



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Clofentezine
SANCO/828/08 – final¹
11 May 2010

Review report for the active substance **clofentezine**

Finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
14 March 2008

in view of the inclusion of clofentezine 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 clofentezine, 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. Clofentezine 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, Makhteshim Agan International Coordination Centre notified to the Commission of their wish to secure the inclusion of the active substance clofentezine in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EC) No 451/2000, the Commission, designated the United Kingdom as rapporteur Member State to carry out the assessment of clofentezine on the basis of the dossiers submitted by the notifier. In Regulation (EC) No 1490/2002 the Commission specified furthermore that the deadline for the notifier with regard to the submission to the rapporteur Member States of the dossiers required under Article 7(2) of Regulation (EC) No 1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

¹ On 11 May 2010 the Standing Committee on Food Chain and Animal Health has taken note of the amendments of chapter 1, 3, 5, 6 and 7 and appendix II based on the EFSA Scientific Report (2009) 269, 1-113 of 4 June 2009.

² OJ No L 55, 29.02.2000, p.25.

³ 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).

Makhteshim Agan International Coordination Centre 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 Makhteshim Agan International Coordination Centre was considered to be the sole data submitter.

In accordance with the provisions of Article 10(1) of Regulation (EC) No 1490/2002, the United Kingdom submitted on 22 August 2005 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 clofentezine in Annex I to the Directive. Moreover, in accordance with the provisions of Article 10(2) of Regulation (EC) 1490/2002, the Commission and the Member States received also the summary dossier on clofentezine from the notifier.

In accordance with the provisions of Article 11 of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Makhteshim Agan International Coordination Centre being the sole data submitter, on 17 February 2006 by making it available.

In accordance with the provisions of Article 11a of Regulation 1490/2002 as last amended by Regulation (EC) 1095/2007 the Commission examined the draft assessment report, the recommendations by the rapporteur Member State and the comments received from other Member States in consultation with experts from a certain number of Member States.

In accordance with the provisions of Article 11b and Article 12 (1) a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, the Commission referred on 14 March 2008 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 14 March 2008.

Finally, in compliance with the provisions of Article 12a of Regulation (EC) No 1490/2002 as last amended by Regulation (EC) 1095/2007, EFSA delivered its conclusions on clofentezine on 4 June 2009⁴. The Commission referred on 10 May 2010 an updated review report to the Standing Committee on the Food Chain and Animal Health, for examination. The updated review report was finalised in the meeting of the Standing Committee on 11 May 2010 as revision number 3.

The present review report contains the conclusions of the final examination by the Standing Committee.

2. Purposes of this review report

This review report, including the background document appendices thereto, has been developed in support of Directives **2008/69/EC**⁵ and **2010/39/EU**⁶ concerning the inclusion of clofentezine in Annex I to Directive 91/414/EEC. The Commission shall request the EFSA to deliver its view on the draft review reports by 31 December 2010 at the latest. When the Member States decide on individual plant protection products containing clofentezine they shall take into account this review report 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. However, when the EFSA has delivered its view on the draft review report, the Commission shall revise it.

⁴ EFSA Scientific Report (2009) 269, 1-113.

⁵ Commission Directive 2008/69/EC (OJ L 172, 02.07.2008, p. 9)

⁶ Commission Directive 2010/39/EC (OJ L 156, 23.06.2010, p. 7-11)

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 13 of Regulation (EC) No 1490/2002, 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 clofentezine 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 clofentezine containing plant protection product for which Member States will grant or review the authorisation.

Furthermore, these indications were reached within the framework of the uses which were proposed and supported by the main 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: 0.02 mg/kg bw/day

ARfD was not set, not appropriate.

AOEL: 0.01 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. A highest Theoretical Maximum Daily Intake (TMDI; excluding water and products of animal origin) of 7% was identified for toddler using French diet data.

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

As an ARfD is not appropriate, the estimates for the acute dietary exposure of adults and toddlers have not been calculated.

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.

It has also been 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

The identity of clofentezine is given in Appendix I.

The active substance shall comply with the FAO specification and there seem not to be reasons for deviating from that specification; the FAO specification is given in Appendix I of this report.

It has been established that for the active substance notified by the main 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 clofentezine

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:

- the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material;
- the operator and worker safety and ensure that conditions of use prescribe the application of adequate personal protective equipment where appropriate;
- the potential for long range transport via air;

- the risk to non target organisms. Conditions of authorisation shall include risk mitigation measures, where appropriate.

7. List of studies to be generated

The Member States concerned shall ensure that the notifier presents to the Commission not later than 31 July 2011 a monitoring programme to assess the long-range atmospheric transport of clofentezine and related environmental risks. The results of this monitoring shall be submitted as a monitoring report to the rapporteur Member State and to the Commission by 31 July 2013 at the latest.

The Member States concerned shall ensure that the notifier submits by 31 June 2012 at the latest information on clofentezine metabolites relating to their toxicological and environmental risk assessment.

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 Scientific report (pag 37-39).

8. Information on studies with claimed data protection

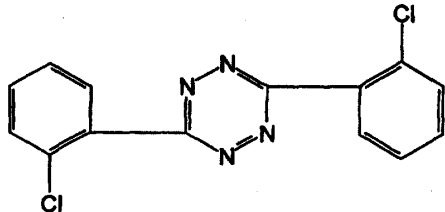
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the main data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I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

APPENDIX I**Identity**

CLOFENTEZINE

Common name (ISO)	Clofentezine
Chemical name (IUPAC)	<i>3,6-bis (2-chlorophenyl)-1,2,4,5-tetrazine</i>
Chemical name (CA)	3,6-bis (2-chlorophenyl)-1,2,4,5-tetrazine
CIPAC No	418
CAS No	74115-24-5
EEC No	277-728-2
FAO SPECIFICATION	980 g/kg (FAO Specification 418/TC, 1995)
Minimum purity	980 g/kg clofentezine
Molecular formula	C ₁₄ H ₈ Cl ₂ N ₄
Molecular mass	303.1
Structural formula	

APPENDIX II

List of uses supported by available data

CLOFENTEZINE

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		
Strawberries	B, E, F, I, NL	Apollo 50 SC	F	E. carpini, P.ulmi	SC	500	Foliar, hydrolic	At occurrence - 85	1	NR	0.01-0.02	500-1500	0.1-0.2	3	
Roses (Ornamentals)	B, F, I, NL	Apollo 50 SC	F/G	Tetranychus ssp.	SC	500	Foliar, hydrolic	At occurrence	1	NR	0.015-0.02	500-2500	0.15-0.2	n.a.	

- Remarks:**
- (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 plants - type of equipment used must be indicated
 - (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) The minimum and maximum number of application possible under practical conditions of use must be provided
 - (l) PHI - minimum pre-harvest interval
 - (m) Remarks may include: Extent of use/economic importance/restrictions