EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Etridiazole

SANCO/13145/2010 final

28 January 2011

Review report for the active substance **etridiazole**

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 etridiazole 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 etridiazole, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Etridiazole 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[1], 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[2] 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 etridiazole was not included through Commission Decision 2008/934/EC[3].

In accordance with Article 13 of Regulation (EC) No 33/2008[4], Chemtura Europe Ltd, the sole data submitter presented, on 4 June 2009 a request to the Netherlands, the designated rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

The Netherlands 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 2 December 2009 and included a recommendation as to include etridiazole in Annex I for the supported uses.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member

[1] O.J. No L 230, 19.8.1991
[2] O.J. No L 224, 21.8.2002
[3] OJ No L 333, 11.12.2008, p.11
[4] OJ No L 252, 20.9.2008, p. 37

States as well as by Chemtura Europe Ltd, being the sole data submitter, on 4 December 2009 by making it available.

In accordance with the provisions of Article 20 of Regulation (EC) No 33/2008, on the basis of the draft assessment report, additional report and comments received through the above consultation, the Commission asked EFSA to deliver its conclusion on the substance.

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 etridiazole[5] 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 **2011/29/EU**[6] concerning the inclusion of etridiazole in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing etridiazole 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.

---

[5] European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance etridiazole. EFSA Journal 2010;8(10):1823. [66 pp.]. doi:10.2903/j.efsa.2010.1823. Available online: www.efsa.europa.eu/efsajournal.htm.

[6] OJ L 61, 8.3.2011, p. 9–13.

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 etridiazole 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 etridiazole 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	0.015 mg/kg bw/day
ARfD	0.15 mg/kg bw
AOEL	0.03 mg/kg bw/day

With particular regard to residues, acute and chronic consumer risk assessments are not relevant for the supported uses.

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 etridiazole is given in Appendix I.

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

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 etridiazole

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 :

- in assessing applications to authorise plant protection products containing etridiazole for uses other than on ornamental plants, Member States shall pay particular attention to the criteria in Article 4(1)(b), and shall ensure that any necessary information is provided before such an authorization is granted;

- only uses as fungicide in non-soil bound systems in greenhouse may be authorised;

- the risk to operators and workers. Member States shall ensure that conditions of use include the application of appropriate risk mitigation measures;

- appropriate waste management practices to handle the waste water from irrigation of non-soil bound growing systems. Member States permitting the release of waste water into the sewage system or into natural water bodies, shall ensure that an appropriate risk assessment is carried out;

- the risk to aquatic organisms. Member States shall ensure that conditions of use include the application of appropriate risk mitigation measures.

7. List of studies to be generated

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

The concerned Member States shall request the submission of confirmatory information as regards:

(1) the specification of the technical material, as commercially manufactured, by appropriate analytical data, including information on the relevance of the impurities;

(2) the equivalence between the specifications of the technical material, as commercially manufactured, and those of the test material used in the ecotoxicity dossiers;

(3) the relevance of the plant metabolites 5-hydroxy-ethoxyetridiazole acid and 3-hydroxymethyletridiazole;

(4) the indirect exposure of groundwater and of soil-dwelling organisms to etridiazole and to its soil metabolites dichloro-etridiazole and etridiazole acid;

(5) the long-range and short-range transport through the atmosphere of etridiazole acid.

The Member States concerned shall ensure that the applicant submits to the Commission the information set out in points (1) and (2) six months after date of entry into force of the Directive of inclusion and the information set out in points (3), (4) and (5) by 31 May 2013.

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

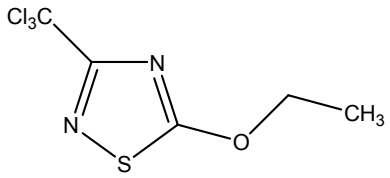
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion.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

APPENDIX I

Identity
ETRIDIAZOLE

Common name (ISO)	Etridiazole
Chemical name (IUPAC)	ethyl-3-trichloromethyl-1,2,4-thiadiazol-5-yl ether
Chemical name (CA)	5-ethoxy-3-trichloromethyl-1,2,4-thiadiazole
CIPAC No	518
CAS No	2593-15-9
EEC No	219-991-8
FAO SPECIFICATION	No specification exists at the time of evaluation
Minimum purity	970 g/kg
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	
Molecular formula	$C_5H_5Cl_3N_2OS$
Molecular mass	247.5
Structural formula	

APPENDIX II
List of uses supported by available data
ETRIDIAZOLE

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		
Non-soil boundglass house ornamental crops	EU	AATERRA ME	G	Soil and root fungi (*Pythium & Phytophthora*)	ME	700 g/l	Application through drip-irrigation	n.a.	1-2	2 weeks	-	1000 min	0.7 g/m^2 substrate (7 kg/ha)	n.a.	

∗ For uses where the column "Remarks" is marked in grey further consideration is necessary.

(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)
(b) Outdoor or field use (F), glasshouse 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
(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) PHI - minimum pre-harvest interval
(m) Remarks may include: Extent of use/economic importance/restrictions