

COMMISSION IMPLEMENTING REGULATION (EU) 2023/223**of 27 January 2023****renewing the approval of the active substance *Pseudomonas chlororaphis* strain MA 342 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) thereof,

Whereas:

- (1) Commission Directive 2004/71/EC ⁽²⁾ included *Pseudomonas chlororaphis* strain MA 342 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 *Pseudomonas chlororaphis* strain MA 342, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 30 April 2023.
- (4) An application for the renewal of the approval of the active substance *Pseudomonas chlororaphis* strain MA 342 was submitted to the Netherlands, 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 Netherlands prepared a draft renewal assessment report in consultation with Denmark, the co-rapporteur Member State, and submitted it to the European Food Safety Authority ('the Authority') and the Commission on 11 January 2016. In its draft renewal assessment report the Netherlands proposed to renew the approval of *Pseudomonas chlororaphis* strain MA 342.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2004/71/EC of 28 April 2004 amending Council Directive 91/414/EEC to include *Pseudomonas chlororaphis* as active substance (OJ L 127, 29.4.2004, p. 104).

⁽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 continues 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.
- (8) On 9 December 2016, the Authority communicated to the Commission its conclusion ⁽⁶⁾ which indicated that *Pseudomonas chlororaphis* strain MA 342 can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (9) Based on discussions at the Standing Committee on Plants, Animals, Food and Feed, the Commission requested the Authority on 3 February 2020 to provide scientific advice on the translocation potential by *Pseudomonas chlororaphis* strain MA 342 in plants after seed treatment of cereals and peas and, if applicable, for a revision of the assessment of the risk to humans by the metabolite 2, 3-deepoxy-2, 3-didehydro-rhizoxin (DDR). In response, on 23 September 2020, the Authority issued a statement on the translocation potential by *Pseudomonas chlororaphis* strain MA 342 in plants after seed treatment of cereals and peas and an assessment of the risk to humans ⁽⁷⁾.
- (10) The Commission presented the renewal report and a draft of this Regulation regarding *Pseudomonas chlororaphis* strain MA 342 to the Standing Committee on Plants, Animals, Food and Feed on 15 October 2022 and 8 December 2022, respectively.
- (11) The Commission invited the applicant to submit its comments on the conclusion and the statement 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.
- (12) It has been established, with respect to one or more representative uses of at least one plant protection product containing the active substance *Pseudomonas chlororaphis* strain MA 342, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (13) It is therefore appropriate to renew the approval of *Pseudomonas chlororaphis* strain MA 342. In accordance with Article 14(1) of Regulation (EC) No 1107/2009, read in conjunction with Article 6 thereof, and in the light of current scientific and technical knowledge ⁽⁸⁾ and the outcome of the risk assessment, it is, however, necessary to set certain conditions. In particular, it is necessary to maintain the existing restriction to use *Pseudomonas chlororaphis* strain MA 342 only as fungicide for seed dressing in closed seed dressing machinery and to set the maximum content of the metabolite DDR in plant protection products containing *Pseudomonas chlororaphis* strain MA 342.
- (14) In addition, in order to increase the confidence in the conclusion that the risk for human beings and the environment following the exposure to *Pseudomonas chlororaphis* strain MA 342 is negligible or very low, the applicant should provide confirmatory information as regards the identification and characterisation of *Pseudomonas chlororaphis* strain MA 342, the metabolite DDR and the potential for gene transfer of antibiotic resistance from *Pseudomonas chlororaphis* strain MA 342 to other micro-organisms.
- (15) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.

⁽⁶⁾ EFSA Journal 2017;15(1):4668. Available online: www.efsa.europa.eu.

⁽⁷⁾ EFSA (European Food Safety Authority), 2020. Statement on the translocation potential by *Pseudomonas chlororaphis* MA342 in plants after seed treatment of cereals and peas and assessment of the risk to humans. <https://doi.org/10.2903/j.efsa.2020.6276>.

⁽⁸⁾ Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf.

Guidance on the approval and low-risk criteria linked to 'antimicrobial resistance' applicable to microorganisms used for plant protection (SANTE/2020/12260): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf.

- (16) Commission Implementing Regulation (EU) 2022/378 ⁽⁹⁾ extended the approval period of *Pseudomonas chlororaphis* strain MA 342 to 30 April 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 *Pseudomonas chlororaphis* strain MA 342, as specified in Annex I to this Regulation, is renewed, subject to the conditions laid down in that Annex.

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, 27 January 2023.

For the Commission
The President
Ursula VON DER LEYEN

⁽⁹⁾ Commission Implementing Regulation (EU) 2022/378 of 4 March 2022 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances abamectin, *Bacillus subtilis* (Cohn 1872) strain QST 713, *Bacillus thuringiensis* subsp. *Aizawai* strains ABTS-1857 and GC-91, *Bacillus thuringiensis* subsp. *Israeliensis* (serotype H-14) strain AM65-52, *Bacillus thuringiensis* subsp. *Kurstaki* strains ABTS 351, PB 54, SA 11, SA12 and EG 2348, *Beauveria bassiana* strains ATCC 74040 and GHA, clodinafop, *Cydia pomonella* Granulovirus (CpGV), cyprodinil, dichlorprop-P, fenpyroximate, fosetyl, malathion, mepanipyrim, metconazole, metrafenone, pirimicarb, *Pseudomonas chlororaphis* strain MA342, pyrimethanil, *Pythium oligandrum* M1, rimsulfuron, spinosad, *Trichoderma asperellum* (formerly *T. harzianum*) strains ICC012, T25 and TV1, *Trichoderma atroviride* (formerly *T. harzianum*) strain T11, *Trichoderma gamsii* (formerly *T. viride*) strain ICC080, *Trichoderma harzianum* strains T-22 and ITEM 908, triclopyr, trinexapac, triticonazole and ziram (OJ L 72, 7.3.2022, p. 2).

ANNEX I

Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
<i>Pseudomonas chlororaphis</i> strain MA 342 Culture collection: NCIMB, UK: NCIMB 40616	Not applicable	The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the in the Microbial Pest Control Agent (MPCA) must not exceed the LOQ (2.0 µg/ml).	1 March 2023	28 February 2038	<p>Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised.</p> <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 <i>Pseudomonas chlororaphis</i> strain MA 342, and in particular Appendices I and II thereof, 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"> — the level of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the Microbial Pest Control Agent (MPCA), which must not exceed 2 µg/ml; — the protection of operators and workers, taking into account that <i>Pseudomonas chlororaphis</i> strain MA 342 is to be considered, as any micro-organism, as a potential sensitiser, and paying special attention to exposure through inhalation. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process, shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the phylogenetic taxonomic identification of the micro-organism in accordance with point 1.3 (identity, taxonomy and phylogeny) of Annex II, Part B of Commission Regulation (EU) 2022/1439 ⁽²⁾; 2. the secondary metabolite DDR in accordance with SANCO/2020/12258 ⁽³⁾, in particular on its degradation rate; 3. the potential for gene transfer of antibiotic resistance from <i>Pseudomonas chlororaphis</i> strain MA 342 to other micro-organisms in accordance with SANTE/2020/12260 ⁽⁴⁾. <p>The applicant shall submit the requested information referred to in point 1, 2 and 3 by 23 February 2025.</p>

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

⁽²⁾ Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).

⁽³⁾ Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf.

⁽⁴⁾ Guidance on the approval and low-risk criteria linked to 'antimicrobial resistance' applicable to microorganisms used for plant protection (SANTE/2020/12260): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf.

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

(1) in Part A, entry 89 on *Pseudomonas chlororaphis* strain MA 342 is deleted;

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

156	<i>Pseudomonas chlororaphis</i> strain MA 342 Culture collection: NCIMB, UK: NCIMB 40616	Not applicable	The amount of the secondary metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the in the Microbial Pest Control Agent (MPCA) must not exceed the LOQ (2.0 µg/ml).	1 March 2023	28 February 2038	<p>Only uses as fungicide for seed dressing in closed seed dressing machinery may be authorised.</p> <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 <i>Pseudomonas chlororaphis</i> strain MA 342, and in particular Appendices I and II thereof, 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"> — the level of the metabolite 2,3-deepoxy-2,3-didehydro-rhizoxin (DDR) in the Microbial Pest Control Agent (MPCA), which must not exceed 2 µg/ml; — the protection of operators and workers, taking into account that <i>Pseudomonas chlororaphis</i> strain MA 342 is to be considered, as any micro-organism, as a potential sensitiser, and paying special attention to exposure through inhalation. <p>Strict maintenance of environmental conditions and quality control analysis during the manufacturing process, shall be assured by the producer, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012.</p> <p>Conditions of use shall include risk mitigation measures, where appropriate.</p> <p>The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:</p> <ol style="list-style-type: none"> 1. the phylogenetic taxonomic identification of the micro-organism in accordance with point 1.3 (identity, taxonomy and phylogeny) of Annex II, Part B of Commission Regulation (EU) 2022/1439 (*); 2. the secondary metabolite DDR in accordance with SANCO/2020/12258 (**), in particular on its degradation rate;
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					<p>3. the potential for gene transfer of antibiotic resistance from <i>Pseudomonas chlororaphis</i> strain MA 342 to other micro-organisms in accordance with SANTE/2020/12260 (**).</p> <p>The applicant shall submit the requested information referred to in points 1, 2 and 3 by 23 February 2025.</p>
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(*) Commission Regulation (EU) 2022/1439 of 31 August 2022 amending Regulation (EU) No 283/2013 as regards the information to be submitted for active substances and the specific data requirements for micro-organisms (OJ L 227, 1.9.2022, p. 8).

(**) Guidance on the risk assessment of metabolites produced by microorganisms used as plant protection active substances (SANCO/2020/12258): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180653_microorganism-metabolites-concern_202011.pdf.

(***) Guidance on the approval and low-risk criteria linked to 'antimicrobial resistance' applicable to microorganisms used for plant protection (SANTE/2020/12260): https://food.ec.europa.eu/system/files/2020-11/pesticides_ppp_app-proc_guide_180652_microorganism-amr_202011.pdf.