



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Triticonazole

SANCO/10442/2005 final rev 1

12 March 2010¹

Review report for the active substance **triticonazole**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
27 January 2006

in view of the inclusion of triticonazole 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 triticonazole, made in the context 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, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000⁽²⁾ 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⁽³⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Triticonazole is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EC) No 451/2000, Aventis Crop Science (France) notified to the Commission of their wish to secure the inclusion of the active substance triticonazole in Annex I to the Directive. On May 7th 2003 the Rapporteur Member State was informed that the triticonazole compound assets (including study reports and summaries) were sold to BASF, as required by the EU (DG - Competition). With immediate effect BASF is now the official sole notifier and owner of the property rights of the European Dossier on triticonazole.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated Austria as rapporteur Member State to carry out the assessment of triticonazole on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 703/2001⁴ the Commission specified furthermore that the deadline for the notifiers with regard to the submission to the rapporteur Member States of the dossiers required under Article 6(2) of

¹ On 12 March 2010 the Standing Committee on the Food Chain and Animal Health has taken note of the revision of the review report after the assessment of the confirmatory data referred to in point 7 of this report (cfr. infra).

² OJ No L 55, 29.02.2000, p.25.

³ OJ No L 224, 21.8.2002, p.23.

⁴ OJ No L 98, 7.4.2001, p. 6.

Regulation (EC) No 451/2000, as well as for other parties with regard to further technical and scientific information was 30 April 2002.

Aventis Crop Science (and by 2003 BASF since the notification and the property rights of the European dossier on triticonazole have been transferred to BASF) submitted by the deadline a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore BASF was considered to be the main data submitter.

In accordance with the provisions of Article 8(1) of Regulation (EC) No 451/2000, Austria submitted on 29 September 2003 to the EFSA the report of their examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of triticonazole in Annex I to the Directive. Moreover, in accordance with the provisions of Article 8(2) of Regulation (EC) 451/2000, the Commission and the Member States received also the summary dossier on triticonazole from BASF, on 24 November 2003.

In accordance with the provisions of Article 8 of Regulation (EC) No 451/2000, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by BASF being the main data submitters, on 4 December 2003 by making it available.

The EFSA organised an intensive consultation of technical 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 8 (7) of Regulation 451/2000 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 triticonazole (finalised: 22 June 2005)⁵]. This conclusion refers to background document A (draft assessment report) and background document B (EFSA peer review report).

In accordance with the provisions of Article 8 (7) of Regulation (EC) No 451/2000, the Commission referred on 23 September 2005 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 18 November 2005.

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 thereto, has been developed and finalised in support of the Directive 2006/39/EC concerning the inclusion of triticonazole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing triticonazole 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.

⁵ *EFSA Scientific Report* (2005) 33, 1-69

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 8(9) of Regulation (EC) No 451/2000, Member States will keep available or make available this review report for consultation by any interested parties or will make it available to them on their specific request.

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.

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 triticonazole 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 triticonazole 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 sole 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:	0.025 mg/kg bw/d
ArfD:	0.05 mg/kg bw
AOEL:	0.025 mg/kg bw/d

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) for a 60 kg adult is 0.14 % of the Acceptable Daily Intake (ADI), based on the FAO/WHO European Diet (August 1994).

Additional intake from water and products of animal origin are not expected to give rise to intake problems.

Estimates of acute dietary exposure of adults and toddlers revealed that the Acute Reference Dose (ARfD) would not be exceeded (European diet - ≤ 0.1 % or ≤ 0.2 % for respectively adults or children).

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, 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 and the physical/chemical properties of triticonazole are given in Appendix I.

At the time of evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the sole data submitter BASF 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 triticonazole

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, varied or withdrawn, as appropriate:

- must pay particular attention to the operator safety. Conditions of authorisation should include protective measures, where appropriate.
- must pay particular attention to the potential for groundwater contamination, in particular from the highly persistent active substance and its metabolite RPA 406341, in vulnerable zones;
- must pay particular attention to the protection of granivorous birds (long term risk).

Conditions of authorisation should include risk mitigation measures, where appropriate.

In assessing applications to authorise plant protection products containing triticonazole for uses other than seed treatment, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary data and information is provided before such an authorisation is granted.

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 triticonazole in Annex I under the current inclusion conditions.

However, the concerned Member States shall request the submission of further studies to confirm the risk assessment for granivorous birds. They shall ensure that the notifier at whose request triticonazole has been included in this Annex provide such studies to the Commission within 2 years from the entry into force of this Directive.

On 12 March 2010 the Standing Committee on the Food Chain and Animal Health has taken note of the revision of the review report after the assessment of the above confirmatory data. This assessment has been carried out in line with the Guidance document on the procedures for submission and assessment of confirmatory data following inclusion of an active substance in Annex I of Council Directive 91/414/EEC⁶. The Committee agrees that, on the basis of the current outcome, the risk for the exposed species is acceptable. No further review by EFSA has been considered necessary.

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 the proposed 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 Scientific report (page 30).

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 main 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

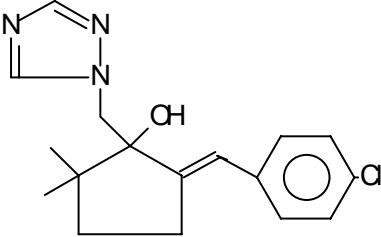
The information in this report may require to be updated from time to time in order to take account of technical and scientific developments as well as of the results of the examination of any information referred to the Commission in the framework of Articles 7, 10 or 11 of Directive 91/414/EEC. Any such adaptation will be finalised in the Standing Committee on the Food

⁶ Doc. SANCO/5634/2009 rev 3, 2.10.2009.

Chain and Animal Health, in connection with any amendment of the inclusion conditions for triticonazole in Annex I of the Directive.

APPENDIX I**Identity, physical and chemical properties**

TRITICONAZOLE

Common name (ISO)	Triticonazole
Chemical name (IUPAC)	(±) - (E) -5-(4-chlorobenzylidene) -2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
Chemical name (CA)	(5 <i>E</i>)-5-[(4-chlorophenyl)methylene]-2,2-dimethyl-1-(1 <i>H</i> -1,2,4-triazol-1-ylmethyl)cyclopentanol
CIPAC No	652
CAS No	131983-72-7
EEC No	not yet allocated
FAO SPECIFICATION	---
Minimum purity	950 g/kg (dry compound)
Molecular formula	C ₁₇ H ₂₀ ClN ₃ O
Molecular mass	317.82
Structural formula	

Melting point (state purity)	First crystalline form: 137 °C, second crystalline form: 141 °C(purity: 998.5 g/kg)																		
Boiling point (state purity)	Not measurable																		
Temperature of decomposition	Starts slightly decomposing after melting. Significant decomposition above 180 °C.																		
Appearance (state purity)	White powder with or without agglutinated mass (technical grade: purity: 959 and 957 g/kg)																		
Relative density (state purity)	$D_4^{20} = 1.21$ (at 22.5 °C) (purity: 99.9 %)																		
Surface tension	$\sigma = 51.7$ mN/m at 23.5 ± 0.5 °C and $c = 13.7$ mg/L																		
Vapour pressure (in Pa, state temperature)	$< 0.1 \times 10^{-5}$ Pa at 50 °C																		
Henry's law constant (Pa m³ mol⁻¹)	KH 3.0×10^{-5} Pa m ³ mol ⁻¹																		
Solubility in water (g/L or mg/L, state temperature)	Dist. Water (pH 7.3 – 8.7; 20 °C): 9.3 mg/L buffer solution pH 5 (20 °C): 7.7 mg/L buffer solution pH 9 (20 °C): 8.3 mg/L																		
Solubility in organic solvents (in g/L of mg/L, state temperature)	<table border="1"> <thead> <tr> <th>Solvent</th> <th>solubility at 20 °C [g/L]</th> </tr> </thead> <tbody> <tr> <td>Hexane</td> <td>0.12</td> </tr> <tr> <td>Toluene</td> <td>12.6</td> </tr> <tr> <td>Methanol</td> <td>18.2</td> </tr> <tr> <td>2-Propanol</td> <td>7.6</td> </tr> <tr> <td>1-Octanol</td> <td>6.2</td> </tr> <tr> <td>Dichloromethane</td> <td>191.0</td> </tr> <tr> <td>Acetone</td> <td>74.5</td> </tr> <tr> <td>Ethyl acetate</td> <td>48.6</td> </tr> </tbody> </table>	Solvent	solubility at 20 °C [g/L]	Hexane	0.12	Toluene	12.6	Methanol	18.2	2-Propanol	7.6	1-Octanol	6.2	Dichloromethane	191.0	Acetone	74.5	Ethyl acetate	48.6
Solvent	solubility at 20 °C [g/L]																		
Hexane	0.12																		
Toluene	12.6																		
Methanol	18.2																		
2-Propanol	7.6																		
1-Octanol	6.2																		
Dichloromethane	191.0																		
Acetone	74.5																		
Ethyl acetate	48.6																		
Partition coefficient (log Pow)	$\log P_{ow} = 3.29 \pm 0.04$ at 20 °C																		
Hydrolytic stability (DT50) (state pH and temperature)	Stable after a 30-day hydrolysis at pH 5, 7 and 9 at 25 ± 1 °C																		
Dissociation constant	No dissociation expected based on the structure and the water solubility																		
UV/VIS absorption (max.) (if absorption >290 nm state ϵ at wavelength)	<table border="1"> <thead> <tr> <th>wavelength [nm]</th> <th>molar absorption coefficient [L x mol⁻¹ x cm⁻¹]</th> </tr> </thead> <tbody> <tr> <td>212</td> <td>23879</td> </tr> <tr> <td>263</td> <td>25731</td> </tr> </tbody> </table> <p>No significant modification was observed between the spectrum obtained in neutral, acid and basic media.</p>	wavelength [nm]	molar absorption coefficient [L x mol ⁻¹ x cm ⁻¹]	212	23879	263	25731												
wavelength [nm]	molar absorption coefficient [L x mol ⁻¹ x cm ⁻¹]																		
212	23879																		
263	25731																		
Photostability (DT₅₀) (aqueous, sunlight, state pH)	The degradation kinetics of triticonazole was not pseudo-first order neither 0 order. Therefore, the half-lives were determined graphically. “Suntest” apparatus:																		

	Half-life: 75.9 h (1st phase: 12.1 h, 2nd phase: 154 h) Summer sunlight in Florida: Half-life: 3.0 d (1st phase: 0.47 d, 2nd phase: 6 d) (pH 5; 25 ± 1°C)
Quantum yield of direct phototransformation in water at $\lambda > 290$ nm	$\Phi = 0.05$ molecules of triconazole degraded per photon absorbed
Flammability	Not highly flammable
Explosive properties	Not explosive

APPENDIX II

List of uses supported by available data

TRITICONAZOLE

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) (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		
Wheat	Northern and Southern Region of Europe	Premis 25 FS	F	Seed and soil-borne disease (Fusarium Tilletia caries, Septoria Ustilago Puccinia)	FS	25	seed treatment	-	1	-	Max. 50 g a.i./t seed	-	0.009 – 0.0125	-	

- Remarks:**
- (a) For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (*e.g.*
 - (b) fumigation of a structure)
 - (c) Outdoor or field use (F), glasshouse application (G) or indoor
 - (d) application (I)
 - (e) *e.g.* biting and suckling insects, soil born insects, foliar fungi,
 - (f) weeds
 - (g) *e.g.* wettable powder (WP), emulsifiable concentrate (EC),
 - (h) granule (GR)
- GCPF Codes - GIFAP Technical Monograph No 2, 1989
All abbreviations used must be explained
Method, *e.g.* high volume spraying, low volume spraying, spreading, dusting, drench
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) application
The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) PHI - minimum pre-harvest interval
Remarks may include: Extent of use/economic importance/restrictions