



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Myclobutanil
SANCO/13039/2010 final
23 November 2010

Review report for the active substance

myclobutanil

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

Myclobutanil 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 market¹, with a view to the possible inclusion of this substance in Annex I to the Directive.

Article 11(e) of Commission Regulation (EC) No 1490/2002² 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. The notifier withdrew its support and myclobutanil was not included through Commission Decision 2008/934/EC³.

In accordance with Article 13 of Regulation (EC) No 33/2008⁴, Dow AgroScience, the sole data submitter presented, on 24 April 2009 a request to Belgium, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Belgium finalised in October 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 22 October 2009 and included a recommendation as to include myclobutanil in Annex I for the supported uses.

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

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 Dow AgroScience being the sole data submitter, on 26 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 conclusions.

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 myclobutanil⁵. 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 **2011/2/EU**⁶ concerning the inclusion of myclobutanil in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing myclobutanil 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

⁵ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance myclobutanil. EFSA Journal 2010 8(10) 1682 [83pp]. doi: 10.2903/jefsa.2010.1682 Available online: www.efsa.europa.eu/efsajournal.htm

⁶ OJ L 3, 6.1.2011, p. 7–8

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 myclobutanil 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 myclobutanil 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	0.025 mg/kg bw/day
ARfD	0.31 mg/kg bw
AOEL	0.03 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 $\leq 16\%$ of the Acceptable Daily Intake (ADI), (EFSA PRIMo). 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 ($\leq 21\%$).

The review has identified 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 myclobutanil 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 myclobutanil.

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.

7. List of studies to be generated

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

The concerned Member States shall request the submission of further information on the residues of myclobutanil and its metabolites in following growing seasons, in addition to further information to confirm that the available residue data cover all compounds of the residue definition.

They shall ensure that the notifier at whose request myclobutanil has been included in this annex provide such studies to the Commission within two years from the entry into force of the Directive of inclusion.

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 myclobutanil in Annex I of the Directive.

APPENDIX I**Identity
MYCLOBUTANIL**

Common name (ISO)	Myclobutanil
Chemical name (IUPAC)	RS)-2-(4-chlorophenyl)-2-(1H-1,2,4-triazol-1-ylmethyl)hexanenitrile
Chemical name (CA)	α -butyl- α -(4-chlorophenyl)-1 <i>H</i> -1,2,4-triazole-1-propanenitrile
CIPAC No	442
CAS No	88671-89-0
EEC No	410-400-0
FAO SPECIFICATION	Not available
Minimum purity	925 g/kg (industrial scale production) (racemic mixture, i.e. ratio of R/S-isomers = 1:1)
Identity of relevant impurities (of toxicological, ecotoxicological and/or environmental concern)	1-methylpyrrolidin-2-one max. 1 g/kg
Molecular formula	C ₁₅ H ₁₇ ClN ₄
Molecular mass	288.8 g/mol
Structural formula	

