



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Fenbutatin oxide  
SANCO/12812/2010 final  
28 January 2011

Review report for the active substance **fenbutatin oxide**  
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on  
28 January 2011  
in view of the inclusion of fenbutatin oxide 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 fenbutatin oxide, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Fenbutatin oxide is a substance that was covered by the third stage of the work programme for review of existing active substances provided for in Article 8(2) of Directive 91/414/EEC concerning the placing of plant protection products on the market<sup>1</sup>, with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 11(e) of Commission Regulation (EC) No 1490/2002<sup>2</sup> laying down detailed rules for the implementation of the third stage of the work programme offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. All notifiers withdrew their support and fenbutatin oxide was not included through Commission Decision 2008/934/EC<sup>3</sup>.

In accordance with Article 13 of Regulation (EC) No 33/2008<sup>4</sup>, BASF Agro B.V., the sole data submitter presented, on 2 June 2009 a request to Belgium, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Belgium finalised in December 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was sent to the Commission and the European Food Safety Authority on 1 December 2009 and included a recommendation as to include fenbutatin oxide in Annex I for the supported uses.

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<sup>1</sup> OJ No L 230, 19.8.1991

<sup>2</sup> OJ No L 224, 21.8.2002

<sup>3</sup> OJ No L 333, 11.12.2008, p.11

<sup>4</sup> OJ No L 252, 20.9.2008, p. 37

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the additional assessment report by all the Member States as well as by BASF Agro B.V. being the sole data submitter, on 2 December 2009 by making it available.

The EFSA organised a focused consultation of scientific experts from a certain number of Member States, to review the draft assessment report and the comments received thereon (peer review).

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 the EFSA sent to the Commission its conclusion on the risk assessment of the active substance fenbutatin oxide<sup>5</sup>. 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 28 January 2011.

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 **2011/30/EU**<sup>6</sup> concerning the inclusion of fenbutatin oxide in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing fenbutatin oxide 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

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<sup>5</sup> *European Food Safety Authority ; Conclusion on the peer review of the pesticide risk assessment of the active substance fenbutatin oxide. EFSA Journal 2010; 8(9):1711. [73 pp.]. doi:10.2903/j.efsa.2010.1711. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)*

<sup>6</sup> OJ L 61, 8.3.2011, p. 14–17

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.

### **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 fenbutatin oxide 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 fenbutatin oxide 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	0.05 mg/kg bw/day
ARfD	0.1 mg/kg bw
AOEL	not allocated, risk assessment by calculation of margins of exposure (MOE)

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) is about 90 % of the Acceptable Daily Intake (ADI), (DE child). Additional intake from water is not expected to give rise to intake problems.

A provisional acute risk assessment conducted by EFSA using the ARfD of 0.1 mg/kg bw and the HR values observed in the supervised residue trials, gives IESTI values of 59% of the ARfD for tomato.

The review has identified several 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 fenbutatin oxide is given in Appendix I.

## **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 fenbutatin oxide.**

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:

- technical specification of the impurity content
- protection of aquatic organisms including appropriate risk mitigations
- residue levels in small tomato varieties (cherry tomatoes)
- the operator safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate,

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

Further studies were identified which were at this stage considered necessary in relation to the inclusion of fenbutatin oxide in Annex I under the current inclusion conditions.

The concerned Member States shall request the submission of further information on genotoxicological potential, ecotoxicological relevance, spectra, storage stability of the relevant impurity bis[hydroxybis(2-methyl-2-phenylpropyl)tin]oxide (SD 31723) and a method for analysis of this impurity in the formulation.

They shall ensure that the notifier at whose request fenbutatin oxide has been included in this annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.

Some other 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. The list of studies to be generated, still ongoing or available but not peer reviewed can be found in the relevant part of the EFSA Conclusions.

## **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

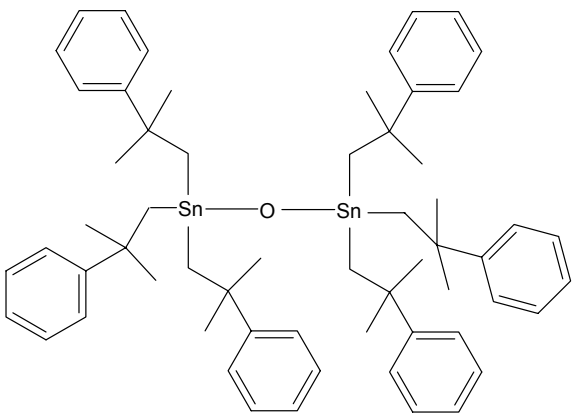
operators with regard to its uses in the implementation of the provisions of Article 13 of the Directive 91/414/EEC and neither does it commit the Commission.

## **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 fenbutatin oxide in Annex I of the Directive.

## APPENDIX I

Identity  
FENBUTATIN OXIDE

<b>Common name (ISO)</b>	Fenbutatin oxide
<b>Chemical name (IUPAC)</b>	<i>Bis[tris(2-methyl-2-phenylpropyl)-tin]oxide</i>
<b>Chemical name (CA)</b>	Hexakis(2-methyl-2-phenylpropyl)distannoxane
<b>CIPAC No</b>	359
<b>CAS No</b>	13356-08-6
<b>EEC No</b>	236-407-7
<b>FAO SPECIFICATION</b>	359/TC/S/F (1993); published in AGP:CP/318 (1995)  minimum purity: 945 g/kg; bis[hydroxybis(2-methyl-2-phenylpropyl)tin]oxide: max. 20 g/kg
<b>Minimum purity</b>	970 g/kg
<b>Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)</b>	bis[hydroxybis(2-methyl-2-phenylpropyl)tin]oxide: max. 3 g/kg
<b>Molecular formula</b>	$C_{60}H_{78}OSn_2$
<b>Molecular mass</b>	1052.7 u
<b>Structural formula</b>	

**APPENDIX II**  
**List of uses supported by available data**  
**FENBUTATIN OXIDE**

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. as g/l (i)	method kind (f-h)	growth stage & season (j)	number min/max (k)	interval between applications (min)	kg as/hL min-max (l)	Water L/ha min-max	kg as/ha min-max (l)		
Tomato	Northern and Southern MS	Torque 50 WP	G	Mites	WP	500 g/kg	spray	At infestation	2	14 days	0.025	1500	0.375	3	

Remarks:	(a)	(b)	(c)	(d)	(e)	(f)	(g)	(h)	(i)	(j)	(k)	(l)	(m)
	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)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	e.g. biting and suckling insects, soil born insects, foliar fungi, weeds	e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	GCPF Codes - GIFAP Technical Monograph No 2, 1989	Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench	All abbreviations used must be explained	Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated	g/kg or g/L	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	The minimum and maximum number of application possible under practical conditions of use must be provided	PHI - minimum pre-harvest interval	Remarks may include: Extent of use/economic importance/restrictions