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

Etoxazole
SANTE/2020/10320/ Rev 2
23 October 2020

FINAL Renewal report for the active substance etoxazole

finalised by the Standing Committee on Plants, Animals, Food and Feed on 23 October 2020
in view of the renewal of the approval of etoxazole as a candidate for substitution with restrictions
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 etoxazole, 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 on 31 July 2021.

Etoxazole is a substance that was included in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market, by Commission Directive 2005/34/EC[4]. Etoxazole 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[5].

An application for renewal of the approval of etoxazole was submitted by Sumitomo Chemical Agro Europe S.A.S in accordance with Article 1 of Regulation No 844/2012.

In addition, Sumitomo Chemical Agro Europe S.A.S submitted an application for maximum residue levels (MRLs) as referred to in Article 7 of Regulation (EC) No 396/2005[6].

The approval period of etoxazole, originally expiring on 31 May 2015, has been extended five times in accordance with Article 17 of Regulation (EC) No 1107/2009 either as part of the organisation of the third stage of the renewal programme or to allow the completion of its review due to delays in the scientific assessment process [7].

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1 Renewal Report established in accordance with Art. 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 125, 18.5.2005, p. 5.
5 OJ L 153, 11.6.2011, p. 1.
6 OJ L 70, 16.03.2005, p. 1.
7 Commission Implementing Regulation (EU) No 1197/2012 extended until 31 July 2017: OJ L 342, 14.12.2012, p. 27.
Commission Implementing Regulation (EU) No 2017/841 extended until 31 July 2018: OJ L 125, 18.5.2017, p. 12.
Commission Implementing Regulation (EU) No 2018/917 extended until 31 July 2019: OJ L 163, 28.6.2018, p. 13.
Commission Implementing Regulation (EU) No 2019/707 extended until 31 July 2020: OJ L 120, 8.5.2019, p. 16.
Commission Implementing Regulation (EU) No 2020/869 extended until 31 July 2021: OJ L 201, 25.6.2020, p. 7.

Commission Implementing Regulation (EU) No 686/2012[8] allocates 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 etoxazole, the rapporteur Member State was Greece and the co-rapporteur Member State was the United Kingdom.

Greece finalised in September 2016 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 20 September 2016 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of etoxazole 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). EFSA also launched a public consultation on the RAR.

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[9] on 12 September 2017. This conclusion refers to several background documents: the renewal assessment report including its revisions and the 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 21 March 2018. The draft renewal report was finalised by the Standing Committee on 23 October 2020.

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 its background documents, these documents are also considered to be part of this renewal report.

2. Purposes of this renewal report

This renewal report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2020/2105[10]** concerning the renewal of approval of etoxazole as an active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing etoxazole 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].

OJ L 200, 27.7.2012, p. 5.

8 OJ L 200, 27.7.2012, p. 5.

9 EFSA (European Food Safety Authority), 2017. Conclusion on the peer review of the pesticide risk assessment of the active substance etoxazole. EFSA Journal 2017;15(10):4988.

10 OJ L 425, 16.12.2020, p. 96.

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 under some restricted conditions that plant protection products containing etoxazole will still fulfil the safety requirements laid down in Article 4(1) to (3) of Regulation (EC) No 1107/2009. The conclusion of the evaluation was reached within the framework of the representative uses and use scenarios which were proposed and supported by the applicant; the conclusion also took into consideration the need to manage issues identified in the corresponding risk assessment (the data submitted were not sufficient to conclude in all cases with respect to the risk to consumers and/or non-target organisms).

Therefore, only uses in permanent greenhouses for ornamentals can be authorised, as this use is the only one for which a safe use can be expected (see Appendix II).

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 etoxazole containing plant protection product for which Member States will grant or review the authorisation.

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

ADI: 0,04 mg/kg bw per day,
ARfD: not allocated, not needed,
AOEL: 0,03 mg/kg bw per day,
AAOEL: not allocated, not needed.

Given the outstanding data gap to finalise the residue definition for risk assessment for processed commodities, the approval is restricted to use on ornamental plants only.

[12] 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 Text with EEA relevance (OJ L 93, 3.4.2013, p. 1).

The following points were considered as a critical area of concern or could not be finalised by EFSA (2017) for etoxazole, but are not considered critical for the renewal of the approval with restrictions for the reasons explained below, in particular:

- *The high risk of etoxazole for aquatic invertebrates for all representative uses.*
- *The high risk for non-target arthropods for all representative uses evaluated.*
- *The high risk for soil mites for representative uses in tomato, cucurbit, ornamentals, pome/stone fruit, grapes, strawberry and cotton.*

  In order to reduce exposure to the environment and mitigate the high risk for the above-listed non-target organisms, only uses in permanent greenhouses (as defined in Art 3.27 of the Regulation (EC) No 1107/2009[13]) can be authorised.

- *The available evidence cannot exclude that etoxazole might be considered a persistent (P) bioaccumulative (B) and toxic (T) or PBT substance. The P criterion may be considered fulfilled for soil, though the evidence for this is from the results of just one of a number of available soil investigations. The B criterion is fulfilled. The T criterion is fulfilled considering the available reliable data regarding the toxicity exerted by etoxazole on aquatic invertebrate species.*

  Given that the etoxazole fulfils the criteria as bioaccumulative (B) and toxic (T) in accordance with the criteria provided for in points 3.7.2.2 and 3.7.2.3 of Annex II to Regulation (EC) No 1107/2009 respectively, it meets the conditions of indent 2 of point 4 of Annex II and therefore shall be approved pursuant to Article 24 of Regulation (EC) No 1107/2009 as a candidate for substitution.

  The P criteria is not considered to be fulfilled in the context of the assessment whether the substance is a PBT because the available information indicates that etoxazole does not exceed the trigger at 20°C (that is the standard temperature in greenhouses) in all available studies. Indeed, according to the EFSA Conclusion only the results of one laboratory soil study (carried out at 20°C) out of six meet the P criteria when results are normalised to 12°C and none of the field dissipation studies indicate persistence greater than the trigger of 120 days.

- *The consumer dietary risk assessment considering the outstanding data to conclude on the residue definition for risk assessment for processed commodities and the fate of persistent soil metabolites in rotational crops.*
- *Potential changes in isomerisation for dietary risk assessment cannot be finalised.*

  Since the risk assessment for processed commodities could not be finalised, uses on edible crops cannot be authorised and a restriction to ornamental crops is required.

With regards to persistent soil metabolites in rotational crops, Member States are requested to pay particular attention to this aspect during zonal/national authorisation processes in cases when crops are grown in the same soil or growing medium.

13 Art 3.27 of the Regulation (EC) No 1107/2009: "greenhouse" a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of PPPs into the environment.

- *The consumer risk assessment from the consumption of drinking water could not be finalised, while 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.*

Given that use will be restricted to permanent greenhouses (as defined in Art 3.27 of the Regulation (EC) No 1107/2009), release to the environment is prevented and as a consequence residues are not expected to be present in surface water that is abstracted for drinking water production.

Taking into account the restrictions, the review has identified an acceptable exposure scenarios for operators and workers which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

As regards the new criteria to identify endocrine disrupting properties introduced by Commission Regulation (EU) 2018/605[14] which became applicable on 10 November 2018, etoxazole is unlikely an endocrine-disruptor (ED) based on the available data and current knowledge, on which EFSA concluded that etoxazole is unlikely to have endocrine disrupting properties in mammals. However, in order to increase the confidence in this conclusion, the applicant is requested to provide an updated assessment as regards the new ED criteria within two years after publication of the implementing regulation renewing the approval of etoxazole in line with the applicable guidance.

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.

4. Identity and Physical/chemical properties

The main identity of etoxazole is given in Appendix I.

The active substance shall have a minimum purity of 948 g/kg.

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.

[14] Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties. (OJ L 101, 20.4.2018, p. 33).

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 etoxazole

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.

– Only use on ornamental plants in permanent greenhouses may be authorised.

Member States shall pay particular attention to:

- possible uptake of persistent soil metabolites in rotational crops;
- the protection of operators, ensuring that conditions of use include the application of adequate personal protective equipment.

7. List of studies to be generated

The applicant shall submit to the Commission, the Member States and the Authority confirmatory information as regards:

1. The applicant shall provide an updated assessment to confirm that etoxazole is not an endocrine disruptor in accordance with Points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605[15], and the guidance for identification of endocrine disruptors[16].

The appliant shall provide the updated assessment in accordance with points 3.6.5 and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, as amended by Commission Regulation (EU) 2018/605 by [*insert date corresponding to two years from the date of entry into force of the Regulation*].

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 (pages 19 and 20).

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.

15 Commission Regulation (EU) 2018/605 of 19 April 2018 amending Annex II to Regulation (EC) No 1107/2009 by setting out scientific criteria for the determination of endocrine disrupting properties (OJ L 101, 20.4.2018, p. 33).

16 Guidance for the identification of endocrine disruptors in the context of Regulations (EU) No 528/2012 and (EC) No 1107/2009. https://efsa.onlinelibrary.wiley.com/doi/epdt710.2903/i.efsa.2018.5311.

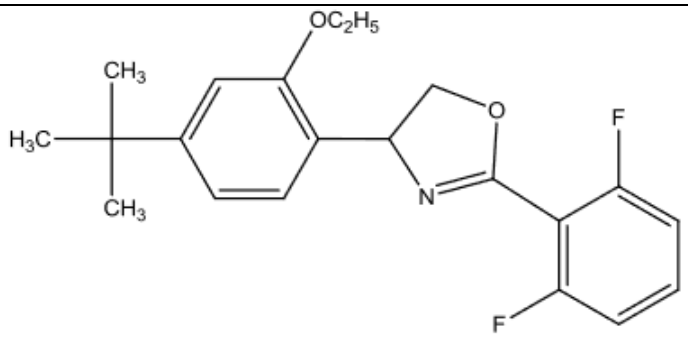
9. Updating of this renewal report

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 etoxazole.

APPENDIX I

Main identity

ETOXAZOLE

Common name (ISO)	Etoxazole (BSI, ISO)
Chemical name (IUPAC)	(RS)-5-tert-butyl-2-[2-(2,6-difluorophenyl)-4,5-dihydro1,3-oxazol-4-yl]phenetole
Chemical name (CA)	2-(2,6-difluorophenyl)-4-[4-(1,1-dimethylethyl)-2ethoxyphenyl]-4,5-dihydrooxazole
CIPAC No	623
CAS No	153233-91-1
EC No (EINECS or ELINCS)	Not allocated
FAO SPECIFICATION	none
Minimum purity	min. 948g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern) in the active substance as manufactured	none
Molecular formula	$C_{21}H_{23}F_2NO_2$
Molecular mass	359.42 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

ETOXAZOLE

Crop and/or situation (a)	Member State or Country	Product Name	F, G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					type (d-f)	conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min-max (k)	interval between appl. (min)	g as/hL min-max	water L/ha min-max	g as/ha min-max	(l)	(m)
Ornamental plants	North-/ Central-/ South-EU	ETOX AZOL E 11 SC'	G	mites	SC	110g /L	Foliar application	from infestation	1	Not applicable	0.0037 - 0.0055	1000-1500	max 0.055	n.a.	-

Remarks:

(a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (e.g. fumigation of a structure)
(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)
(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), watersoluble granule (WG)
(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 plants - type of equipment used must be indicated
(i) g/kg or g/l
(j) Growth stage at 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) The minimum and maximum number of application possible under practical conditions of use must be provided
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/ restrictions