COMMISSION IMPLEMENTING REGULATION (EU) 2016/1414

of 24 August 2016

approving the active substance cyantraniliprole, 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 13(2) thereof,

Whereas:

- (1) In accordance with Article 7(1) of Regulation (EC) No 1107/2009 the United Kingdom received on 29 June 2011 an application from DuPont Crop Protection and Syngenta Crop Protection for the approval of the active substance cyantraniliprole. In accordance with Article 9(3) of that Regulation, the United Kingdom, as rapporteur Member State, notified the applicant, the other Member States, the Commission and the European Food Safety Authority (hereinafter 'the Authority') on 10 August 2011 of the admissibility of the application.
- (2) On 31 May 2013 the rapporteur Member State submitted a draft assessment report to the Commission with a copy to the Authority, assessing whether that active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.
- (3) The Authority complied with Article 12(1) of Regulation (EC) No 1107/2009. In accordance with Article 12(3) of Regulation (EC) No 1107/2009, it requested the applicant to 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 format of an updated draft assessment report on 12 June 2014
- (4) On 18 August 2014 the Authority communicated to the applicant, the Member States and the Commission its conclusion on whether the active substance cyantraniliprole can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 (2). The Authority made its conclusion available to the public. A revised version of this conclusion was published on 11 November 2014 and 28 May 2015 (3).
- (5) On 13 July 2015 the Commission presented to the Standing Committee on Plants, Animals, Food and Feed the review report for cyantraniliprole and a draft Regulation providing that cyantraniliprole is approved.
- (6) The applicant was given the possibility to submit comments on the review report.
- (7) It has been established with respect to one or more representative uses of at least one plant protection product containing the active substance, and in particular the uses which were examined and detailed in the review report, that the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 are satisfied. It is therefore appropriate to approve cyantraniliprole.
- (8) In accordance with Article 13(2) 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 include certain conditions and restrictions. It is, in particular, appropriate to require further confirmatory information.

⁽¹⁾ OJ L 309, 24.11.2009, p. 1.

⁽²⁾ EFSA Journal 2014;12(9):3814. Available online: www.efsa.europa.eu

⁽³⁾ EFSA Journal 2014;12(9):3814. Available online: www.efsa.europa.eu

- (9) In accordance with Article 13(4) of Regulation (EC) No 1107/2009, the Annex to Commission Implementing Regulation (EU) No 540/2011 (¹) should be amended accordingly.
- (10) 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

Approval of active substance

The active substance cyantraniliprole, as specified in Annex I, is approved subject to the conditions laid down in that Annex.

Article 2

Amendment 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

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, 24 August 2016.

For the Commission
The President
Jean-Claude JUNCKER

⁽¹) 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).

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Common Name, Identification Numbers	IUPAC Name	Purity (¹)	Date of approval	Expiration of approval	Specific provisions
Cyantraniliprole CAS No: 736994-63-1 CIPAC No: Not allocated.	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carboxanilide	≥ 940 g/kg IN-Q6S09 max. 1 mg/kg IN-RYA13 max. 20 mg/kg methanesulfonic acid max. 2 g/kg acetonitrile max. 2 g/kg heptane max. 7 g/kg 3-picoline max. 3 g/kg.	14 September 2016	14 September 2026	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyantraniliprole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic organisms, bees and other non-target arthropods; (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

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

In Part B of the Annex to Implementing Regulation (EU) No 540/2011, the following entry is added:

Number	Common Name, Identification Numbers	IUPAC Name	Purity (*)	Date of approval	Expiration of approval	Specific provisions
·99	Cyantraniliprole CAS No: 736994-63-1 CIPAC No: Not allocated.	3-bromo-1-(3-chloro-2-pyridyl)-4'-cyano-2'-methyl-6'-(methylcarbamoyl)pyrazole-5-carbox-anilide	≥ 940 g/kg IN-Q6S09 max. 1 mg/kg IN-RYA13 max. 20 mg/kg methanesulfonic acid max. 2 g/kg acetonitrile max. 2 g/kg heptane max. 7 g/kg 3-picoline max. 3 g/kg.	14 September 2016	14 September 2026	For the implementation of the uniform principles as referred to in Article 29(6) of Regulation (EC) No 1107/2009, the conclusions of the review report on cyantraniliprole, and in particular Appendices I and II thereto, shall be taken into account. In this overall assessment Member States shall pay particular attention to: (a) the risk to operators; (b) the risk to aquatic organisms, bees and other non-target arthropods; (c) the risk to bees and bumble bees released for pollination, when the substance is applied in glasshouses; (d) the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions. Conditions of use shall include risk mitigation measures, where appropriate. The applicant shall submit to the Commission, Member States and the Authority confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface and groundwater, when surface water or groundwater are abstracted for drinking water within 2 years after adoption of a guidance document on evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

ANNEX II

^(*) Further details on identity and specification of active substance are provided in the review report.