EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY
Food and feed safety, innovation
Pesticides and biocides

COMMISSION STAFF WORKING DOCUMENT[1]

Cyantraniliprole

SANTE/00111/2015 rev 1

12 July 2016

Final Review report for the active substance **cyantraniliprole**
finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on **12 July 2016** in view of the approval of cyantraniliprole as active substance in accordance with Regulation (EC) No 1107/2009[2]

1. Procedure followed for the evaluation process

This review report has been established as a result of the evaluation of the new active substance cyantraniliprole, made in the context of the work provided for in Articles 7 to 13 of Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC, with a view to the possible approval of this substance for the use in plant protection products.

In accordance with the provisions of Article 7 of that Regulation, the authority of the United Kingdom received on 29 June 2011 an application from DuPont Crop Protection and Syngenta Crop Protection, hereafter referred to as the applicants, for the approval of the active substance cyantraniliprole for use in plant protection products. The authority of the United Kingdom indicated to the Commission on 10 August 2011 the results of their examination of the completeness of the dossier satisfying the requirements of Article 8, according to the provisions of Article 9 of the Regulation. Subsequently, and in accordance with the requirements of Article 9(3), a dossier on cyantraniliprole was distributed to the Member States, the European Food Safety Authority (EFSA) and the Commission.

Thereupon, United Kingdom as rapporteur Member State, together with France, acting as co-rapporteur, started the detailed examination of the dossier provided by the applicant. According to the provisions of Article 11, the rapporteur Member State shall prepare and submit it to the Commission and EFSA within twelve months a report (the draft assessment report), assessing whether the active substance can be expected to meet the criteria provided for in Article 4 of the Regulation.

1 Does not necessarily represent the views of the Commission.
2 OJ L 309, 24.11.2009, p. 1.

The United Kingdom submitted that draft assessment report to the Commission and EFSA on 31 May 2013.

On 20 June 2013, EFSA circulated the draft assessment report to Member States and the applicant and, in addition, organised a public consultation on it, in line with the provisions of Article 12(1) of the Regulation.

EFSA organised a consultation to review the draft assessment report and the comments received thereon (peer review) in accordance with the provisions of Article 12(2) and 12(3). In this framework, EFSA decided to request additional information from the applicant and to conduct specific consultations of experts from Member States and the rapporteur.

According to the provisions of Article 12(2) of the Regulation, EFSA sent to the Commission its conclusion on the risk assessment [Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole (approved: 13 August 2014, revised on 11 November 2014 and 28 May 2015)[3]]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 13 of that Regulation, the Commission produced a draft review report and a draft Regulation on cyantraniliprole. The Commission referred the draft review report to the applicant for commenting on 2 July 2015 and on 13 July 2015 to the Standing Committee on Plants, Animals, Food and Feed for final examination. The draft review report was finalised in the meeting of the Standing Committee on 12 July 2016.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of EFSA, and the comments and clarifications submitted after the conclusion of EFSA (background document C), these documents are also considered to be part of this review report.

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2016/1414**[4] concerning the approval of cyantraniliprole as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing cyantraniliprole they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011.

This review report provides also for the evaluation required under part I, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011, submitted for the purpose of approval of the active substances, as well as the result of the evaluation of those data.

[3] EFSA (2014) Conclusion on the peer review of the pesticide risk assessment of the active substance cyantraniliprole. EFSA Journal 2014;12(9):3814, 249 pp. Available online: www.efsa.europa.eu/efsajournal.

[4] OJ L 230, 25.8.2016, p. 16–19.

In accordance with the provisions of Article 10 of Regulation (EU) No 188/2011, this review report will be made available to the public.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Regulation (EC) No 1107/2009. It is therefore recommended that this review report would not be accepted to support any registration outside the context of that Regulation, e.g. in third countries, for which the applicant has not demonstrated to have regulatory access to the information on which this review report is based.

3. Overall conclusion in the context of Regulation (EC) No 1107/2009

The overall conclusion from the evaluation is that it may be expected that plant protection products containing cyantraniliprole will fulfil the safety requirements laid down in Article 4(1) - (3) of Regulation (EC) No 1107/2009. This conclusion is however subject to compliance with the particular requirements in sections 4, 5, 6 and 7 of this report, as well as to the implementation of the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, for each cyantraniliprole containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these conclusions were reached within the framework of the uses which were proposed and supported by the data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

Extension of the use pattern beyond those described above will require an evaluation at Member State level in order to establish whether the proposed extensions of use can satisfy the requirements of Article 29(1) of Regulation (EC) No 1107/2009 and of the uniform principles laid down in Regulation (EU) No 546/2011.

The following reference values have been finalised as part of this evaluation:

ADI: 0.01 mg/kg bw/day,
AOEL: 0.007 mg/kg bw/day.

With particular regard to residues, no data gaps or areas of concern were identified in the residues area. The International Estimated Daily Intake (IEDI) for all considered consumer groups[5] is not higher than 20% of the Acceptable Daily Intake (ADI), based on EFSA PRIMo Model rev.2.

The review has identified several acceptable exposure scenarios for operators, workers, bystanders and groundwater which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles. In particular, Member States shall pay particular attention to the protection of groundwater, when the substance is applied in regions with vulnerable soil and/or climatic conditions.

The review of the uses supported by available data, as listed in Appendix II, has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the

[5] Based on an assessment of all uses for which an MRL was proposed on basis of either the peer review or the MRL application.

environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report. For other representative uses evaluated in the EFSA conclusion, data gaps and risks with regard to bees were identified for which Member States are requested to pay particular attention as highlighted in section 6.

4. Identity and Physical/chemical properties

The main identity of cyantraniliprole is given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The active substance shall have a minimum purity of 940 g/kg.

The manufacturing impurities IN-Q6S09, IN-RYA13, methanesulfonic acid, acetonitrile, heptane and 3-picoline are of toxicological, ecotoxicological and/or environmental concern and must not exceed the maximum concentration, as indicated in appendix I, in the active substance as manufactured.

5. Endpoints and related information

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011, the most important endpoints were identified during the evaluation process. These endpoints are listed in the conclusion of EFSA, and in section 3 of this report.

6. Particular conditions to be taken into account on short term basis by Member States in relation to the granting of authorisations of plant protection products containing cyantraniliprole

On the basis of the proposed and supported uses (as listed in Appendix II), the following issues have been identified as requiring particular and short term attention from all Member States, in the framework of any authorisations to be granted, varied or withdrawn, as appropriate:

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 risk to groundwater.

Conditions of use shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

Further studies were identified which were at this stage considered necessary in relation to the approval of cyantraniliprole under the current approval conditions.

The applicant shall submit 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.

The applicant shall submit the relevant information two 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.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 23-24).

8. Information on studies with claimed data protection

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the sole data submitter has claimed data protection and which during the evaluation process were considered as essential with a view to approval under Regulation (EC) No 1107/2009. This information is only given to facilitate the operation of the provisions of Article 62 of Regulation (EC) No 1107/2009 in the Member States. It is based on the best information available but it does not prejudice any rights or obligations of Member States or operators with regard to its uses in the implementation of the provisions of Article 62 of Regulation (EC) No 1107/2009 and neither does it commit the Commission.

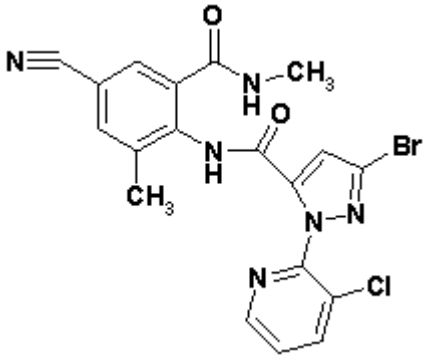
9. Updating of this review report

The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 13, 21, 38, 44, 56 of Regulation (EC) No 1107/2009. Any such adaptation will be finalised in the Standing Committee on Plants, Animals, Food and Feed, in connection with any amendment of the approval conditions for cyantraniliprole.

APPENDIX I

Main identity

CYANTRANILIPROLE

Common name (ISO)	Cyantraniliprole
Chemical name (IUPAC)	3-bromo-1-(3-chloro-2-pyridyl)-4′-cyano-2′-methyl-6′-(methylcarbamoyl)pyrazole-5-carboxanilide
Chemical name (CA)	*3-bromo-1-(3-chloro-2-pyridinyl)*-N-*[4-cyano-2-methyl-6-[(methylamino)carbonyl]phenyl]-1*H-*pyrazole-5-carboxamide*
CIPAC No	Not assigned
CAS No	736994-63-1
EC No (EINECS or ELINCS) ‡	Not allocated
FAO SPECIFICATION	Not available
Minimum purity	940 g/kg Relevant impurities: 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.
Molecular formula	$C_{19}H_{14}BrClN_6O_2$
Molecular mass	473.72 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

CYANTRANILIPROLE

Crop and/or situation	Member State or Country	Product Name	F G or	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks
					Type	Conc. of a.s.	Method Kind	Growth stage & season (j)	Number min max (k)	Interval between apps. (min)	kg a.s./hL min max	water (L/ha) min max	g a.s. /ha min max		
(a)			I (b)	(c)	(d-f)	(i)	(f-h)							(l)	(m)
Potatoes	NEU SEU	DPX-HGW86 100 g/L OD	F	*L. decemlineata*	OD	100 g/L	hydraulic ground directed boom	BBCH 31-BBCH 60	1-2	14	-	300-600	12.5	14	With or without addition of adjuvant oil
Aubergine, tomato	NEU, SEU	DPX-HGW86 200 g/L SC	G	White fly *Bemisia tabaci Trialeurodes vaporariorum*	SC	200 g/L	hydroponic	BBCH10-BBCH89	1-4	7-14	75 -100 g a.s./ha	n.a.	100	1	
Cucurbits edible and inedible peel	NEU, SEU	DPX-HGW86 200 g/L SC	G	White fly *Bemisia tabaci Trialeurodes vaporariorum*	SC	200 g/L	Hydroponic	BBCH10-BBCH89	1-4	7-14	75 -100 g a.s./ha	n.a.	100	1	
Pepper	NEU, SEU	DPX-HGW86 200 g/L SC	G	White fly *Bemisia tabaci Trialeurodes vaporariorum*	SC	200 g/L	Hydroponic	BBCH10-BBCH89	1-4	7-14	75 -100 g a.s./ha	n.a.	100	1	

Remarks:	(a) For crops the EU and Codex classifications (both) should be used. (b) Outdoor or field use (F), glasshouse application (G) or indoor application (I) (c) e.g. biting and sucking insects, soil borne insects, foliar fungi, weeds (d) e.g. wettable powder (WP),emulsifiable concentrate (EC), granule (GR) (e) GIFAP Codes - GIFAP Technical Monograph No. 2, 1989 (f) All abbreviations must be explained	(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench (h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants (i) g/kg or g/l (j) Growth stage at last treatment, including where relevant information on season at time of application (k) The minimum and maximum number of applications possible under practical conditions must be given (l) PHI - Pre-harvest interval (m) Remarks may include: Extent of use/ economic importance/restrictions (e.g. feeding/grazing)/minimal intervals between applications. Indicate uses not yet authorised.