EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

COMMISSION STAFF WORKING DOCUMENT[1]

esfenvalerate
SANTE/10362/2015 Rev 1
9 October 2015

Final

Review report for the active substance **esfenvalerate**
finalised in the Standing Committee on Plants, Animals, Food and Feed at its meeting on 9 October 2015
in view of the renewal of the approval of esfenvalerate as active substance in accordance with Regulation (EC) No 1107/2009

1. Procedure followed for the re-evaluation process

This review report has been established as a result of the evaluation of esfenvalerate, in accordance with Regulation (EC) No 1107/2009[2] and Commission Regulation (EU) No 1141/2010[3] following the submission of an application to renew the approval of this active substance expiring in December 2015.

Commission Regulation (EU) No 1141/2010, as amended by Commission Implementing Regulation (EU) No 380/2013[4], lays down the procedure for the renewal of the second group of active substances in Annex I to Directive 91/414/EEC[5] and includes esfenvalerate.

Esfenvalerate 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 2000/67/EC[6]. Esfenvalerate 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[7].

In accordance with the provisions of Article 5 of Directive 91/414/EEC, Sumitomo Chemical Agro Europe S.A.S. notified to the Commission of their wish to renew the approval of the active substance esfenvalerate in Annex I to the Directive.

Commission Directive 2010/77/EU[8] extended until 31 December 2015 the period of approval of esfenvalerate to allow the completion of its review.

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1 Does not necessarily represent the views of the Commission.
2 OJ L 309, 24.11.2009, p. 1.
3 OJ L 322, 8. 12.2010, p. 10.
4 OJ L 116, 26.4.2013, p.4.
5 OJ L 230, 19.8.1991, p. 1.
6 OJ L 276, 28.10.2000, p. 38.
7 OJ L 153, 11.6.2011, p. 1.
8 OJ L 293, 11.11.2010, p. 48

Commission Regulation (EU) No 1141/2010 designated the rapporteur Member States and the co-rapporteur Member States which had to submit the relevant renewal assessment reports and recommendations to the European Food Safety Authority (EFSA).

For esfenvalerate the rapporteur Member State was United Kingdom and the co-rapporteur Member State was Portugal.

United Kingdom finalised in July 2013 its examination, in the form of a renewal assessment report. This Report was sent to the Commission and the European Food Safety Authority on 30 July 2013 and included a recommendation concerning the decision to be taken with regard to the renewal of the approval of esfenvalerate for the supported uses.

In accordance with Article 16 of Commission Regulation (EU) No 1141/2010, the Commission requested the EFSA to arrange an expert consultation on the rapporteur Member State's renewal assessment report and to deliver its conclusions.

Therefore, the EFSA organised an intensive consultation of technical experts from Member States, to review the renewal assessment report and the comments received thereon (peer review).

The EFSA sent to the Commission its conclusion on the risk assessment (Conclusions regarding the peer review of the pesticide risk assessment of the active substance)[9] on 22 October 2014. This conclusion refers to background document A (final revised version of the renewal assessment report) and background document B (EFSA peer review report).

According to the provisions of Article 17 of Regulation (EU) No 1141/2010, the Commission referred a draft review report on the renewal of approval to the Standing Committee on Plants, Animals, Food and Feed, for examination on 20 March 2015. The draft review report on renewal of approval was finalised in the meeting of the Standing Committee on 9 October 2015.

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

2. Purposes of this review report

This review report, including the background documents and appendices hereto, has been developed and finalised in support of **Commission Implementing Regulation (EU) 2015/2047**[10] concerning the renewal of approval of esfenvalerate as active substance under Regulation (EC) No 1107/2009, and to assist the Member States in decisions on individual plant protection products containing esfenvalerate they have to take in accordance with the provisions of that Regulation, and in particular the provisions of Article 29(1) of Regulation (EC) No 1107/2009 and the uniform principles laid down in Regulation (EU) No 546/2011[11].

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9 EFSA Journal 2014;12(11):3873. Conclusion on the peer review of the pesticide risk assessment of the active substance esfenvalerate. doi:10.2903/j.efsa.2014.3873. Available online: www.efsa.europa.eu/efsajournal.

10 OJ L 300, 17.11.2015, p. 8–12 .

11 OJ L 155, 11.6.2011, p. 127.

This review report provides also for the evaluation required under part II, Section A.2(b) of the above mentioned uniform principles, as well as under several specific sections of chapter B of these principles. In these sections it is provided that Member States, in evaluating applications and granting authorisations, shall take into account the information concerning the requirements of Regulation (EU) No 544/2011[12], submitted for the purpose of (renewal of) approval of the active substances, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 18 of Regulation (EU) No 1141/2010, this review report will be made available to the public.

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

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

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

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

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

ADI: 0.0175 mg/kg bw per day,
AOEL: 0.011 mg/kg bw per day,
ARfD: 0.0175 mg/kg bw.

With particular regard to residues, the review has established that the residues arising from the proposed uses, consequent on application consistent with good plant protection practice, have no harmful effects on human or animal health. The highest Theoretical Maximum Daily Intake (TMDI) for all considered consumer groups is less then 10% of the Acceptable Daily Intake (ADI) and regarding acute exposure the highest intake was calculated to be below the ARfD.

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

[12] OJ L 155, 11.6.2011, p. 1.

The review has identified several acceptable exposure scenarios for operators, workers, bystanders which require however to be confirmed for each plant protection product in accordance with the relevant sections of the above mentioned uniform principles.

Further information on the possible occurrence of impurities in the technical material and the relevance of the test material used in the toxicity dossier had been considered appropriate by EFSA. However, as there has been no change in the manufacturing process or in the production site since the first approval of the substance, the Committee concludes it can be assumed that the information contained in the toxicological data base is still accurate and that any relevant impurities have duly been covered. As a consequence, the Committee does not consider necessary to request additional information in this field.

The review of the uses supported by available data, as listed in Appendix II, has also concluded that under the proposed and supported conditions of use there are no unacceptable effects on the environment, as provided for in Article 4(3)(e) of Regulation (EC) No 1107/2009, provided that certain conditions are taken into account as detailed in section 6 of this report. For other representative uses evaluated, data gaps with regard to the groundwater exposure assessment were identified for which Member States are requested to pay particular attention as highlighted in section 6.

From the review, it can be concluded that under the proposed and supported conditions of use esfenvalerate complies with two of the three criteria (bio-accumulation and aquatic toxicity) to be considered as a PBT substance. Therefore, esfenvalerate cannot be considered as a PBT substance but is a candidate for substitution in accordance with Article 24 of Regulation (EC) No 1107/2009.

4. Identity and Physical/chemical properties

The main identity of esfenvalerate is given in Appendix I.

The active substance shall have a minimum purity of 830 g/kg.

The manufacturing impurity toluene is of toxicological concern and must not exceed 10 g/kg in the active substance as manufactured.

5. Endpoints and related information

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

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

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

– the risk from esfenvalerate and the 2SαR-isomer of fenvalerate to aquatic organisms including the risk for bio-accumulation through the food chain;
– the risk to honeybees and non-target arthropods;
– The protection of groundwater when the substance is applied in regions with vulnerable soils and/or climatic conditions.

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

7. List of studies to be generated

No further information was identified which is at this stage considered necessary in relation to the approval of esfenvalerate under the current approval conditions.

Some endpoints however may require the generation or submission of additional studies to be submitted to the Member States in order to ensure authorisations for use under certain conditions such as the need for further data regarding the aquatic risk assessment of the 2SαR-isomer of fenvalerate.

A complete list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusion (page 16).

8. Information on studies with claimed data protection

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

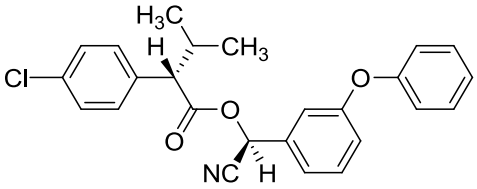
9. Updating of this review report

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

APPENDIX I

Main identity

ESFENVALERATE

Common name (ISO)	Esfenvalerate
Chemical name (IUPAC)	(αS)-α-cyano-3-phenoxybenzyl (2S)-2-(4-chlorophenyl)-3-methylbutyrate
Chemical name (CA)	(S)-cyano(3-phenoxyphenyl)methyl (αS)-4-chloro-α-(1-methylethyl)benzeneacetate
CIPAC No	481
CAS No	66230-04-4
EC No (EINECS or ELINCS) ‡	Not allocated.
FAO SPECIFICATION	Not available.
Minimum purity	830 g/kg toluene Maximum content: 10 g/kg
Molecular formula	$C_{25}H_{22}ClNO_3$
Molecular mass	419.91 g/mol
Structural formula	

APPENDIX II

List of uses supported by available data

ESFENVALERATE

Crop and/ or situation (a)	Country and/or Region	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Formulation		Application				Application rate per treatment			PHI (days) (l)	Remarks (m)
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min max (k)	interval between applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max		
Spring cereals (Wheat, Barley, Rye, Triticale, Oat)	NEU	Esfen-valerate 5EC	F	Aphids	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-75	1-2	14	0.003-0.005	300-500	0.015	35	
Spring cereals (Wheat, Barley, Rye, Triticale, Oat)	SEU	Esfen-valerate 5EC	F	Aphids	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-75	1-2	14	0.0019-0.005	300-800	0.015	28	
Potatoes	N&SEU	Esfen-valerate 5EC	F	Aphids, Colorado Potato beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12 onwards	1-3	14	0.0025-0.015	100-600	0.015	7	
Spring oilseed rape	NEU	Esfen-valerate 5EC	F	Stem weevils, Rape beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 31-59	1-2	14	0.00375-0.015	100-400	0.015	42	

Crop and/ or situation (a)	Country and/or Region	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 applications (min)	kg as/hL min max	water L/ha min max	kg as/ha min max	(l)	(m)
Spring oilseed rape	NEU	Esfen-valerate 5EC	F	Seed weevil	EC	50 g/L	Tractor mounted downward sprayer	BBCH 70-79	1-2	14	0.00375-0.015	100-400	0.015	42	
Spring oilseed rape	SEU	Esfen-valerate 5EC	F	Flea beetle, Stem weevil, Rape beetle	EC	50 g/L	Tractor mounted downward sprayer	When pest occurs from BBCH 12-59	1-2	14	0.00375-0.015	100-400	0.015	42	
Spring oilseed rape	SEU	Esfen-valerate 5EC	F	Seed weevil	EC	50 g/L	Tractor mounted downward sprayer	BBCH 70-79	1-2	14	0.00375-0.015	100-400	0.015	42	

(a) For crops, the Codex and EU (or other) classifications 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 sucking insects, soil borne insects, foliar fungi, weeds
(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989
(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) Indicate the minimum and maximum number of applications possible under practical conditions of use
(l) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions