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- ★ Commission Implementing Regulation (EU) 2020/18 of 10 January 2020 concerning the non-renewal of the approval of the active substance chlorpyrifos, 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 ⁽²⁾ 14

⁽²⁾ Text with EEA relevance.

II

(Non-legislative acts)

INTERNATIONAL AGREEMENTS

**Information concerning the entry into force of the agreement between the European Community
and the Hashemite Kingdom of Jordan on certain aspects of air services**

Agreement between the European Community and the Hashemite Kingdom of Jordan on certain aspects of air services, signed in Brussels on 25 February 2008, entered into force on 12 June 2015, in accordance with Article 9(1) of the Agreement, as the last notification was deposited on 12 June 2015.

**Information concerning the entry into force of the Agreement between the European Community
and the Republic of Lebanon on certain aspects of air services**

The Agreement between the European Community and the Republic of Lebanon on certain aspects of air services, signed in Beirut on 7 July 2006, entered into force on 25 October 2017, in accordance with Article 8(1) of the Agreement, as the last notification was deposited on 25 October 2017.

Information concerning the entry into force of the Agreement between the European Union and the Government of the Macao Special Administrative Region of the People's Republic of China on certain aspects of air services

The Agreement between the European Union and the Government of the Macao Special Administrative Region of the People's Republic of China on certain aspects of air services, signed in Macao on 23 November 2013, entered into force on 30 September 2016, in accordance with Article 8(1) of the Agreement, as the last notification was deposited on 29 September 2016.

**Information concerning the entry into force of the Agreement between the European Community
and the Republic of Maldives on certain aspects of air services**

The Agreement between the European Community and the Republic of Maldives on certain aspects of air services, signed in Brussels on 21 September 2006, entered into force on 15 April 2008, in accordance with Article 9(1) of the Agreement, as the last notification was deposited on 15 April 2008.

**Information concerning the entry into force of the Agreement between the European Community
and the Government of Kyrgyz Republic on certain aspects of air services**

The Agreement between the European Community and the Government of Kyrgyz Republic on certain aspects of air services, signed in Brussels on 1 June 2007, entered into force on 28 April 2008, in accordance with Article 9(1) of the Agreement, as the last notification was deposited on 28 April 2008.

REGULATIONS

COMMISSION IMPLEMENTING REGULATION (EU) 2020/16

of 10 January 2020

authorising the placing on the market of nicotinamide riboside chloride as a novel food under Regulation (EU) 2015/2283 of the European Parliament and of the Council and amending Commission Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 ⁽¹⁾, and in particular Article 12 thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470 ⁽²⁾ establishing a Union list of authorised novel foods was adopted.
- (3) Pursuant to Article 12 of Regulation (EU) 2015/2283, the Commission is to submit a draft implementing act authorising placing on the Union market of a novel food and on the updating of the Union list.
- (4) On 10 May 2018, the company ChromaDex Inc. ('the Applicant') made a request to the Commission to place nicotinamide riboside chloride on the Union market as a novel food within the meaning of Article 10(1) of Regulation (EU) 2015/2283. The application requested for nicotinamide riboside chloride to be used as a source of niacin in food supplements intended for the general adult population at the maximum use levels of 300 mg/day. Furthermore, the application requested for nicotinamide riboside to be also added to the list of niacin forms specified in Annex II of Directive 2002/46/EC of the European Parliament and of the Council ⁽³⁾ as a source of niacin.
- (5) The Applicant also made a request to the Commission for the protection of proprietary data for a number of studies submitted in support of the application namely, an in vitro study evaluating the metabolism of nicotinamide riboside in blood (Study No 160312) ⁽⁴⁾; an oral 7-day dose range finding toxicity study in juvenile dogs (StudyNo

⁽¹⁾ OJ L 327, 11.12.2015, p. 1.

⁽²⁾ Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72).

⁽³⁾ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51).

⁽⁴⁾ Keystone Bioanalytical Inc., The Metabolism of Nicotinamide Riboside in Human Blood (Study No 160312), 10 January 2018, unpublished.

17-921) ⁽⁷⁾; a hERG screening assay (Study No 20151223) ⁽⁸⁾; a 28-day repeat-dose oral toxicity study in juvenile dogs (Study No 17-940) ⁽⁷⁾; a 90-day repeated-dose oral toxicity study in Sprague–Dawley rats (Study No S14022) ⁽⁸⁾; a reproductive toxicity study (Study No G10959) ⁽⁹⁾; and a developmental toxicity study in rats (Study No G10957) ⁽¹⁰⁾.

- (6) The Commission consulted the European Food Safety Authority ('Authority') on 8 October 2018, asking it to provide a scientific opinion on the safety of nicotinamide riboside as a novel food in accordance with Article 10(3) of Regulation (EU) 2015/2283, and on the assessment for the intended use as a food supplement.
- (7) On 4 July 2019, the Authority adopted the scientific opinion on the 'Safety of nicotinamide riboside chloride as a novel food pursuant to Regulation (EU) 2015/2283 and bioavailability of nicotinamide from this source, in the context of Directive 2002/46/EC' ⁽¹¹⁾. That scientific opinion is in line with the requirements of Article 11 of Regulation (EU) 2015/2283.
- (8) In its opinion, the Authority concluded that nicotinamide riboside chloride is safe when used in food supplements at the maximum level of 300 mg/day for the general adult population, excluding pregnant and lactating women, and at the maximum level of 230 mg/day for pregnant and lactating women.
- (9) The opinion of the Authority gives sufficient grounds to establish that nicotinamide riboside chloride under the assessed conditions of use complies with Article 12(1) of Regulation (EU) 2015/2283.
- (10) The Authority considered that, in elaborating its opinion on nicotinamide riboside chloride as a novel food, data from the in vitro study evaluating the metabolism of nicotinamide riboside in blood (Study No 160312) served as a basis to assess the bioavailability of nicotinamide, while data from five toxicity studies (an oral 7-day dose range finding toxicity study in juvenile dogs (Study No 17-921); a 28-day repeat-dose oral toxicity study in juvenile dogs (Study No 17-940); a 90-day repeated-dose oral toxicity study in Sprague–Dawley rats (Study No S14022); a reproductive toxicity study (Study No G10959); and a developmental toxicity study in rats (Study No G10957)) served as a basis to assess the safety of nicotinamide riboside chloride. Therefore, it is considered that the conclusions on the safety of nicotinamide riboside chloride could not have been reached without the data from the unpublished reports of those studies.
- (11) The Commission requested the applicant to further clarify the justification provided with regard to their proprietary claim over the in vitro study evaluating the metabolism of nicotinamide riboside in blood and the five toxicity studies, and to clarify their claim to an exclusive right of reference to these studies, as referred to in Article 26(2)(b) of Regulation (EU) 2015/2283.
- (12) The Applicant declared that, at the time the application was submitted, it held ownership and proprietary exclusive right of reference to these studies, and that therefore third parties cannot lawfully access or use these studies or refer to that data.
- (13) The Commission assessed all the information provided by the Applicant and considered that the Applicant has sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the in vitro study evaluating the metabolism of nicotinamide riboside in blood and the five toxicity studies contained in the Applicant's file should not be used by the Authority for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation. Accordingly, the placing on the market within the Union of nicotinamide riboside chloride should be restricted to the Applicant for that period.

⁽⁷⁾ Experimur, Oral 7-Day Dose Range Finding Toxicity Study in Juvenile Dogs (Study No 17-921), 27 November 2017, unpublished.

⁽⁸⁾ IPS Therapeutique, Inc., Evaluation of the effects of Nicotinamide Riboside Chloride on the human potassium channel using human embryonic kidney (HEK) 293 cells transfected with a human ether-a-go-go-related gene (hERG), 25 March 2016, unpublished.

⁽⁷⁾ Experimur, Oral 28-Day Toxicity Study in Juvenile Dogs (Study No 17-940), 20 February 2018, unpublished.

⁽⁸⁾ Syngene International Limited, Comparative 90-Day Oral Toxicity Study in Sprague Dawley Rats (Study No S14022), 12 May 2015, unpublished.

⁽⁹⁾ Advinus Therapeutics Limited, Nicotinamide riboside chloride: one generation reproduction toxicity study through diet in Sprague–Dawley rats (Study No G10959), 21 November 2016, unpublished.

⁽¹⁰⁾ Advinus Therapeutics Limited, Nicotinamide riboside chloride: embryo-fetal developmental toxicity study in Sprague–Dawley rats by oral route (Study No G10957), 30 September 2016.

⁽¹¹⁾ EFSA Journal 2019;17(8):5775.

- (14) However, restricting the authorisation of nicotinamide riboside chloride and of the reference to the studies contained in the Applicant's file for the sole use of the Applicant does not prevent other applicants from applying for an authorisation to place on the market the same novel food provided that, their application is based on legally obtained information supporting the authorisation under this Regulation.
- (15) The Directive 2002/46/EC lays down requirements on food supplements. The use of nicotinamide riboside chloride should be authorised without prejudice to the requirements of that Directive.
- (16) 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

1. Nicotinamide riboside chloride as specified in the Annex to this Regulation shall be included in the Union list of authorised novel foods established in Implementing Regulation (EU) 2017/2470.
2. For a period of five years from the date of entry into force of this Regulation only the initial Applicant:
 - Company: ChromaDex Inc.;
 - Address: 10900 Wilshire Boulevard Suite 600, Los Angeles, CA 90024 USA,is authorised to place on the market within the Union the novel food referred to in paragraph 1, unless a subsequent applicant obtains authorisation for the novel food without reference to the data protected pursuant to Article 2 of this Regulation or with the agreement of ChromaDex Inc.
3. The entry in the Union list referred to in paragraph 1 shall include the conditions of use and labelling requirements laid down in the Annex.
4. The authorisation provided for in this Article shall be without prejudice to the provisions of Directive 2002/46/EC.

Article 2

The studies contained in the application file on the basis of which the novel food referred to in Article 1 has been assessed by the Authority, claimed by the Applicant as proprietary and without which the novel food could not have been authorised, shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of ChromaDex Inc.

Article 3

The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

Article 4

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, 10 January 2020.

For the Commission
The President
Ursula VON DER LEYEN

The Annex to Implementing Regulation (EU) 2017/2470 is amended as follows:

- (1) the following entry is inserted in Table 1 (Authorised novel foods) in alphabetical order:

Authorised novel food	Conditions under which the novel food may be used		Additional specific labelling requirements	Other requirements	Data Protection
Nicotinamide riboside chloride	<i>Specified food category</i>	<i>Maximum levels</i>	The designation of the novel food on the labelling of the foodstuffs containing it shall be “Nicotinamide riboside chloride”		Authorised on 20 February 2020. This inclusion is based on proprietary scientific evidence and scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283. Applicant: ChromaDex Inc., 10900 Wilshire Boulevard Suite 600, Los Angeles, CA 90024 USA. During the period of data protection, the novel food is authorised for placing on the market within the Union only by ChromaDex Inc. unless a subsequent applicant obtains authorisation for that novel food without reference to the proprietary scientific evidence or scientific data protected in accordance with Article 26 of Regulation (EU) 2015/2283 or with the agreement of ChromaDex Inc. End date of the data protection: 20 February 2025.’
	Food Supplements as defined in Directive 2002/46/EC	300 mg/day for the general adult population, excluding pregnant and lactating women 230 mg/day for pregnant and lactating women			

(2) the following entry is inserted in Table 2 (Specifications) in alphabetical order:

Authorised Novel Food	Specification
Nicotinamide riboside chloride	Description/Definition: The novel food is a synthetic form of nicotinamide riboside. The novel food contains ≥ 90 % nicotinamide riboside chloride, predominantly in its β form, the remaining components being residual solvents, reaction by-products and degradation products. Nicotinamide riboside chloride: CAS number: 23111-00-4 EC number: 807-820-5 IUPAC name: 1-[(2R,3R,4S,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]pyridin-1-ium-3-carboxamide;chloride Chemical formula: $C_{11}H_{15}N_2O_5Cl$ Molecular weight: 290,7 g/mol Characteristics/Composition: Colour: White to light brown Form: Powder Identification: Conforms by NMR (nuclear magnetic resonance) Nicotinamide riboside chloride: ≥ 90 % Water content: ≤ 2 % Residual solvents: Acetone: $\leq 5\,000$ mg/kg Methanol: $\leq 1\,000$ mg/kg Acetonitrile: ≤ 50 mg/kg Methyl tert-butyl ether: ≤ 500 mg/kg Reaction by-products: Methyl acetate: $\leq 1\,000$ mg/kg Acetamide: ≤ 27 mg/kg Acetic acid: $\leq 5\,000$ mg/kg Heavy metals: Arsenic: ≤ 1 mg/kg Microbiological criteria: Total Plate Count: $\leq 1\,000$ CFU/g Yeast and Mould: ≤ 100 CFU/g <i>Escherichia coli</i>: Absence in 10 g

COMMISSION IMPLEMENTING REGULATION (EU) 2020/17**of 10 January 2020****concerning the non-renewal of the approval of the active substance chlorpyrifos-methyl, 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) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2005/72/EC ⁽²⁾ included chlorpyrifos-methyl 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 chlorpyrifos-methyl, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2020.
- (4) Applications for the renewal of the approval of the active substance chlorpyrifos-methyl were 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 applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a 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 3 July 2017.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 4 July 2018, the Authority requested that the applicants 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 renewal assessment report.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances. (OJ L 279, 22.10.2005, p. 63).

⁽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).

- (9) The Authority organised an expert discussion in April 2019, to discuss certain elements related to the human health risk assessment. Due to concerns about genotoxicity and developmental neurotoxicity raised during that discussion, on 1 July 2019 the Commission sent a mandate to the Authority requesting a statement on the available outcomes of the human health assessment and an indication whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.
- (10) On 31 July 2019, the Authority sent its initial statement ⁽⁶⁾ to the Commission on the available outcomes of the human health assessment. On 11 November 2019, the Authority sent its updated statement ⁽⁷⁾ to the Commission following an additional expert discussion held in September 2019. In its updated statement, the Authority confirmed its conclusions on the human health assessment that critical areas of concerns exist. A genotoxic potential of chlorpyrifos-methyl cannot be ruled out, when taking into account the concerns raised for chlorpyrifos and the available scientific open literature on chlorpyrifos-methyl in a weight of evidence approach. During the peer review, experts considered a read-across approach between the two substances justified as they are structurally similar and have similar toxicokinetic behaviour. Consequently, it is not possible to establish health-based reference values for chlorpyrifos-methyl and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, concerns were identified concerning developmental neurotoxicity (DNT) for which epidemiological evidence exists, showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. Moreover, the peer review experts indicated that it may be appropriate to classify chlorpyrifos-methyl as toxic for reproduction, category 1B, in accordance with the criteria established under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁸⁾.
- (11) The Commission invited the applicants to submit their comments on the statements of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the draft renewal report. The applicants submitted their comments, which have been carefully examined.
- (12) However, despite the arguments put forward by the applicants, the concerns regarding the active substance could not be eliminated.
- (13) Consequently, it has not been established, with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision-making on the renewal of the approval of the active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos-methyl in accordance with Article 20(1)(b) of that Regulation.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing chlorpyrifos-methyl.
- (16) For plant protection products containing chlorpyrifos-methyl, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 3 months from the date of entry into force of this Regulation.
- (17) Commission Implementing Regulation (EU) 2018/1796 ⁽⁹⁾ extended the approval period of chlorpyrifos-methyl to 31 January 2020, in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is being taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

⁽⁶⁾ EFSA (European Food Safety Authority), 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(5):5810. <https://doi.org/10.2903/j.efsa.2019.5810>.

⁽⁷⁾ European Food Safety Authority (EFSA), 2019. Updated statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos-methyl. *EFSA Journal* 2019;17(11):5908, 21 pp. <https://doi.org/10.2903/j.efsa.2019.5908>.

⁽⁸⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁹⁾ Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflubenzuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, mecoprop-p, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ L 294, 21.11.2018, p. 15).

- (18) This Regulation does not prevent the submission of a further application for the approval of chlorpyrifos-methyl pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (19) 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

Non-renewal of the approval of the active substance

The approval of the active substance chlorpyrifos-methyl is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 112, on chlorpyrifos-methyl, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorpyrifos-methyl as an active substance by 16 February 2020.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 16 April 2020.

Article 5

Entry into force

This Regulation shall enter into force on the third 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, 10 January 2020.

For the Commission

The President

Ursula VON DER LEYEN

COMMISSION IMPLEMENTING REGULATION (EU) 2020/18**of 10 January 2020****concerning the non-renewal of the approval of the active substance chlorpyrifos, 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) and Article 78(2) thereof,

Whereas:

- (1) Commission Directive 2005/72/EC ⁽²⁾ included chlorpyrifos 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 chlorpyrifos, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 31 January 2020.
- (4) Applications for the renewal of the approval of the active substance chlorpyrifos were 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 applicants submitted the supplementary dossiers required in accordance with Article 6 of Implementing Regulation (EU) No 844/2012. The applications were found to be complete by the rapporteur Member State.
- (6) The rapporteur Member State prepared a 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 3 July 2017.
- (7) The Authority made the supplementary summary dossier available to the public. The Authority also circulated the renewal assessment report to the applicants and to the Member States for comments and launched a public consultation on it. The Authority forwarded the comments received to the Commission.
- (8) On 4 July 2018, the Authority requested that the applicants 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 renewal assessment report.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2005/72/EC of 21 October 2005 amending Council Directive 91/414/EEC to include chlorpyrifos, chlorpyrifos-methyl, mancozeb, maneb, and metiram as active substances (OJ L 279, 22.10.2005, p. 63).

⁽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).

- (9) The Authority organised an expert discussion in April 2019 to discuss certain elements related to the human health risk assessment. Due to concerns about genotoxicity and developmental neurotoxicity raised during that discussion, on 1 July 2019 the Commission sent a mandate to the Authority requesting a statement on the available outcomes of the human health assessment and an indication whether the active substance can be expected to meet the approval criteria which are applicable to human health as laid down in Article 4 of Regulation (EC) No 1107/2009.
- (10) On 31 July 2019, the Authority sent its statement ⁽⁶⁾ to the Commission. In its statement, the Authority confirmed that its conclusions on the human health assessment indicate that critical areas of concerns exist. Based on the information available, it cannot be excluded that chlorpyrifos has a genotoxic potential, since positive results were found in a number of *in vitro* and *in vivo* studies. Consequently, it is not possible to establish health-based reference values for chlorpyrifos and to conduct the relevant consumer and non-dietary risk assessments. Furthermore, developmental neurotoxicity (DNT) effects were observed in the available study on developmental neurotoxicity in rats and epidemiological evidence exists showing an association between exposure to chlorpyrifos and/or chlorpyrifos-methyl during development and adverse neurodevelopmental outcomes in children. Moreover, it is indicated that the peer review experts considered it appropriate to classify chlorpyrifos as toxic for reproduction, category 1B, in accordance with the criteria established under Regulation (EC) No 1272/2008 of the European Parliament and of the Council ⁽⁷⁾.
- (11) The Commission invited the applicants to submit their comments on the statement of the Authority. Furthermore, in accordance with the third subparagraph of Article 14(1) of Implementing Regulation (EU) No 844/2012, the Commission invited the applicants to submit comments on the draft renewal report. The applicants submitted their comments, which have been carefully examined.
- (12) However, despite the arguments put forward by the applicants, the concerns regarding the active substance could not be eliminated.
- (13) Consequently, it has not been established, with respect to one or more representative uses of at least one plant protection product that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. The environmental risk assessment, although not finalised, cannot alter this conclusion since the approval criteria related to the effects on human health are not satisfied and should therefore not delay further the decision-making on the renewal of the approval of the active substance. It is therefore appropriate not to renew the approval of the active substance chlorpyrifos in accordance with Article 20(1)(b) of that Regulation.
- (14) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (15) Member States should be given sufficient time to withdraw authorisations for plant protection products containing chlorpyrifos.
- (16) For plant protection products containing chlorpyrifos, where Member States grant any grace period in accordance with Article 46 of Regulation (EC) No 1107/2009, that period should not exceed 3 months from the date of entry into force of this Regulation.
- (17) Commission Implementing Regulation (EU) 2018/1796 ⁽⁸⁾ extended the approval period of chlorpyrifos to 31 January 2020 in order to allow the renewal process to be completed before the expiry of the approval period of that substance. However, given that a decision on the non-renewal of the approval is being taken ahead of the expiry of that extended approval period, this Regulation should apply as soon as possible.

⁽⁶⁾ EFSA (European Food Safety Authority), 2019. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos. *EFSA Journal* 2019;17(5):5809. <https://doi.org/10.2903/j.efsa.2019.5809>

⁽⁷⁾ Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

⁽⁸⁾ Commission Implementing Regulation (EU) 2018/1796 of 20 November 2018 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances amidosulfuron, bifenox, chlorpyrifos, chlorpyrifos-methyl, clofentezine, dicamba, difenoconazole, diflufenuron, diflufenican, dimoxystrobin, fenoxaprop-p, fenpropidin, lenacil, mancozeb, metiram, nicosulfuron, oxamyl, picloram, pyraclostrobin, pyriproxyfen and tritosulfuron (OJ L 294, 21.11.2018, p. 15).

- (18) This Regulation does not prevent the submission of a further application for the approval of chlorpyrifos pursuant to Article 7 of Regulation (EC) No 1107/2009.
- (19) 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

Non-renewal of the approval of the active substance

The approval of the active substance chlorpyrifos is not renewed.

Article 2

Amendment to Implementing Regulation (EU) No 540/2011

In Part A of the Annex to Implementing Regulation (EU) No 540/2011, row 111, on chlorpyrifos, is deleted.

Article 3

Transitional measures

Member States shall withdraw authorisations for plant protection products containing chlorpyrifos as an active substance by 16 February 2020.

Article 4

Grace period

Any grace period granted by Member States in accordance with Article 46 of Regulation (EC) No 1107/2009 shall expire by 16 April 2020.

Article 5

Entry into force

This Regulation shall enter into force on the third 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, 10 January 2020.

For the Commission

The President

Ursula VON DER LEYEN

ISSN 1977-0677 (electronic edition)
ISSN 1725-2555 (paper edition)



Publications Office of the European Union
2985 Luxembourg
LUXEMBOURG

