Peer review of the targeted hazard assessment of the pesticide active substance quinoxyfen

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Abstract

The conclusions of EFSA following the peer review of the initial assessments carried out by the competent authorities of the rapporteur Member State, the United Kingdom, and co-rapporteur Member State, Austria, for the pesticide active substance quinoxyfen 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 information targeted at the assessment of the potential persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and persistent organic pollutant (POP) properties of quinoxyfen according to Article 11(2) of Regulation (EC) No 1107/2009. The reliable end points, appropriate for use in these regulatory hazard cut off assessments are presented. Missing information identified as being required by the regulatory framework is listed. The concern is identified that quinoxyfen may be considered to exhibit the hazard properties of both a PBT and vPvB substance considering the triggers specified in Annex II of Regulation (EC) No 1107/2009.

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Keywords: quinoxyfen, peer review, hazard assessment, pesticide, fungicide

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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. Quinoxyfen 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), the United Kingdom, and co-rapporteur Member State (co-RMS), Austria, received an application from Dow AgroSciences GmbH for the renewal of approval of the active substance quinoxyfen. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Austria), the European Commission and the European Food Safety Authority (EFSA) about the admissibility.

The RMS provided its initial evaluation of the dossier on quinoxyfen. According to Article 11(2) of Regulation (EC) No 1107/2009, this evaluation was limited to a targeted assessment of identity, methods of analysis, environmental fate and behaviour and ecotoxicology information that related to the potential persistent bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and persistent organic pollutant (POP) properties of quinoxyfen. This evaluation was presented in the renewal assessment report (RAR), which was received by EFSA on 5 December 2016. In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Dow AgroSciences GmbH, for comments on 23 January 2017. 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 27 March 2017.

Following consideration of the comments received on the RAR, it was concluded that additional information should be requested from the applicant and that there was no need to conduct an experts’ consultation.

In accordance with Article 13(1) of the Regulation, EFSA should adopt a conclusion on whether quinoxyfen 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. In this case, the conclusion is limited to a hazard targeted assessment (Point 3.7 in Annex II of Regulation (EC) No 1107/2009) and will not cover all the approval criteria.

A data gap was identified for an appropriate report of any search of the scientific peer-reviewed open literature on the active substance.

There were no data gaps identified for the area of identity of the active substance or analytical methods.

Considering the available data that enable rates of quinoxyfen transformation to breakdown products to be estimated, it may be considered both persistent (P) and very persistent (vP) in both soil and natural water systems when a comparison is made to the relevant P and vP triggers specified in Annex II of Regulation (EC) No 1107/2009.

Based on the available data, quinoxyfen is considered to meet the bioaccumulative (B), toxicity (T) and the very bioaccumulative (vB) criteria when compared to the triggers specified in Annex II of Regulation (EC) No 1107/2009.

Quinoxyfen may therefore be considered to exhibit the hazard properties of both a PBT and vPvB substance. Therefore, a critical area of concern was identified in relation to these properties.
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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 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 experts’ 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 additional 3 months where additional information is required to be submitted by the applicant in accordance with Article 13(3).

In accordance with Article 1 of the Regulation, the RMS United Kingdom and co-RMS Austria received an application from Dow AgroSciences GmbH for the renewal of approval of the active substance quinoxyfen. Complying with Article 8 of the Regulation, the RMS checked the completeness of the dossier and informed the applicant, the co-RMS (Austria), the European Commission and EFSA about the admissibility.

The RMS provided its initial evaluation of the dossier on quinoxyfen. According to Article 11(2) of Regulation (EC) No 1107/2009, this evaluation was limited to a targeted assessment of identity, methods of analysis, environmental fate and behaviour and ecotoxicology information that related to the potential persistent, bioaccumulative and toxic (PBT), very persistent and very bioaccumulative (vPvB) and persistent organic pollutant (POP) properties of quinoxyfen. This evaluation was presented in the renewal assessment report (RAR), which was received by EFSA on 5 December 2016 (United Kingdom, 2016).

In accordance with Article 12 of the Regulation, EFSA distributed the RAR to the Member States and the applicant, Dow AgroSciences GmbH, for consultation and comments on 23 January 2017. 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 27 March 2017. 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 responses were evaluated by the RMS in column 3.

The need for experts’ 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, the RMS, the co-RMS and the European Commission on 3 May 2017. 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 there was no need to conduct an experts’ consultation.

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, 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 written consultation on the assessment of additional information, where this 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 targeted hazard assessment took place with Member States via a written procedure in October 2017.

This conclusion report summarises the outcome of the peer review of the targeted assessment of the active substance relating to identity, methods of analysis, environmental fate and behaviour and ecotoxicology information that related to the potential PBT, vPvB and POP properties of quinoxyfen. A

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\(^1\) 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.
list of the relevant end points for the targeted hazard assessment of the active substance 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 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 (3 May 2017);
- the evaluation table (3 October 2017);
- 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 (United Kingdom, 2016, 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

Quinoxyfen is the ISO common name for 5,7-dichloro-4-quinolyl 4-fluorophenyl ether (IUPAC).

The conclusion does not consider data and information about the representative formulated products and the representative uses as the evaluation is limited to the targeted assessment of the potential PBT, vPvB and POP properties of quinoxyfen.

A data gap has been identified for an adequate report of the scientific peer-reviewed open literature on the parent active substance quinoxyfen, using search terms designed to identify all literature that would inform a PBT, vPvB and POP hazard consideration for the parent compound 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, 2000) and SANCO/825/00-rev. 8.1 (European Commission, 2010).

As the data submitted for the targeted assessment do not affect the identity of quinoxyfen, new data provided in this area have not been evaluated for this application, except those relevant for the targeted hazard assessment. The main data regarding the identity of quinoxyfen and its physical and chemical properties related to the targeted assessment are given in Appendix A.

Adequate methods are available for the generation of pre-approval data required for the hazard assessment considered in the targeted assessment.

Monitoring residues of quinoxyfen in food of plant origin can be done by liquid chromatography with tandem mass spectrometry (LC-MS/MS) with a limit of quantification (LOQ) of 0.01 mg/kg in all commodity groups. Quinoxyfen residues can be monitored in food of animal origin by LC-MS/MS with a LOQ of 0.01 mg/kg in milk, eggs, meat, fat and liver. The quick, easy, cheap, effective, rugged, and safe (QuEChERS) multiresidue method with LC-MS/MS is also applicable for the determination of quinoxyfen residues in food and feed of plant and animal origin, with a LOQ of 0.01 mg/kg in high water content, high acid content and dry commodities as well as in milk, meat, kidney and eggs.

Appropriate LC-MS/MS method exists for monitoring quinoxyfen in soil with a LOQ of 0.05 mg/kg. Determination of quinoxyfen in surface water and drinking water can be done by LC-MS/MS method with a LOQ of 0.05 μg/L. Quinoxyfen residues in air can be determined by LC-MS/MS with a LOQ of 6.1 μg/m³.

3 Dow AgroSciences, 2014. Summary Dossier Quinoxyfen, DOCUMENT M-CA Section 2: Physical and chemical properties of the active substance. October 2014. Available in the EFSA register of questions: www.efsa.europa.eu
LC-MS/MS enforcement methods exist for the determination of quinoxyfen residues in body fluids with a LOQ of 0.05 mg/L in blood and urine and with a LOQ of 0.01 mg/kg in body tissues.

2. 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 at 20°C and either 40% maximum water holing capacity (MWHC) or pf 2.5 soil moisture, quinoxyfen had single first-order (SFO) DT₉₀ or half-lives in the range from 209 to 560 days (8 different soils investigated). In an anaerobic flooded soil incubation at 20°C, quinoxyfen had a half-life of 289 days. In a laboratory soil photolysis study at 25°C, quinoxyfen had a half-life of 206 days when equated to sunlight conditions in southern England. In satisfactory field dissipation studies carried out at four sites in France, two in Germany, two in the UK and two sites in North America (California (USA) and Ontario (Canada), all spray applications to the soil surface on bare soil plots in late spring), quinoxyfen residues remaining in the top 20 cm had best fit DT₉₀ in the range from 14.7 to 588 days. Only at the UK trial sites were the values fitted (536 and 588 days) true half-lives (SFO DT₉₀). At all the other trial sites the pattern of decline fitted was biphasic when following the FOCUS (2006) guidance. The range of DT₉₀ was from 391 to >10,000 days. Half-lives estimated by dividing these DT₉₀ by 3.32 (as discussed in ECHA guidance (2014) and European Commission working document (2012)), both applicable to PBT properties assessment, resulted in the range from 118 to >3,012 days. When this approach was just followed when the fitted model was first-order multicompartment (FOMC), but for the double first-order in parallel (DFOP) fits, the half-life for the slow phase (K₂) was selected (as discussed in ECHA guidance (2017)), the range of the half-lives estimated becomes from 153 to 7.7 × 10¹¹ days. Only two of the DT₉₀ values resulting from the kinetic fitting were not extrapolated beyond the field study durations that were from 489 to 750 days.

In an aerobic aquatic mineralisation study at 21°C in fresh water, quinoxyfen had half-lives of 115 and 129 days. In laboratory incubations at 20°C in dark aerobic natural sediment water systems, quinoxyfen moved to the sediment and had whole system half-lives of 16–136 days (four different sediment water systems investigated). The rate of decline of quinoxyfen in a laboratory sterile aqueous photolysis experiment at 25°C was estimated to have a half-life of 18 min (light energy equated to 40°N latitude). Although quinoxyfen has the potential to enter the atmosphere via the formation of aerosols when sprayed, it was considered unlikely to be subject to long range atmospheric transport. This conclusion was reached as its atmospheric half-life was estimated to be 1.9 days considering its calculated potential for indirect photochemical oxidation mediated by hydroxyl radicals in the upper atmosphere (i.e. below the trigger of 2 days, FOCUS (2008)), combined with it not being detected in available rainwater monitoring studies at two remote sites in Sweden. There was therefore no evidence in the information assessed to indicate that quinoxyfen might be considered a POP.

With the available information quinoxyfen may be considered to fulfil the persistence (P) criterion in relation to its PBT properties according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009. Regarding soil transformation rate in the available laboratory soil incubation investigations at 20°C, all had half-lives above the P trigger for soil of 120 days (20°C being a reference temperature discussed in the pertinent European Commission (2012)). This is of course also the case when 20°C half-life values are normalised⁴ to a temperature of 12°C when this approach was just followed when the fitted model was first-order multicompartment (FOMC), but for the double first-order in parallel (DFOP) fits, the half-life for the slow phase (K₂) was selected (as discussed in ECHA guidance (2017)), the range of the half-lives estimated becomes from 153 to 7.7 × 10¹¹ days. Only two of the DT₉₀ values resulting from the kinetic fitting were not extrapolated beyond the field study durations that were from 489 to 750 days.

Regarding soil transformation rate in the available laboratory soil incubation investigations at 20°C, all had half-lives above the P trigger for soil of 120 days (20°C being a reference temperature discussed in the pertinent European Commission (2012)). This is of course also the case when 20°C half-life values are normalised⁴ to a temperature of 12°C when this approach was just followed when the fitted model was first-order multicompartment (FOMC), but for the double first-order in parallel (DFOP) fits, the half-life for the slow phase (K₂) was selected (as discussed in ECHA guidance (2017)), the range of the half-lives estimated becomes from 153 to 7.7 × 10¹¹ days. Only two of the DT₉₀ values resulting from the kinetic fitting were not extrapolated beyond the field study durations that were from 489 to 750 days.

With the available information quinoxyfen may be considered to fulfil the persistence (P) criterion in relation to its PBT properties according to point 3.7.2 of Annex II of Regulation (EC) 1107/2009. With the available information quinoxyfen may be considered to fulfil the very persistence (vP) criterion in relation to its very persistent and very bioaccumulative (vPvB) properties according to point 3.7.3 of Annex II of Regulation (EC) 1107/2009.

⁴ Using a Q10 of 2.58 according to EFSA (2008).
3.7.3 of Annex II of Regulation (EC) 1107/2009. Regarding soil transformation rate in the available laboratory soil incubation investigations at 20°C, all soils investigated had half-lives above the vP trigger for soil of 180 days. This is of course also the case when 20°C half-life values are normalised to a temperature of 12°C. Eight of the 10 soil field dissipation trial sites had half-lives above the vP trigger for soil of 180 days, with the half-life estimated following ECHA (2014) and European Commission (2012) (DT$_{90}$ divided by 3.32 approach). This becomes 9 out of the 10 trial sites following ECHA (2017) (half-life taken as the slow phase (K2) of biphasic fits approach). All the eight European trial sites had half-lives above 180 days following the ECHA (2017). This was seven out of eight European trial sites following the earlier ECHA guidance. Regarding the aquatic environmental compartment, transformation in the available OECD 309 aerobic aquatic mineralisation study with water from a fresh water system, resulted in half-lives at 21°C of 115 and 129 days equating to 244 and 273 days when normalised to 12°C (i.e. above the water trigger for this system = 60 days). In water sediment systems as quinoxyfen partitions to sediment, the relevant P trigger is that for sediment of 180 days. This trigger is not exceeded in any of the four sediment water systems investigated at the incubation temperature of 20°C, but following normalisation to 12°C it is exceeded in one of the four sediment water systems investigated.

3. Ecotoxicology

 Chronic toxicity data were available on all the aquatic standard Tier 1 species and on one additional fish species. The toxicity of quinoxyfen to aquatic organisms was in the range 0.0015-35 mg/L. The chronic endpoint (no observed effect concentration (NOEC)) for the two most sensitive species _Americamysis bahia_ and _Cyprinodon variegatus_ were both below 0.01 mg/L. Therefore, with the available information quinoxyfen is considered to fulfil the toxicity (T) criterion in relation to its PBT properties according to point 3.7.2 of the Regulation (EC) No 1107/2009.

 Two studies investigating the bioaccumulation potential of quinoxyfen in rainbow trout were available. The available kinetic bioconcentration factors (BCF), when adjusted for the lipid content, were consistent and both above 5,000 L/kg. Based on the available data, quinoxyfen is considered to fulfil both the bioaccumulative (B) and very bioaccumulative (vB) criteria in relation to its PBT properties according to point 3.7.2 of the Regulation (EC) No 1107/2009 and vPvB properties according to point 3.7.3 of the Regulation.

4. Data gaps

 This is a list of data gaps identified during the peer review process only in the context of the targeted hazard assessment, 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).

- An adequate report of the scientific peer-reviewed open literature on the active substance carried out in accordance with the EFSA guidance (2011) published within the 10 years before the date of submission of the dossier was not available. Search terms designed to identify all literature that would inform a PBT, vPvB and POP hazard consideration for the parent compound quinoxyfen needed to have been used.

5. Concerns

5.1. 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 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).

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5 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.
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.

- None identified in the context of this targeted hazard assessment.

5.2. 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 the higher tier level could not be finalised due to lack of information, and if the assessment performed at the 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.

1) The available evidence indicated that quinoxyfen may be considered a P, B and toxic or PBT substance according to point 3.7.2 of Annex II of Regulation (EC) No 1107/2009. The P criterion may be considered fulfilled for soil and freshwater (see Section 4). The B criterion is fulfilled. The T criterion is fulfilled considering the available reliable data regarding the toxicity exerted by quinoxyfen on fish and aquatic invertebrates (see Section 5).

2) The available evidence indicated that quinoxyfen may be considered a vP and vB or vPvB substance according to point 3.7.3 of Annex II of Regulation (EC) No 1107/2009. The vP criterion may be considered fulfilled for soil and natural water (see Section 4). The vB criterion is fulfilled (see Section 5).

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Abbreviations

| Abbreviation | Description |
|--------------|-------------|
| B            | bioaccumulative |
| BCF          | bioconcentration factor |
| DFOP         | double first-order in parallel |
| DT<sub>50</sub> | period required for 50% dissipation (define method of estimation) |
| DT<sub>90</sub> | period required for 90% dissipation (define method of estimation) |
| ECHA         | European Chemicals Agency |
| EEC          | European Economic Community |
| FOCUS        | Forum for the Co-ordination of Pesticide Fate Models and their Use |
| FOMC         | first-order multicompartment |
| ISO          | International Organization for Standardization |
| IUPAC        | International Union of Pure and Applied Chemistry |
| LC-MS/MS     | liquid chromatography with tandem mass spectrometry |
| LOQ          | limit of quantification |
| MWHC         | maximum water-holding capacity |
| NOEC         | no observed effect concentration |
| OECD         | Organisation for Economic Co-operation and Development |
| P            | persistence |
| PBT          | persistent, bioaccumulative and toxic |
| POP          | persistent organic pollutant |
| QuEChERS     | Quick, Easy, Cheap, Effective, Rugged, and Safe (analytical method) |
| RAR          | Renewal Assessment Report |
| RMS          | rapporteur Member State |
| SFO          | single first-order |
| T            | toxicity |
| vB           | very bioaccumulative |
| vP           | very persistence |
Appendix A – List of end points for the active substance in the context of the targeted hazard assessment of the potential PBT, vPvB and POP properties

Appendix A can be found in the online version of this output ('Supporting information' section): https://doi.org/10.2903/j.efsa.2018.5085