CONCLUSION ON PESTICIDES PEER REVIEW

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# Peer review of the pesticide risk assessment of the active substance forchlorfenuron

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## Abstract

The conclusions of EFSA following the peer review of the initial risk assessments carried out by the competent authorities of the rapporteur Member State, Spain, and co-rapporteur Member State, Greece, for the pesticide active substance forchlorfenuron are reported. The context of the peer review was that required by Commission Implementing Regulation (EU) No 844/2012. The conclusions were reached on the basis of the evaluation of the representative uses of forchlorfenuron as a plant growth regulator on kiwifruit and grapes. The reliable end points, appropriate for use in regulatory risk assessment, are presented. Missing information identified as being required by the regulatory framework is listed. Concern is identified.



**Keywords:** forchlorfenuron, peer review, risk assessment, pesticide, plant growth regulator

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## Summary

Commission Implementing Regulation (EU) No 844/2012 (hereinafter referred to as 'the Regulation') lays down the procedure for the renewal of the approval of active substances submitted under Article 14 of Regulation (EC) No 1107/2009. The list of those substances is established in Commission Implementing Regulation (EU) No 686/2012. Forchlorfenuron is one of the active substances listed in Regulation (EU) No 686/2012.

In accordance with Article 1 of the Regulation, the rapporteur Member State (RMS), Spain, and co-rapporteur Member State (co-RMS), Greece, received an application from AlzChem AG for the renewal of approval of the active substance forchlorfenuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Greece), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on forchlorfenuron in the renewal assessment report (RAR), which was received by EFSA on 27 May 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, AlzChem AG, for comments on 25 July 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 25 September 2016.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and residues.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether forchlorfenuron can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council.

The conclusions laid down in this report were reached on the basis of the evaluation of the representative uses of forchlorfenuron as a plant growth regulator on kiwifruit and grapes as proposed by the applicant. Full details of the representative uses can be found in Appendix A of this report.

Data were submitted to conclude that the uses of forchlorfenuron according to the representative uses proposed at the European Union (EU) level result in sufficient efficacy as a plant growth regulator.

A data gap was identified for a more detailed assessment of the review of the scientific peer-reviewed open literature on the active substance and its relevant metabolites in the residue and mammalian toxicology sections.

There were no data gaps identified in sections on identity and physical and chemical properties and analytical methods and mammalian toxicology.

The consumer risk assessment could not be finalised considering the data gap identified for a new metabolism study on a fruit crop and compliant with the representative uses on kiwi fruits and grapes. Meanwhile, the proposed residue definition for risk assessment as forchlorfenuron is regarded as provisional. A data gap was also identified for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom.

The data available on environmental fate and behaviour are sufficient to carry out the required environmental exposure assessments at EU level for the representative uses, with the notable exception that information is missing regarding the potential for indirect aqueous photolysis. Consequently, a data gap was identified and the exposure definition for surface water needed for risk assessment was not finalised. In addition, a data gap was identified for field soil dissipation rates of forchlorfenuron and field information for metabolite 4-amino-2-chloropyridine (ACP) in soil, consequent to their $DT_{50}$ values in the available laboratory soil incubations triggering this information being provided. The potential for groundwater exposure from the representative uses by forchlorfenuron and its metabolite ACP above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all seven pertinent FOCUS groundwater scenarios.

In the area of ecotoxicology, data gaps were identified for a study on a taxonomic group of algae other than green algae and for further information to address the risk to possible photodegradation metabolites. Data gaps for further information to address the risk to honeybees were also identified.

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## Background

Commission Implementing Regulation (EU) No 844/2012[1] (hereinafter referred to as 'the Regulation') lays down the provisions for the procedure of the renewal of the approval of active substances, submitted under Article 14 of Regulation (EC) No 1107/2009[2]. This regulates for the European Food Safety Authority (EFSA) the procedure for organising the consultation of Member States, the applicant(s) and the public on the initial evaluation provided by the rapporteur Member State (RMS) and/or co-rapporteur Member State (co-RMS) in the renewal assessment report (RAR), and the organisation of an expert consultation where appropriate.

In accordance with Article 13 of the Regulation, unless formally informed by the European Commission that a conclusion is not necessary, EFSA is required to adopt a conclusion on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009 within 5 months from the end of the period provided for the submission of written comments, subject to an extension of an additional 3 months where additional information is required to be submitted by the applicant(s) in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS Spain and co-RMS Greece received an application from AlzChem AG for the renewal of approval of the active substance forchlorfenuron. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Greece), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on forchlorfenuron in the RAR, which was received by EFSA on 27 May 2016 (Spain, 2016).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, AlzChem AG, for consultation and comments on 25 July 2016. EFSA also provided comments. In addition, EFSA conducted a public consultation on the RAR. EFSA collated and forwarded all comments received to the European Commission on 25 September 2016. At the same time, the collated comments were forwarded to the RMS for compilation and evaluation in the format of a reporting table. The applicant was invited to respond to the comments in column 3 of the reporting table. The comments and the applicant's response were evaluated by the RMS in column 3.

The need for expert consultation and the necessity for additional information to be submitted by the applicant in accordance with Article 13(3) of the Regulation were considered in a telephone conference between EFSA and the RMS on 15 November 2016. On the basis of the comments received, the applicant's response to the comments and the RMS's evaluation thereof, it was concluded that additional information should be requested from the applicant, and that EFSA should conduct an expert consultation in the areas of mammalian toxicology and residues.

The outcome of the telephone conference, together with EFSA's further consideration of the comments, is reflected in the conclusions set out in column 4 of the reporting table. All points that were identified as unresolved at the end of the comment evaluation phase and which required further consideration, including those issues to be considered in an expert consultation, were compiled by EFSA in the format of an evaluation table.

The conclusions arising from the consideration by EFSA, and as appropriate by the RMS, of the points identified in the evaluation table, together with the outcome of the expert consultation and the written consultation on the assessment of additional information, where these took place, were reported in the final column of the evaluation table.

A final consultation on the conclusions arising from the peer review of the risk assessment took place with Member States via a written procedure in May 2017.

This conclusion report summarises the outcome of the peer review of the risk assessment of the active substance and the representative formulation, evaluated on the basis of the representative uses of forchlorfenuron as a plant growth regulator on kiwifruit and grapes, as proposed by the applicant. A list of the relevant end points for the active substance and the formulation is provided in Appendix A.

In addition, a key supporting document to this conclusion is the peer review report (EFSA, 2017), which is a compilation of the documentation developed to evaluate and address all issues raised in the peer review, from the initial commenting phase to the conclusion. The peer review report comprises

[1] 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. 26–32.

[2] Regulation (EC) No 1107/2009 of 21 October 2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC OJ L 309, 24.11.2009, p. 1–50.

the following documents, in which all views expressed during the course of the peer review, including minority views, where applicable, can be found:

- the comments received on the RAR;
- the reporting table (16 November 2016);
- the evaluation table (29 May 2017);
- the reports of the scientific consultation with Member State experts (where relevant);
- the comments received on the assessment of the additional information (where relevant);
- the comments received on the draft EFSA conclusion.

Given the importance of the RAR, including its revisions (Spain, 2017), and the peer review report, both documents are considered as background documents to this conclusion and thus are made publicly available.

It is recommended that this conclusion report and its background documents would not be accepted to support any registration outside the European Union (EU) for which the applicant has not demonstrated that it has regulatory access to the information on which this conclusion report is based.

## The active substance and the formulated product

Forchlorfenuron is the ISO common name for 1-(2-chloro-4-pyridyl)-3-phenylurea (IUPAC).

The representative formulated product for the evaluation was 'SITOFEX EC', an emulsifiable concentrate (EC), containing 10 g/L forchlorfenuron.

The representative uses evaluated were field applications by spraying as a plant growth regulator in kiwifruit and grapes. Full details of the Good Agricultural Practices (GAPs) can be found in the list of end points in Appendix A.

Data were submitted to conclude that the uses of forchlorfenuron according to the representative uses proposed at EU level result in a sufficient efficacy as a plant growth regulator following the guidance document SANCO/2012/11251-rev. 4 (European Commission, 2014).

A data gap has been identified for a more detailed assessment of the review of the scientific peer-reviewed open literature on the active substance and its relevant metabolites, dealing with side effects on health, in the area of mammalian toxicology and residues and published within the 10 years before the date of submission of the dossier, to be conducted and reported in accordance with EFSA guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009 (EFSA, 2011).

## Conclusions of the evaluation

### 1. Identity, physical/chemical/technical properties and methods of analysis

The following guidance documents were followed in the production of this conclusion: SANCO/3029/99-rev. 4 (European Commission, 2000a), SANCO/3030/99-rev. 4 (European Commission, 2000b) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

The new proposed reference specification for forchlorfenuron is based on batch data from industrial scale production. The minimum purity of the technical material is 978 g/kg. There is no FAO specification available for forchlorfenuron. The initial reference specification for first approval is no longer supported. As a consequence, it is recommended to update the reference specification of the first approval.

The assessment of the data package revealed no issues that need to be included as critical areas of concern with respect to the identity, physical, chemical and technical properties of forchlorfenuron or the representative formulation. The main data regarding the identity of forchlorfenuron and its physical and chemical properties are given in Appendix A.

The methods for the generation of pre-approval data required for the risk assessment were adequately addressed. High-performance liquid chromatography-ultraviolet (HPLC-UV) methods are available for the determination of forchlorfenuron in the technical material and in the representative formulation, and for the determination of the respective impurities in the technical material.

Forchlorfenuron residues can be monitored in food and feed of plant origin by the QuEChERS method using high-pressure or high-performance liquid chromatography with tandem mass spectrometry (HPLC–MS/MS) with limit of quantifications (LOQs) of 0.01 mg/kg in the all commodity groups.

An analytical method for food of animal origin is not required due to the fact that no residue definition is required.

Adequate HPLC–MS/MS methods are available for monitoring residues of forchlorfenuron in soil and water with LOQs of 0.05 mg/kg and 0.1 μg/L, respectively. Monitoring forchlorfenuron in air can be done by HPLC-UV with a LOQ of 1.26 μg/m$^3$.

The modified QuEChERS method can be used for the determination of forchlorfenuron in body fluids and tissues by HPLC–MS/MS with a LOQ of 0.05 mg/L for blood and urine and a LOQ of 0.1 mg/kg in meat.

## 2. Mammalian toxicity

The following guidance documents were followed in the production of this conclusion: SANCO/221/2000-rev. 10-final (European Commission, 2003), SANCO/10597/2003-rev. 10.1 (European Commission, 2012) and Guidance on dermal absorption (EFSA PPR Panel, 2012).

Forchlorfenuron has been discussed during the Pesticides Peer Review Meeting 155 in March 2017.

Considering the new technical specification, it can be considered that the batches used in the toxicity studies are representative of the manufactured technical material.

Extensively absorbed after oral administration (> 80% in rat), forchlorfenuron was widely distributed in the body but did not accumulate and was rapidly excreted via faeces, bile and urine. No significant differences were observed in the available *in vivo* and *in vitro* metabolism studies with rat, mouse and human cells. Of low acute toxicity, forchlorfenuron was not irritant, sensitiser and did not show a phototoxic potential *in vitro*.

In short-term toxicity studies, the target organs were the liver, the kidneys and the haematological parameters. The no observed adverse effect level (NOAEL) in the 90-day rat study was 16.2 mg/kg body weight (bw) per day based on effects in the liver and kidneys. The NOAEL in the 12-month dog study was 100 mg/kg per day on the basis of decreased body weight, increased kidney weight and changes in haematological parameters. In the standard battery of genotoxicity studies, forchlorfenuron did not induce gene mutations or clastogenic effects; therefore, it was considered unlikely to be genotoxic. In the long-term studies, the lowest NOAEL was 4.9 mg/kg bw per day based on non-neoplastic and possibly also neoplastic renal findings in mice. These renal tumours were considered as supporting the harmonised classification **Carcinogen category 2**[3] of forchlorfenuron. With regard to reproductive toxicity, no specific effect was observed in the rat multigeneration study, and no teratogenic effect was observed in developmental toxicity studies with rats or rabbits. No neurotoxic effect of forchlorfenuron was observed in the available toxicity data set including a specific acute neurotoxicity study in rats.

Forchlorfenuron is classified as carcinogenic category 2[3] but not as toxic for reproduction category 2, in accordance with the provisions of Regulation (EC) No 1272/2008[4], and therefore, the conditions of the interim provisions of Annex II, Point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met. On the basis of the available information/toxicity data, the experts also agreed that forchlorfenuron is unlikely to be an endocrine disruptor.

With regard to potential metabolites, no toxicological assessment is triggered by the predicted levels in groundwater or in residues (pending the finalisation of the residue definition for risk assessment in plants, see Section 3) for the representative uses.

For forchlorfenuron, the reference values from the original peer review (European Commission, 2005) included an acceptable daily intake (ADI) of 0.05 mg/kg bw per day based on the 2-year mouse study, an acute reference dose (ARfD) of 1 mg/kg bw based on the rat teratology study, and an acceptable operator exposure level (AOEL) of 0.25 mg/kg bw per day based on the rabbit teratology study (applying an uncertainty factor (UF) of 100). For the renewal assessment, the agreed ADI is 0.05 mg/kg bw per day based on the 2-year mouse study, the agreed ARfD is 0.5 mg/kg bw based on skeletal variations in the rabbit teratology study, the agreed AOEL is 0.16 mg/kg bw per day based on the 90-day rat study, and the agreed AAOEL is 0.5 mg/kg bw (same study basis as for the ARfD) (applying an UF of 100).

With regard to dermal absorption, the default value of 75% was applied for both concentrate and spray dilution (both containing ≤ 5% active substance).

[3] Forchlorfenuron has a harmonised classification (see Annex VI to the Regulation (EC) No 1272/2008), formally proposed and decided in accordance with the Regulation (EC) No 1272/2008.

[4] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 OJ L 353, 31.12.2008, p. 1–1355.

According to the German model, UK Predictive Operator Exposure Model (POEM) and EUROPOEM calculations, the operator exposure estimates are below the AOEL for all representative uses without the use of personal protective equipment (PPE). According to the German model (Martin et al., 2008) and UK guidance (CRD, 2008), the exposure estimates for bystanders and residents are below the AOEL. According to EUROPOEM II, the worker exposure estimates are below the AOEL for re-entry in treated grapes or kiwifruit orchards.

## 3. Residues

The assessment is based on the OECD guidance document on overview of residue chemistry studies (OECD, 2009), the OECD publication on maximum residue level (MRL) calculations (OECD, 2011), the European Commission guideline document on MRL setting (European Commission, 2011) and the Joint Meeting on Pesticide Residues (JMPR) recommendations on livestock burden calculations (JMPR, 2004, 2007).

Forchlorfenuron has been discussed during the Pesticides Peer Review Meeting 156 in March 2017.

Metabolism of forchlorfenuron was investigated in kiwi fruits following fruit painting at 15 mg/kg equivalent to 4.2 g a.s./ha (0.4 N) and at 75 mg/kg equivalent to 21 g a.s./ha (2 N), 4 weeks after petal fall (preharvest interval (PHI): 127 days) and on grapes following leaf injection and fruit clusters brushing with $^{14}$C forchlorfenuron labelled on the phenyl ring only. No identification was attempted in grapes. From the low- and high-dosed studies on kiwi fruits, forchlorfenuron was recovered as a major component of the total residues in the whole fruit (54–59% total radioactive residue (TRR)), in the pulp (40% TRR) and in the peel (84.5% TRR) while 3-OH forchlorfenuron accounted only for up to 4% TRR (0.018 mg eq/kg) from the high-dosed kiwi fruit. However characterisation and metabolites' identification were not further attempted on the numerous extracted fractions (up to 15% TRR; 0.072 mg eq/kg) and on the unextractable residues (14–21% TRR; 0.037–0.072 mg eq/kg) of the whole fruit. It is acknowledged that in view of the deficiencies noted in the kiwi fruits metabolism study with a rate of metabolites' identification in kiwi fruits that is deemed insufficient in accordance with the current OECD guidance recommendations and considering that fruit painting is not representative for a foliar application, a new metabolism study on a fruit crop and compliant with the representative uses on kiwi fruits and grapes should be provided (data gap). Furthermore, the available metabolism study on kiwi fruits was conducted with the phenyl labelling moiety only. Considering the structure of the parent molecule and since there is no evidence that no cleavage can be anticipated, the requested metabolism study should also address the fate of the pyridine moiety in fruit crops. Considering the chemical structure of the parent compound, EFSA is of the opinion that the metabolism data addressing the fate of the pyridine moiety in fruit crops should be submitted to exclude the potential degradation of forchlorfenuron leading to the formation of aniline. The RMS also indicated that a metabolism study on cherry with radiolabels, respectively, on phenyl and pyridine rings has been commissioned in order to support the uses on grapes and kiwi.

Based on the kiwi fruits metabolism data, the residue definition for monitoring is proposed as forchlorfenuron only. Since kiwi fruits belong to the crop category of the miscellaneous fruits with inedible peel,[5] it is questionable whether this crop can be considered as representative of the fruit crops and the majority of the experts were of the opinion that the proposed residue definition should be extended to the fruit crops category. For risk assessment, the residue definition is provisionally set as forchlorfenuron and will be reconsidered pending upon the outcome of the requested new metabolism study on fruit crops.

Metabolism in rotational crops was not investigated and is not triggered considering that kiwi fruits and grapes are permanent crops.

The need to investigate the effects of processing on the nature and magnitude of the residues will be reconsidered once the residue definition for risk assessment on fruit crops will have been finalised.

Regarding the magnitude of residues, a sufficient number of supervised residue trials compliant with the respective GAPs on kiwi fruits and grapes is available, which allowed proposing MRLs for forchlorfenuron on these crops at 0.01* mg/kg (LOQ of the method). The available residue trials are supported by sufficient storage stability data and validated analytical methods. This assessment should, however, be reconsidered pending upon the finalisation of the residue definition for risk

[5] Annex I – Part A of Commission Regulation (EU) No 752/2014 of 24 June 2014 replacing Annex I to Regulation (EC) No 396/2005 of the European Parliament and of the Council OJ L 208, 15.7.2014, p. 1–71.

assessment and the need to require additional residue trials in compliance with the agreed residue definition for risk assessment for fruit crops.

The investigation of the metabolism of forchlorfenuron in livestock was not triggered by the representative uses.

Chronic consumer exposure resulting from the representative uses was calculated using the EFSA PRIMo model. The highest chronic exposure calculated as the theoretical maximum daily intake (TMDI) with the proposed MRLs accounted for < 1% of the ADI (French all population). Acute exposure was at the maximum 0.1% of the ARfD (table grapes). The consumer exposure assessment is regarded as not finalised as a data gap has been identified for a new metabolism study on fruit crop and compliant with the representative uses on kiwi fruits and grapes.

The ARfD has been decreased compared to the one used in the review of the existing maximum residue levels (MRLs) for forchlorfenuron (EFSA, 2012). On the basis of the uses on kiwi fruits and grapes assessed during the review of the existing MRLs (Article 12 of Regulation (EC) No 396/2005[6]), no acute intake concern was identified.

The data requirement for the determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom could not be addressed considering the outstanding metabolism data on fruit crops to conclude on the systemic properties of the parent compound and the potentially relevant degradation products in kiwi fruits and grapes (data gap). It is noted that the RMS disagreed with this data gap.

## 4. Environmental fate and behaviour

The rates of dissipation and degradation in the environmental matrices investigated were estimated using FOCUS (2006) kinetics guidance. In soil laboratory incubations under aerobic conditions in the dark, forchlorfenuron exhibited moderate to very high persistence (moderate persistence occurred in an acidic (pH 5.3) soil), forming the major (> 10% applied radioactivity (AR)) 4-amino-2-chloropyridine (ACP, max. 60% AR), which exhibited high to very high persistence. Mineralisation of the phenyl ring $^{14}$C radiolabel to carbon dioxide accounted for 3–25% AR after 120 days. This range for the pyridine ring label was 0.3–5% AR. The formation of unextractable residues (not extracted by acetone followed by acidified acetone) for the phenyl ring $^{14}$C radiolabel accounted for 17–46% AR after 120 days. This range for the pyridine ring label was 14–25% AR. In an anaerobic soil incubation, forchlorfenuron exhibited high persistence just being transformed to unextracted radioactivity and carbon dioxide. Forchlorfenuron exhibited low to slight mobility in soil with no evidence of adsorption being pH dependent. ACP exhibited high to slight soil mobility with adsorption decreasing as pH increased. Field dissipation studies were not available. Their provision has been identified as a data gap (see Section 7) as their provision is triggered by the results of the laboratory incubations according to the data requirements. Consequently, the exposure assessment at the EU level was completed for the representative uses, using just the available laboratory endpoints.

In laboratory incubations in dark aerobic natural sediment water systems, forchlorfenuron exhibited high persistence, forming the major metabolite ACP (max. 6% AR in water and 14% AR in sediment, also exhibiting high persistence). The unextractable sediment fraction (not extracted by acetonitrile/water) was a sink for both $^{14}$C radiolabels, accounting for 33–39% AR at study end (365 days). Mineralisation of the phenyl ring $^{14}$C radiolabel accounted for 28–29% AR at the end of the study with this range for the pyridine ring label being 9–23% AR. In direct laboratory aqueous photolysis investigations, forchlorfenuron was stable. In an indirect photolysis investigation using acetone as a photosensitiser, transformation was indicated. Consequently, a data gap was identified for an indirect screening photodegradation study (see Section 7). This results in the exposure assessment residue definition for surface water remaining open. The necessary surface water and sediment exposure assessments (predicted environmental concentrations (PEC) calculations) were carried out for forchlorfenuron and the metabolite ACP, using the FOCUS (2001) step 1 and step 2 approach (version 3.2 of the Steps 1–2 in FOCUS calculator). For both these compounds, appropriate step 3 (FOCUS, 2001) were available.[7] PEC also accounted for the accumulation of forchlorfenuron in sediment.

The necessary groundwater exposure assessments were appropriately carried out using FOCUS (2009) scenarios and the models PEARL 4.4.4 and PELMO 5.5.3[7] for the active substance forchlorfenuron and its metabolite ACP. The potential for groundwater exposure from the representative uses by

[6] Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414 OJ L 70, 16.3.2005, p. 1–16.

[7] Simulations utilised the agreed Q10 of 2.58 (following EFSA, 2008) and Walker equation coefficient of 0.7.

forchlorfenuron and its metabolite above the parametric drinking water limit of 0.1 μg/L was concluded to be low in geoclimatic situations that are represented by all seven pertinent FOCUS groundwater scenarios.

The available step 3 FOCUS surface water simulations for the representative uses described above, indicated low residues in small edge of field surface water bodies (FOCUS ponds, streams and ditches, max. 0.17 μg/L for forchlorfenuron, 0.027 μg/L for ACP). Consequently, it was considered that in larger lakes or rivers where surface water would be abstracted for drinking water, residues would be below the drinking water limit of 0.1 μg/L. Therefore, it was concluded that for the representative uses information to address the effect of water treatments processes on the nature of the residues that might be present in surface water, when surface water is abstracted for drinking water were not needed.

The PEC in soil, surface water, sediment and groundwater covering the representative uses assessed can be found in Appendix A of this conclusion.

## 5. Ecotoxicology

The risk assessment was based on the following documents: European Commission (2002a,b), SETAC (2001), EFSA (2009), EFSA PPR Panel (2013) and EFSA (2013). According to Regulation (EU) No 283/2013[8], data should be provided regarding the acute and chronic toxicity to honeybees and data to address the development of honeybee brood and larvae. As the European Commission (2002a) does not provide a risk assessment scheme which is able to use the chronic toxicity data for adult honeybees and the honeybee brood, when performing the risk assessment according to European Commission (2002a), the risk to adult honeybees from chronic toxicity and the risk to bee brood, could not be finalised due to the lack of a risk assessment scheme. Therefore, EFSA (2013) was used for risk assessment in order to reach a conclusion for the representative uses.

A low acute and long-term risk to **birds** and wild **mammals** was concluded for all the relevant exposure routes and for all the representative uses of forchlorfenuron.

Concerning the **aquatic organisms**, a low acute and chronic risk was concluded for forchlorfenuron for all the representative uses. It is, however, noted that forchlorfenuron is a plant growth regulator and a valid study on a second species from a different taxonomic group than green algae was not available and is required (data gap). Valid acute endpoints were available for the surface water metabolite ACP for fish and aquatic invertebrates while chronic toxicity data for fish and aquatic invertebrates and toxicity data for aquatic plants were not available. By using these endpoints, and by assuming the metabolites as 10 times more toxic than the parent compound for algae, aquatic plants, for fish (chronic) and aquatic invertebrates (chronic), a low acute and chronic risk to aquatic organisms could be concluded for all the representative uses. As reported in Section 4, an indirect screening photodegradation study was not available; therefore, a data gap was identified to address the risk to aquatic organisms for possible indirect photolysis products.

A low risk to adult honey**bees** (acute and chronic) and to honeybees larvae was concluded for all the representative uses and exposure routes with the exception of exposure to guttation water; a high risk to honeybees larvae via this exposure route cannot be excluded when the first tier risk assessment according to EFSA (2013) is performed (data gap). A low risk via exposure to contaminated water was concluded in the case of surface water exposure while data were not sufficient to assess the risk via exposure to water in puddles (data gap). No assessment was available for sublethal effects, e.g. effects on hypopharyngeal gland (HPG) (data gap). It is noted that the RMS disagreed with this data gap since behavioural effects were not observed in the acute toxicity and chronic tests with forchlorfenuron. A suitable assessment for accumulative effects was not available. Information regarding metabolites occurring in pollen and nectar was not available (data gap). It is noted that the RMS disagreed with this data gap. No data were available for bumblebees and solitary bees.

A low risk to **non-target arthropods**, **earthworms** and other **soil macroorganisms** and **microorganisms**, **non-target terrestrial plants** and **biological methods of sewage treatment** was concluded for all the representative uses of forchlorfenuron. A low risk to soil organisms was concluded for metabolite ACP.

With regard to the endocrine disruption potential, as discussed in Section 2, it is unlikely that forchlorfenuron is an endocrine disruptor in mammals; however, no firm conclusion can be drawn regarding fish and birds.

[8] Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, 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 OJ L 93, 3.4.2013, p. 1–84.

# 6. Overview of the risk assessment of compounds listed in residue definitions triggering assessment of effects data for the environmental compartments (Table 1–5)

**Table 1:** Soil

| Compound (name and/or code) | Persistence | Ecotoxicology |
|---|---|---|
| Forchlorfenuron | Moderate to very high persistence<br>Single first-order and biphasic kinetics $DT_{50}$ 27–736 days ($DT_{90}$ 182 to > 1,000 days, 20–25°C 40–45% MWHC or pF 2.5 soil moisture) pH dependent, degraded faster in a pH 5.3 soil | Low risk |
| ACP | High to very high persistence<br>Single first-order $DT_{50}$ 139–593 days (20°C pF 2 soil moisture) | Low risk |

ACP: 4-amino-2-chloropyridine; $DT_{50}$: period required for 50% dissipation; $DT_{90}$: period required for 90% dissipation; MWHC: maximum water-holding capacity.

**Table 2:** Groundwater

| Compound (name and/or code) | Mobility in soil | > 0.1 µg/L at 1 m depth for the representative uses[a] | Pesticidal activity | Toxicological relevance |
|---|---|---|---|---|
| Forchlorfenuron | Low to slight mobility<br>$K_{Foc}$ 852–3,320 mL/g | No | Yes | Yes |
| ACP | High to slight mobility<br>$K_{Foc}$ 75–2,847 mL/g pH dependent, sorption decreased as pH increased | No | Assessment not triggered | Assessment not triggered<br>Ames test negative |

ACP: 4-amino-2-chloropyridine; $K_{Foc}$: Freundlich organic carbon adsorption coefficient.
(a): FOCUS scenarios or a relevant lysimeter.

**Table 3:** Surface water and sediment

| Compound (name and/or code) | Ecotoxicology |
|---|---|
| Forchlorfenuron | Low risk but data gap for second species of algae |
| ACP | Low risk |
| Data gap, possible indirect photolysis novel metabolites | Data gap |

ACP: 4-amino-2-chloropyridine.

**Table 4:** Air

| Compound (name and/or code) | Toxicology |
|---|---|
| Forchlorfenuron | Low acute toxicity by inhalation ($LC_{50}$ > 3 mg/L) |

$LC_{50}$: lethal concentration, median.

# 7. Data gaps

This is a list of data gaps identified during the peer review process, including those areas in which a study may have been made available during the peer review process but not considered for procedural reasons (without prejudice to the provisions of Article 56 of Regulation (EC) No 1107/2009 concerning information on potentially harmful effects).

- Further details on the literature review for the mammalian toxicology (e.g. search criteria, selection criteria and full text assessment) have not been provided in the revised RAR. Further details on the literature review for the residues with the list of the excluded bibliographic references with justification for their exclusion should be provided, including a comprehensive assessment of the review by the RMS (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 2 and 3).
- A new metabolism study on a fruit crop and compliant with the representative uses on kiwi fruits and grapes (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Determination of the residues in pollen and bee products for human consumption resulting from residues taken up by honeybees from crops at blossom (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 3).
- Information to address the field soil dissipation rates of forchlorfenuron and field information for metabolite ACP in soil in line with the data requirement 7.1.2.2.1 in the Annex to the Regulation (EU) No 283/2013 was not available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Section 4).
- An indirect screening photodegradation study according to US EPA (1988) relevant for surface water exposure assessment and should novel metabolites be formed a consequent aquatic risk assessment, were not available (relevant for all representative uses evaluated; submission date proposed by the applicant: unknown; see Sections 4 and 5).
- An aerobic mineralisation in surface water study in line with the data requirement 7.2.2.2 in the Annex to the Regulation (EU) No 283/2013, or information to demonstrate that contamination of open water (freshwater, estuarine and marine) will not occur was not available (not needed to support the representative uses evaluated at EU level following FOCUS guidance; submission date proposed by the applicant: unknown; see Section 4 of the evaluation table in the peer review report, EFSA (2017)).
- A study on a taxonomic group of algae other than green algae such as a diatom, e.g. *Navicula pelliculosa* (relevant for all representative uses evaluated, submission date proposed by the applicant: April 2017; see Section 5).
- Further information to address the sublethal effects on honeybees (e.g. effect on the HPG); further information to address the risk to honeybees larvae via exposure to guttation water and the risk to honeybees via exposure to puddle water (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).
- Further information on the metabolites occurring in pollen and nectar (relevant for all representative uses evaluated, submission date proposed by the applicant: unknown; see Section 5).

# 8. Particular conditions proposed to be taken into account to manage the risk(s) identified

- No particular conditions are proposed for the representative uses evaluated.

# 9. Concerns

## 9.1. Issues that could not be finalised

An issue is listed as 'could not be finalised' if there is not enough information available to perform an assessment, even at the lowest tier level, for the representative uses in line with the uniform principles in accordance with Article 29(6) of Regulation (EC) No 1107/2009 and as set out in

Commission Regulation (EU) No 546/2011[9] and if the issue is of such importance that it could, when finalised, become a concern (which would also be listed as a critical area of concern if it is of relevance to all representative uses).

An issue is also listed as 'could not be finalised' if the available information is considered insufficient to conclude on whether the active substance can be expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

1) The consumer risk assessment could not be finalised considering the data gap identified for a new metabolism study on a fruit crop and compliant with the representative uses on kiwi fruits and grapes (see Section 3).

## 9.2. Critical areas of concern

An issue is listed as a critical area of concern if there is enough information available to perform an assessment for the representative uses in line with the uniform principles in accordance with Article 29 (6) of Regulation (EC) No 1107/2009 and as set out in Commission Regulation (EU) No 546/2011, and if this assessment does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if the assessment at a higher tier level could not be finalised due to lack of information, and if the assessment performed at a lower tier level does not permit the conclusion that, for at least one of the representative uses, it may be expected that a plant protection product containing the active substance will not have any harmful effect on human or animal health or on groundwater, or any unacceptable influence on the environment.

An issue is also listed as a critical area of concern if, in the light of current scientific and technical knowledge using guidance documents available at the time of application, the active substance is not expected to meet the approval criteria provided for in Article 4 of Regulation (EC) No 1107/2009.

None identified for the representative uses.

## 9.3. Overview of the concerns identified for each representative use considered

(If a particular condition proposed to be taken into account to manage an identified risk, as listed in Section 8, has been evaluated as being effective, then 'risk identified' is not indicated in Table 5.)

**Table 5:** Overview of concerns

| Representative use | | Kiwi | Grapes |
|---|---|---|---|
| **Operator risk** | Risk identified | | |
| | Assessment not finalised | | |
| **Worker risk** | Risk identified | | |
| | Assessment not finalised | | |
| **Resident/bystander risk** | Risk identified | | |
| | Assessment not finalised | | |
| **Consumer risk** | Risk identified | | |
| | Assessment not finalised | X[1] | X[1] |
| **Risk to wild non-target terrestrial vertebrates** | Risk identified | | |
| | Assessment not finalised | | |
| **Risk to wild non-target terrestrial organisms other than vertebrates** | Risk identified | | |
| | Assessment not finalised | | |

[9] Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products. OJ L 155, 11.6.2011, p. 127–175.

| Representative use | | Kiwi | Grapes |
|---|---|---|---|
| **Risk to aquatic organisms** | Risk identified | | |
| | Assessment not finalised | | |
| **Groundwater exposure to active substance** | Legal parametric value breached | | |
| | Assessment not finalised | | |
| **Groundwater exposure to metabolites** | Legal parametric value breached | | |
| | Parametric value of 10 μg/L[(a)] breached | | |
| | Assessment not finalised | | |

Columns are grey if no safe use can be identified. The superscript numbers relate to the numbered points indicated in Sections 9.1 and 9.2. Where there is no superscript number, see Sections 2–6 for further information.
(a): Value for non-relevant metabolites prescribed in SANCO/221/2000-rev. 10 final, European Commission, 2003.

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## Abbreviations

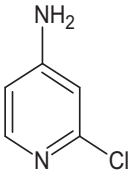
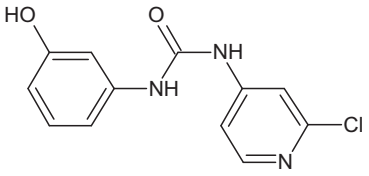
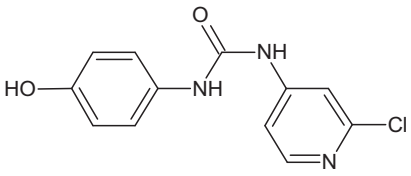
| | |
|---|---|
| a.s. | active substance |
| AAOEL | acute acceptable operator exposure level |
| ACP | 4-amino-2-chloropyridine |
| ADI | acceptable daily intake |
| AOEL | acceptable operator exposure level |
| AR | applied radioactivity |
| ARfD | acute reference dose |
| bw | body weight |
| CFU | colony forming units |
| $DT_{50}$ | period required for 50% dissipation (define method of estimation) |
| $DT_{90}$ | period required for 90% dissipation (define method of estimation) |
| EC | emulsifiable concentrate |
| EEC | European Economic Community |
| EUROPOEM | European Predictive Operator Exposure Model |
| FAO | Food and Agriculture Organization of the United Nations |
| FOCUS | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| GAP | Good Agricultural Practice |
| HPG | hypopharyngeal glands |

| | |
|---|---|
| HPLC–MS/MS | high-pressure or high-performance liquid chromatography with tandem mass spectrometry |
| ISO | International Organization for Standardization |
| IUPAC | International Union of Pure and Applied Chemistry |
| JMPR | Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues) |
| $K_{Foc}$ | Freundlich organic carbon adsorption coefficient |
| $LC_{50}$ | lethal concentration, median |
| LOQ | limit of quantification |
| MRL | maximum residue level |
| MS | mass spectrometry |
| MWHC | maximum water-holding capacity |
| NOAEL | no observed adverse effect level |
| NOEL | no observed effect level |
| OECD | Organisation for Economic Co-operation and Development |
| PEC | predicted environmental concentration |
| $PEC_{air}$ | predicted environmental concentration in air |
| $PEC_{gw}$ | predicted environmental concentration in groundwater |
| $PEC_{sed}$ | predicted environmental concentration in sediment |
| $PEC_{soil}$ | predicted environmental concentration in soil |
| $PEC_{sw}$ | predicted environmental concentration in surface water |
| PHI | preharvest interval |
| PPE | personal protective equipment |
| QuEChERS | Quick, Easy, Cheap, Effective, Rugged and safe |
| RAR | renewal Assessment Report |
| RMS | rapporteur Member State |
| SFO | single first-order |
| SMILES | simplified molecular-input line-entry system |
| TMDI | theoretical maximum daily intake |
| TRR | total radioactive residue |
| UF | uncertainty factor |
| UV | ultraviolet |
| WHO | World Health Organization |

## Appendix A – List of end points for the active substance and the representative formulation

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2017.4874

## Appendix B – Used compound codes

| Code/trivial name[(a)] | Chemical name/SMILES notation | Structural formula |
|---|---|---|
| **ACP**<br>4-Amino-2-chloropyridine | 4-Amino-2-chloropyridine<br>Nc1ccnc(Cl)c1 |  |
| **3-OH forchlorfenuron**<br>*m*-Hydroxy-CPPU | 1-(2-Chloropyridin-4-yl)-3-(3-hydroxyphenyl)urea<br>Clc2cc(NC(=O)Nc1cccc(O)c1)ccn2 |  |
| **4-OH forchlorfenuron**<br>*p*-Hydroxy-CPPU | 1-(2-Chloropyridin-4-yl)-3-(4-hydroxyphenyl)urea<br>Clc2cc(NC(=O)Nc1ccc(O)cc1)ccn2 |  |

SMILES: simplified molecular-input line-entry system.
(a): The compound name in bold is the name used in the conclusion.