



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Bromuconazole
SANCO/12620/2010 final
23 November 2010

Review report for the active substance **bromuconazole**
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 bromuconazole 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 bromuconazole, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Bromuconazole 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⁽¹⁾ 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⁽²⁾.

At the outcome of that evaluation, bromuconazole was not included through Commission Decision 2008/832/EC³ as, on the basis of the available information, it was not possible to assess the potential contamination of surface water and because the risk to aquatic organisms was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/120/08 final of 17 June 2008).

In accordance with Article 13 of Regulation (EC) No 33/2008, Sumitomo Chemical Agro Europe, the sole data submitter presented, on 10 April 2009 a request to Belgium, the original rapporteur Member State.

Belgium finalised in October 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 8 October 2009.

¹ 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).

² 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).

³ OJ L 295, 4.11.2008, p. 53.

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 Sumitomo Chemical Agro Europe being the sole data submitter, on 20 October 2009 by making it available.

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

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 [Conclusion on the peer review of the pesticide risk assessment of the active substance bromuconazole⁴]. 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 **2010/92/EU**⁵ concerning the inclusion of bromuconazole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing bromuconazole 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

⁴ EFSA Journal 2010; 8(8):1704 – *Conclusion on pesticide peer review – Conclusion on the peer review of the pesticide risk assessment of the active substance bromuconazole*

⁵ *OJ L 338, 22.12.2010, p. 44–46*

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 bromuconazole 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 bromuconazole 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	0.1 mg/kg bw/day
AOEL	0.025 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:

- 4% and 14% of the Acceptable Daily Intake (ADI), based on the UK diet for children and infants respectively;

- 10 % of the Acceptable Daily Intake (ADI) according to the Dutch diet for children.

Additional intake from water is not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and children revealed that the Acute Reference Dose (ARfD) would not be exceeded (According to the EFSA model, critical consumer = infant UK diet- potatoes (succeeding crop) = 7,7% ARfD).

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 bromuconazole 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 bromuconazole

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 safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;
- the protection of aquatic organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate, such as adequate buffer zones.

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 bromuconazole in Annex I under the current inclusion conditions.

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

- information to further address the long-term risk to herbivorous mammals;
- information on residues of triazole derivative metabolites (TDMs) in primary crops, rotational crops and products of animal origin.

The Member States concerned shall ensure that the applicant submits to the Commission further information addressing the potential endocrine disrupting properties of bromuconazole within

two years after the adoption of the OECD test guidelines on endocrine disruption or, alternatively, of Community agreed test guidelines.

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

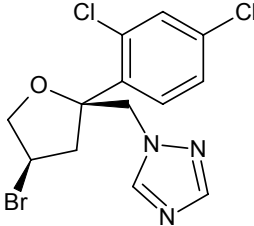
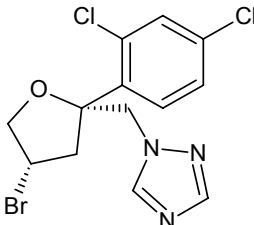
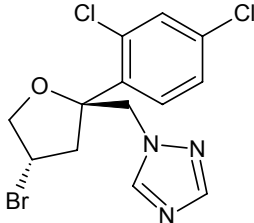
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion. 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.

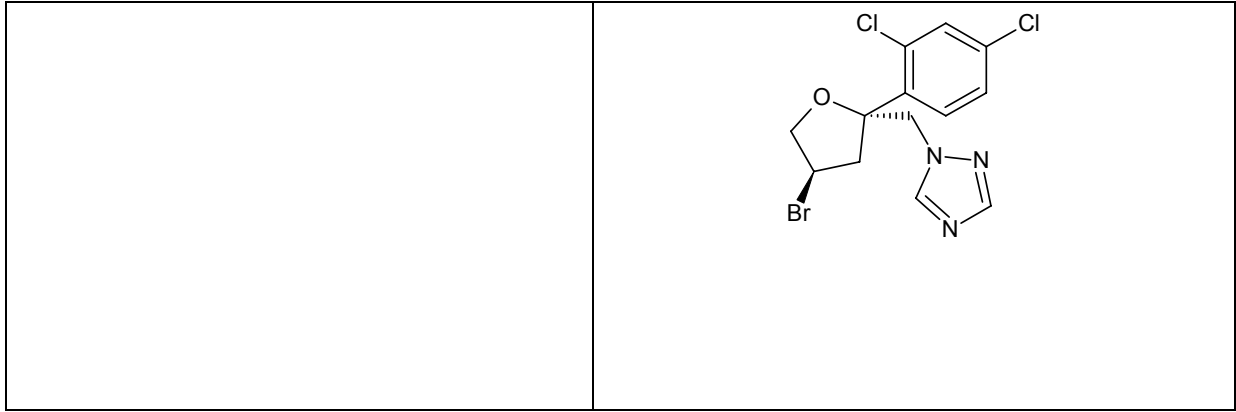
9. Updating of this review report

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 bromuconazole in Annex I of the Directive.

APPENDIX I

Identity
BROMUCONAZOLE

Common name (ISO)	Bromuconazole
Chemical name (IUPAC)	(1-[(2 <i>RS</i> ,4 <i>RS</i> :2 <i>RS</i> ,4 <i>SR</i>)-4-bromo-2-(2,4-dichlorophenyl)tetrahydrofurfuryl]-1 <i>H</i> -1,2,4-triazole
Chemical name (CA)	1-[[4-bromo-2-(2,4-dichlorophenyl)tetrahydro-2-furanyl]methyl]-1 <i>H</i> -1,2,4-triazole
CIPAC No	680
CAS No	116255-48-2
EEC No	408-060-3
FAO SPECIFICATION	None
Minimum purity	Min. 960 g/kg Bromuconazole (LS850646 + LS850647), with LS850646 ranging between 500 to 560 g/kg and LS850647 ranging between 420 to 480 g/kg. These ranges imply ratios LS850646/LS850647 between 1.04:1 and 1.33:1
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	None
Molecular formula	C ₁₃ H ₁₂ BrCl ₂ N ₃ O
Molecular mass	377.1 g/mol
Structural formula	<p>LS 850646 (2<i>RS</i>,4<i>SR</i>)</p>   <p>LS 850647(2<i>RS</i>,4<i>RS</i>)</p> 



APPENDIX II
List of uses supported by available data
BROMUCONAZOLE

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 (day) (l)	Remarks (m)	
					Type (d-f)	Conc. of a.s. (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			
Wheat	Europe	Granit 200 SC	F	<i>Tapesia</i> spp. <i>Mycosphaerella graminicola</i> <i>Stagonospora nodorum</i> <i>Puccinia recondita</i> <i>Puccinia striiformis</i> <i>Blumeria graminis</i> f.sp. <i>tritici</i> <i>Fusarium</i> spp	SC	200 g/l	spraying	BBCH 29-31	1	c.a. 2 months	0.050-0.100	200-400	0.200			
								BBCH 49-51 (S.E)	1		0.050-0.100					55 days (S.E.)
								59-65 (N.E.)								45 days (N.E.)

- Remarks:**
- | | |
|---|--|
| <p>(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)</p> <p>(b) Outdoor or field use (F), glasshouse application (G) or indoor application (I)</p> <p>(c) e.g. biting and suckling insects, soil born insects, foliar fungi, weeds</p> <p>(d) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)</p> <p>(e) GCPF Codes - GIFAP Technical Monograph No 2, 1989</p> <p>(f) All abbreviations used must be explained</p> | <p>(i) g/kg or g/l</p> <p>(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</p> <p>(k) The minimum and maximum number of application possible under practical conditions of use must be provided</p> <p>(l) PHI - minimum pre-harvest interval</p> |
|---|--|

- (g) Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting,
- (h) drench
Kind, *e.g.* overall, broadcast, aerial spraying, row, individual plant, between
the plants - type of equipment used must be indicated

- (m) Remarks may include: Extent of use/economic importance/restrictions