



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate E – Safety of the food chain  
**Unit E.3 - Chemicals, contaminants , pesticides**

Buprofezin  
SANCO/12256/2010 final  
23 November 2010

Review report for the active substance **buprofezin**  
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
23 November 2010  
in view of the inclusion of buprofezin in Annex I of Directive 91/414/EEC

## 1. Procedure followed for the re-evaluation process

This review report has been established as a result of the re-evaluation of buprofezin, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Buprofezin is a substance that was covered by the third stage of the work programme for review of existing active substances regulated by Commission Regulation (EC) No 451/2000<sup>1</sup> laying down the detailed rules for the implementation of the second and third stages of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 1490/2002<sup>2</sup>.

At the outcome of that evaluation, buprofezin was not included through Commission Decision 2008/771/EC<sup>3</sup> as, on the basis of the available information, it was not possible to assess the consumer exposure due to a substantial lack of data. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/110/08 final of 24 August 2009).

In accordance with Article 13 of Regulation (EC) No 33/2008, Nihon Nohyaku Co., the sole data submitter presented, on 27 February 2009 a request to United Kingdom, the new rapporteur Member State which replaced Finland pursuant to provisions laid down in Article 14 of Regulation (EC) No 33/2008.

The United Kingdom finalised in August 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 21 August 2009.

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<sup>1</sup> OJ No L 55, 29.02.2000, p.25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

<sup>2</sup> OJ No L 224, 21.8.2002, p.23. Regulation as last amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.09.2007, p. 19).

<sup>3</sup> OJ L 263, 2.10.2008, p. 18.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the additional report by all the Member States as well as by Nihon Nohyaku Co. being the sole data submitter, on 24 August 2009 by making it available.

Following consideration of the Additional Report and the comments received, the EFSA sent to the Commission its conclusion on the risk assessment [Conclusion on the peer review of the pesticide risk assessment of the active substance buprofezin<sup>4</sup>], in accordance with the provisions of Article 20 of Regulation (EC) No 33/2008. This conclusion refers to background document A (draft assessment report and additional report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 21 of Regulation (EC) No 33/2008, the Commission referred a draft review report to the Standing Committee on the Food Chain and Animal Health, for final examination. The draft review report was finalised in the meeting of the Standing Committee on 23 November 2010.

The present review report contains the conclusions of the final examination by the Standing Committee. Given the importance of the conclusion of the EFSA, and the comments and clarifications submitted after the conclusion of the EFSA (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 **Directive 2011/6/EU**<sup>5</sup> concerning the inclusion of buprofezin in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing buprofezin they have to take in accordance with the provisions of that Directive, and in particular the provisions of article 4(1) and the uniform principles laid down in Annex VI.

This review report provides also for the evaluation required under Section A.2.(b) of the above mentioned uniform principles, as well as under several specific sections of part 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 active substance in Annex II of the directive, submitted for the purpose of inclusion of the active substance in Annex I, as well as the result of the evaluation of those data.

In accordance with the provisions of Article 22 of Regulation (EC) No 33/2008, this review report will be made available for public consultation by any interested parties.

The information in this review report is, at least partly, based on information which is confidential and/or protected under the provisions of Directive 91/414/EEC. It is therefore recommended that this review report would not be accepted to support any registration outside the context of Directive 91/414/EEC, 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.

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<sup>4</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance buprofezin. EFSA Journal 2010; 8(6):1624. [77 pp.]. doi:10.2903/j.efsa.2010.1624. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

<sup>5</sup> OJ L 18, 21.1.2011, p. 38–40

### 3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion from the evaluation is that it may be expected that plant protection products containing buprofezin will fulfil the safety requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. 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 4(1) and the uniform principles laid down in Annex VI of Directive 91/414/EEC, for each buprofezin 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 data submitter and mentioned in the list of uses supported by available data (attached as Appendix II to this review report).

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 4(1) and of the uniform principles laid down in Annex VI of Directive 91/414/EEC.

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

ADI	0.01 mg/kg bw/day
ARfD	0.5 mg/kg bw/day
AOEL	0.04 mg/kg bw/day

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 Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) is:

- 83% of the Acceptable Daily Intake (ADI), according to the Dutch diet for children.
  - 9 % of the Acceptable Daily Intake (ADI), in the refined chronic calculation, calculated according to STMRs and the processing factor for citrus pulp ( WHO Cluster diet B).
- Additional intake from water is not expected to give rise to intake problems.

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

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 (1) (b) (iv) and (v) of Directive 91/414/EEC.

### 4. Identity

The main identity of buprofezin is given in Appendix I.

There were no FAO specifications at the moment this report was drafted.

The review has established that for the active substance notified by the data submitter none of the manufacturing impurities considered are, on the basis of information currently available, of toxicological or environmental concern.

## **5. Endpoints and related information**

In order to facilitate Member States, in granting or reviewing authorisations, to apply adequately the provisions of Article 4(1) of Directive 91/414/EEC and the uniform principles laid down in Annex VI of that Directive, the most important endpoints were identified during the re-evaluation process. These endpoints are listed in the conclusion of the EFSA, and at section 3 of this report.

## **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 buprofezin**

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

Member States should pay particular attention to:

- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,
- the dietary exposure of consumers to the buprofezin (aniline) metabolites in processed food,
- the application of an appropriate waiting period for rotational crops in greenhouses,
- the risk to aquatic organisms and ensure that conditions of use prescribe the application of adequate risk mitigation measures, where appropriate.

Where appropriate, conditions of authorisation shall include further risk mitigation measures.

## **7. List of studies to be generated**

No further studies were identified which were at this stage considered necessary in relation to the inclusion of buprofezin in Annex I under the current inclusion conditions.

However, the concerned Member States shall request the submission of:

- information to confirm the processing and conversion factors for consumer risk assessment.

Some other endpoints may require the generation or submission of additional data to be submitted to the Member States in order to ensure authorisations for use under certain conditions.

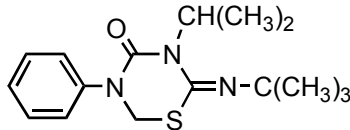
## **8. Information on studies with claimed data protection**

For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. This information is only given to facilitate the operation of the provisions of Article 13 of Directive 91/414/EEC 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 13 of the Directive 91/414/EEC 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 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food Chain and Animal Health, in connection with any amendment of the inclusion conditions for buprofezin in Annex I of the Directive.

**APPENDIX I****Identity  
BUPROFEZIN**

<b>Common name (ISO)</b>	Buprofezin
<b>Chemical name (IUPAC)</b>	<i>(Z)</i> -2- <i>tert</i> -butylimino-3-isopropyl-5-phenyl-1,3,5-thiadiazinan-4-one
<b>Chemical name (CA)</b>	2-[(1,1-dimethylethyl)imino]tetrahydro-3-(1-methylethyl)-5-phenyl-4-H-1,3,5-thiadiazin-4-one
<b>CIPAC No</b>	681
<b>CAS No</b>	953030-84-7
<b>EEC No</b>	Not allocated
<b>FAO SPECIFICATION</b>	None
<b>Minimum purity</b>	985 g/kg
<b>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)</b>	None
<b>Molecular formula</b>	C <sub>16</sub> H <sub>23</sub> N <sub>3</sub> OS
<b>Molecular mass</b>	305.44 g/mol
<b>Structural formula</b>	

**APPENDIX II**  
**List of uses supported by available data**  
**BUPROFEZIN**

Crop and/or situation (a)	Member State or Country	Product name	F G or I (b)	Pests or Group of pests controlled (c)	Preparation		Application				Application rate per treatment (for explanation see the text in front of this section)			PHI (days) (m)	Remarks
					Type (d-f)	Conc. of as (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	g as/hL min-max (l)	Water L/ha min-max	g as/ha min-max (l)		
Tomato	N-EU/ S-EU	Applaud 25 WP	F	Whitefly	WP	250 g/kg	High volume spraying	BBCH 89	2	3 day	20	1000	200	7	
Tomato	N-EU/ S-EU	Applaud 25 WP	G	Whitefly	WP	250 g/kg	High volume spraying	BBCH 87	3	7 day	25	1000	250	3	
Citrus	S-EU	Applaud 25 WP	F	Scales, Whitefly	WP	250 g/kg	High volume spraying	BBCH 89	1		25	4000	1000	7	

Uses should be crossed out when the notifier no longer supports this use(s).

- (a) For crops, the EU and Codex classifications (both) should be taken into account; where relevant, the use situation should be described (e.g. fumigation of a structure)
- (b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)
- (c) e.g. biting and suckling insects, soil born 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 plant- type of equipment used must be indicated

- (i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypr). **In certain cases, where only one variant is synthesised, it is more appropriate to give the rate for the variant (e.g. benthialicarb-isopropyl).**
- (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 application possible under practical conditions of use
- (l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha)
- (m) PHI - minimum pre-harvest interval