

COMMISSION IMPLEMENTING REGULATION (EU) 2023/1001**of 23 May 2023****renewing the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713 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 ⁽¹⁾, and in particular Article 20(1) thereof,

Whereas:

- (1) Commission Directive 2007/6/EC ⁽²⁾ included *Bacillus amyloliquefaciens* strain QST 713 in Annex I to Council Directive 91/414/EEC ⁽³⁾ with the name of *Bacillus subtilis* (Cohn 1872) QST 713.
- (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 *Bacillus amyloliquefaciens* strain QST 713, as set out in Part A of the Annex to Implementing Regulation (EU) No 540/2011, expires on 15 August 2024.
- (4) An application for the renewal of the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713 was submitted to Germany, the rapporteur Member State, and Denmark, the co-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. 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 European Food Safety Authority ('the Authority') and the Commission on 4 June 2018. In its draft renewal assessment report, the rapporteur Member State proposed to renew the approval of the active substance *Bacillus amyloliquefaciens* strain QST 713.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ Commission Directive 2007/6/EC of 14 February 2007 amending Council Directive 91/414/EEC to include metrafenone, *Bacillus subtilis*, spinosad and thiamethoxam as active substances (OJ L 43, 15.2.2007, p. 13).

⁽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).

- (7) The Authority communicated the draft renewal assessment report to the applicant and to the other Member States for comments in accordance with Article 12(1) of Regulation (EC) No 1107/2009, launched a public consultation and forwarded the comments received to the Commission. The Authority also made the supplementary summary dossier available to public.
- (8) On 16 April 2021, the Authority communicated to the Commission its conclusion ⁽⁶⁾ on whether the active substance *Bacillus amyloliquefaciens* strain QST 713 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 Regulation regarding *Bacillus amyloliquefaciens* strain QST 713 to the Standing Committee on Plants, Animals, Food and Feed on 13 October 2022 and 25 January 2023, respectively.
- (9) 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 ⁽⁷⁾, on the renewal report. The applicant submitted its comments, which have been carefully examined.
- (10) It has been established with respect to one or more representative uses of least one plant protection product containing the active substance *Bacillus amyloliquefaciens* strain QST 713 that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied.
- (11) It is therefore appropriate to renew the approval of *Bacillus amyloliquefaciens* strain QST 713.
- (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 necessary to include certain conditions to the renewal of approval of that active substance. In particular, the Commission considers that *Bacillus amyloliquefaciens* strain QST 713 is a micro-organism within the meaning of Regulation (EC) No 1107/2009, for which a critical area of concern was identified as regards bees. For this reason, it is necessary to provide for specific risk mitigation measures in order to ensure a proper protection of bees.
- (13) Implementing Regulation (EU) No 540/2011 should therefore be amended accordingly.
- (14) Commission Implementing Regulation (EU) 2023/689 ⁽⁸⁾ extended the approval period to 15 August 2024 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 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,

⁽⁶⁾ Peer review of the pesticide risk assessment of the active substance *Bacillus amyloliquefaciens* strain QST 713 (formerly *Bacillus subtilis* strain QST 713): <https://doi.org/10.2903/j.efsa.2021.6381>.

⁽⁷⁾ 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.

⁽⁸⁾ Commission Implementing Regulation (EU) 2023/689 of 20 March 2023 amending Implementing Regulation (EU) No 540/2011 as regards the extension of the approval periods of the active substances *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, pyridaben, pyrimethanil, 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 91, 29.3.2023, p. 1).

HAS ADOPTED THIS REGULATION:

Article 1

Renewal of the approval of the active substance

The approval of the active substance *Bacillus amyloliquefaciens* strain QST 713, 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 July 2023.

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

Done at Brussels, 23 May 2023.

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
<i>Bacillus amyloliquefaciens</i> strain QST 713	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> strain QST 713 in the technical product and formulation is Minimum: 1×10^{12} CFU/kg Maximum: 3×10^{13} CFU/kg No relevant impurities	1 July 2023	30 June 2038	<p>When authorising plant protection products containing <i>Bacillus amyloliquefaciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall:</p> <ul style="list-style-type: none"> — only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees; — implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles). <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>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account.</p> <p>In addition, Member States shall pay particular attention to:</p> <ul style="list-style-type: none"> — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾; — the specification of the technical material as commercially manufactured used in plant protection products; — the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.

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

⁽²⁾ pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf (europa.eu).

ANNEX II

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

- (1) in Part A, entry 138 on *Bacillus subtilis* (Cohn 1872) strain QST 713 is deleted.
 (2) in Part B, the following entry is added:

No.	Common Name, Identification Numbers	IUPAC Name	Purity ⁽¹⁾	Date of approval	Expiration of approval	Specific provisions
158	<i>Bacillus amyloliquefaciens</i> strain QST 713	n.a.	The nominal content of <i>Bacillus amyloliquefaciens</i> strain QST 713 in the technical product and formulation is Minimum: 1×10^{12} CFU/kg Maximum: 3×10^{13} CFU/kg No relevant impurities	1 July 2023	30 June 2038	When authorising plant protection products containing <i>Bacillus amyloliquefaciens</i> strain QST 713 for spray applications outdoors, in order to ensure the protection of non-target organisms, including bees, Member States shall: <ul style="list-style-type: none"> — only authorise field applications in flowering crops or in presence of flowering weed in the field outside the daily foraging period of bees; — implement risk mitigation measures which aim to reduce drift to off-field areas (e.g. considering the application of buffer zones and drift reduction nozzles). 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>Bacillus amyloliquefaciens</i> strain QST 713, and in particular Appendices I and II thereof, shall be taken into account. In addition, Member States shall pay particular attention to: <ul style="list-style-type: none"> — the assurance by the producer of strict maintenance of environmental conditions and quality control analysis during the manufacturing process, in order to ensure the fulfilment of the limits on microbiological contamination as referred to in the Working Document SANCO/12116/2012 ⁽²⁾ — the specification of the technical material as commercially manufactured used in plant protection products; — the protection of operators and workers, taking into account that micro-organisms are per se considered as potential sensitizers, ensuring that adequate personal protective equipment is included as a condition of use.'

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

⁽²⁾ pesticides_ppp_app-proc_guide_phys-chem-ana_microbial-contaminant-limits.pdf (europa.eu).