



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Triflumizole
SANCO/10455/2010 final
12 March 2010

Review report for the active substance **triflumizole**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
12 March 2010
in view of the inclusion of triflumizole 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 triflumizole, made in the context of a new application by the data submitter after the non-inclusion of this substance.

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

At the outcome of that evaluation, triflumizole was not included through Commission Decision 2008/748/EC¹ as, on the basis of the available information, it had not been demonstrated that the risk to operators and workers was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/1061/2008 final of 25 April 2008).

In accordance with Article 13 of Regulation (EC) No 33/2008, Certis Europe BV, the sole data submitter presented, on 20 September 2008 a request to the Netherlands, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

The Netherlands finalised in March 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 6 March 2009 and included a recommendation as to include triflumizole in Annex I for the supported uses.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Certis Europe BV being the sole data submitter, on 10 March 2009 by making it available.

¹ OJ No L 252, 20.9.2008, p. 37.

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 20 of Regulation (EC) No 33/2008 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 triflumizole (re-issued on 4 December 2009)²]. 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 12 March 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 2010/27/EU**³ concerning the inclusion of triflumizole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing triflumizole 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.

² *European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance triflumizole. EFSA Journal 2009; 7(12):1415. [49 pp.]. doi:10.2903/j.efsa.2009.1415. Available online: www.efsa.europa.eu ..*

³ OJ L 104, 24.4.2010, p. 54–56

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 triflumizole 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 triflumizole 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/day
AOEL	0.05 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) is 9.8 % of the Acceptable Daily Intake (ADI), (WHO Cluster Diet B). 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 PRIMo model less than 58% for tomatoes and 7.7% for cucumber).

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 triflumizole is given in Appendix I.

At the time of the evaluation no FAO specification was allocated.

The review has established that for the active substance notified by the data submitter the manufacturing impurity toluene is considered to be of toxicological concern and the maximum level of 1 g/kg is established.

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 triflumizole

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: conditions of use shall prescribe the use of adequate personal protective equipment;

7. List of studies to be generated

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

-information on the stability of residues and if necessary new residue trials.

8. Information on studies with claimed data protection

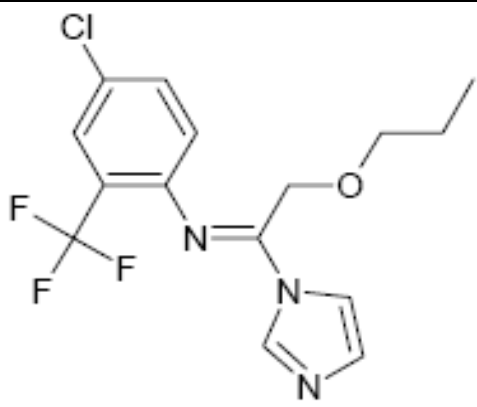
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion.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

APPENDIX I**Identity
TRIFLUMIZOLE**

Common name (ISO)	Triflumizole
Chemical name (IUPAC)	<i>(E)</i> -4-chloro- <i>a,a,a</i> -trifluoro- <i>N</i> -(1-imidazol-1-yl-2-propoxyethylidene)- <i>o</i> -toluidine
Chemical name (CA)	1-[(1 <i>E</i>)-1-[[4-chloro-2-(trifluoromethyl)phenyl]imino]-2-propoxyethyl]-1 <i>H</i> -imidazole
CIPAC No	730
CAS No	99387-89-0
EEC No	Not available
FAO SPECIFICATION	Not available
Minimum purity	980 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	max. 1 g/kg Toluene
Molecular formula	C ₁₅ H ₁₅ ClF ₃ N ₃ O
Molecular mass	345.75 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
TRIFLUMIZOLE

Crop and/or situation	Member State or Country	Product name	F G or I	Pests or Group of pests controlled	Formulation		Application				Application rate per treatment			PHI (days)	Remarks:
					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		
Cucumber	NL, BE	ROCKET EC	I	Powdery mildew	EC	150g/l	spaying	*	1-6 ¹	7 days ¹	0.0156	500-1500	0.078-0.234	3	Artificial substrates
Courgette	NL, BE	ROCKET EC	I	Powdery mildew	EC	150g/l	spaying	*	1-3	7 days	0.0156	500-1500	0.078-0.234	3	Artificial substrates
Gherkin	BE	ROCKET EC	I	Powdery mildew	EC	150g/l	spaying	*	1-6 ¹	7 days ¹	0.0104	500-1500	0.052-0.156	3	Artificial substrates
Tomato	NL, BE	ROCKET EC	I	Powdery mildew	EC	150g/l	spaying	*	1-5 ²	7 days ²	0.0156	500-1500	0.078-0.234	3	Artificial substrates
Ornamentals	NL, BE	ROCKET EC	I	Powdery mildew	EC	150g/l	spaying	all	1-6 ¹	7 days ¹	0.0156	500-1500	0.078-0.234	-	Only grown on artificial substrates

* Treatment during harvesting period (adult plants), not before May 1st or 4 weeks after planting (juvenile plants)

1 The GAP involves up to 6 applications in 2 spray-programmes. 1 spray programme is 3 applications with a seven-day interval followed by a different fungicide. The minimum interval to the next spray-programme is 28 days.

2 The GAP involves up to 5 applications in 2 spray-programmes. The first spray programme is 3 applications with a seven-day interval followed by at least two other different fungicides. The minimum interval to the second spray-programme of 2 applications is 49 days.

Remarks:	*	Uses for which risk assessment could not been concluded due to lack of essential data are marked grey	(h)	Kind, <i>e.g.</i> overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated
	(a)	For crops, the EU and Codex classifications (both) should be used; where relevant, the use situation should be described (<i>e.g.</i> fumigation of a structure)	(i)	g/kg or g/L
	(b)	Outdoor or field use (F), glasshouse application (G) or indoor application (I)	(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
	(c)	<i>e.g.</i> biting and suckling insects, soil born insects, foliar fungi, weeds		
	(d)	<i>e.g.</i> wettable powder (WP), emulsifiable concentrate (EC), granule (GR)	(k)	The minimum and maximum number of application possible under practical conditions of use must be provided
	(e)	GCPF Codes - GIFAP Technical Monograph No 2, 1989		
	(f)	Method, <i>e.g.</i> high volume spraying, low volume spraying, spreading, dusting, drench	(l)	PHI - minimum pre-harvest interval
	(g)	All abbreviations used must be explained	(m)	Remarks may include: Extent of use/economic importance/restrictions