Acetamiprid
SANTE/10502/2017 Rev 4
13 December 2017

Final Renewal report for the active substance **acetamiprid**

finalised in the Standing Committee on Plants, Animals, Food and Feed
at its meeting on 13 December 2017
in view of the renewal of the approval of acetamiprid as active substance in accordance with Regulation (EC) No 1107/2009[1]

1. Procedure followed for the re-evaluation process

This renewal report has been established as a result of the evaluation of acetamiprid, in accordance with Regulation (EC) No 1107/2009[2] and Commission Implementing Regulation (EU) No 844/2012[3] following the submission of an application to renew the approval of this active substance expiring in April 2017.

Commission Implementing Regulation (EU) No 844/2012 lays down the procedure for the renewal of the third group of active substances and includes acetamiprid.

Acetamiprid is a substance that was included in Annex I to Council Directive 91/414/EEC[4] concerning the placing of plant protection products on the market, by Commission Directive 2002/37/EC[5]. Acetamiprid is deemed to have been approved under Regulation (EC) No 1107/2009 and is listed in Part A of the Annex to Commission Implementing Regulation (EU) No 540/2011[6].

An application for renewal of the approval of acetamiprid was submitted by Nisso Chemical Europe GmbH in accordance with Article 1 of Regulation (EU) No 844/2012.

Commission Implementing Regulation 2016/2016[7] extended until 30 April 2018 the period of approval of acetamiprid to allow the completion of its review.

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1 Renewal report established in accordance with Article 14 of Regulation (EU) No 844/2012; does not necessarily represent the views of the European Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 252, 19.9.2012, p. 26.
4 OJ L 230, 19.8.1991, p. 1.
5 OJ L 1174.5.2002 p. 10-12.
6 OJ L 153, 11.6.2011, p. 1.
7 OJ L 312, 18.11.2016, p. 21.

Implementing Regulation (EU) No 686/2012[8] designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For acetamiprid the rapporteur Member State was the Netherlands and the co-rapporteur Member State was Spain.

The Netherlands finalised in November 2015 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 17 December 2015 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of acetamiprid for the supported uses.

In accordance with Article 13 of Implementing Regulation (EU) No 844/2012, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusion regarding the peer review of the pesticide risk assessment of the active substance acetamiprid)[9] on 19 October 2016. This conclusion refers to background document A (final revised version of the renewal assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 14 of Implementing Regulation (EU) No 844/2012, the Commission referred a draft renewal report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 23 January 2017. The draft renewal report was finalised in the meeting of the Standing Committee on 13 December 2017.

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

2. Purposes of this review report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2018/113**[10] concerning the renewal of approval of acetamiprid as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing acetamiprid 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[11].

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8 OJ L 200, 27.7.2012, p. 5.

9 EFSA (European Food Safety Authority), 2016. Conclusion on the peer review of the pesticide risk assessment of the active substance acetamiprid. EFSA Journal 2016;14(11):4610, 26 pp. doi:10.2903/j.efsa.2016.4610.

10 OJ L 20, 25.1.2018, p. 7.

11 OJ L 155, 11.6.2011, p. 127.

This renewal 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 283/2013[12], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

This renewal report will be made available to the public.

The information in this renewal 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 renewal 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 renewal 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 acetamiprid will still fulfil the safety requirements laid down in Article 4(1) to (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 acetamiprid 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 applicant and mentioned in the list of uses supported by available data (attached as Appendix II to this renewal report).

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

ADI: 0.025 mg/kg bw per day,
AOEL: 0.025 mg/kg bw per day,
AAOEL: 0.025 mg/kg bw per day,
ARfD: 0.025 mg/kg bw.

With particular regard to residues, no data gaps or areas of concern were identified in the residues area in relation to the representative use on potato where the highest chronic intake was estimated to be less than 1% of the Acceptable Daily Intake (ADI), (DE child) and the highest acute intake 6% of the Acute Reference Dose (ARfD) (UK infant), using the EFSA PRIMo rev.2 model. As no MRL could be derived for the uses on pome fruits and tomato a consumer risk assessment taking these uses into account could not be carried out.

Based on the agreed ARfD of 0.025 mg/kg bw a number of acute exceedances were identified for uses authorised in the EU, taking into account the maximum residue levels currently set in

[12] OJ L 93, 3.4.2013, p. 1.

Annex II to Regulation (EC) No 396/2005. Member States should pay particular attention to ensure that authorised GAPs would not result in any unacceptable risk to consumers when carrying out assessments for the renewal of plant protection products.

The review has identified acceptable exposure scenarios for operators, workers, residents, 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.

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 review has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the 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.

The following point could not be finalised by EFSA (2016):

- ***The consumer risk assessment from the consumption of water could not be finalised, whilst satisfactory information was not available to address the effect of water treatment processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water.***

No guidance is currently available to assess the impact of water treatment processes on drinking water and therefore confirmatory information as regards the effect of water treatment processes on the nature of residues present in surface water, when surface water is abstracted for drinking water, is requested within a period of two years after a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface water being made public by the Commission.

Taking into account this point and the specific conditions under section 6, the Committee considered that an overall acceptable use of products containing acetamiprid is expected.

4. Identity and Physical/chemical properties

The main identity of acetamiprid is given in Appendix I.

The active substance shall have a minimum purity of 990 g/kg.

The reference specification as established at the time of first approval of acetamiprid was updated during the renewal assessment. The original specification was based on pilot plant production. The new specification is based on batch data from industrial scale production. The minimum purity of the active substance as manufactured is 990 g/kg, which is the same as the original application. There is no FAO specification available.

On the basis of information currently available for the active substance notified by the applicant and considered in the renewal review, none of the manufacturing impurities are considered of toxicological or ecotoxicological concern.

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 re-evaluation process. These endpoints are listed in the conclusion of the EFSA.

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 acetamiprid

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:

- the risk to aquatic organisms, bees and other non-target arthropods;
- the risk to birds and mammals;
- the risk to consumers;
- the risk to operators.

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

7. List of studies to be generated

No further studies were identified which were at this stage considered necessary in relation to the approval of acetamiprid under the current approval conditions.

However, with respect to the issue that could not be finalised identified in the EFSA conclusions concerning the effect of water treatment processes on the nature of residues present in surface water, when surface water is abstracted for drinking water, it will have to be fully addressed by the applicant following the adoption of a guidance document on the evaluation of the effect of water treatment processes on the nature of residues present in surface and groundwater.

The corresponding information should be submitted by the applicant to all Member States.

On this purpose, Member States are strongly recommended to coordinate via the zonal system of authorization, the evaluation of new information to ensure a harmonized approach and to avoid duplication of work in this area.

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 18-19).

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 applicant has claimed data protection and which during the re-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.

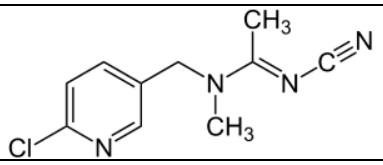
9. Updating of this renewal report

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 acetamiprid.

APPENDIX I

Main identity

ACETAMIPRID

Common Name (ISO)	Acetamiprid
Chemical name (IUPAC)	(E)-N1-[(6-Chloro-3-pyridyl)methyl]-N2-cyano-N1-methylacetamidine
Chemical name (CA)	(E)-N-[(6-Chloro-3-pyridinyl)methyl]-N'-cyano-N-methylethanimidamide
CIPAC No	649
CAS No	135410-20-7
EC No (EINECS or ELINCS)	Not allocated
FAO Specification (including year of publication)	None
Minimum purity of the active substance as manufactured	990 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	None
Molecular formula	C10H11ClN4
Molar mass	222.68 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

ACETAMIPRID

1	2	3	4	5	6	7	8	10	11	12	13	14
Use-No.	**Member state(s)**	**Crop and/ or situation (crop destination / purpose of crop)**	**F G or I**	**Pests or Group of pests controlled** (additionally: developmental stages of the pest or pest group)	**Application**			**Application rate**			**PHI** (days)	**Remarks:**
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		e.g. safener/synergist per ha e.g. recommended or mandatory tank mixtures
3	EU	Potato	F	Colorado potato beetle / aphids	Foliar	BBCH 45 – 93 (May-October)	a) 3 (7) b) 3 (7)	a) 0.250 b) 0.750	a) 0.05 b) 0.150	400 – 600	7	

(a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
(c) *e.g.* biting and sucking insects, soil born insects, foliar fungi, weeds
(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) CropLife International Technical Monograph no 2, 6th Edition. Revised May 2008. Catalogue of pesticide formulation types and international coding system
(f) All abbreviations used 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 plant- type of equipment used must be indicated
(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**
(j) Growth stage range from first to last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
(k) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha
(m) PHI - minimum pre-harvest interval