



EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Methomyl
SANCO/5449/2009 final
1 September 2009

FINAL
Review report for the active substance **methomyl**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
12 June 2009
in view of the inclusion of methomyl 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 methomyl, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Methomyl is a substance that was covered by the second 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, methomyl has not been included through Commission Decision 2007/628/EC¹ as, on the basis of the available information, it has not been demonstrated that the risk to operators, workers, bystanders, birds, mammals, aquatic organisms, bees and non-target arthropods was acceptable. All information as regards this initial evaluation is recorded in the relevant Commission Review Report (document SANCO/10038/2006 final of 29 September 2007).

In accordance with Article 13 of Regulation (EC) No 33/2008, DuPont de Nemours (Deutschland GmbH), the sole data submitter presented, on 11 February 2008 a request to the United Kingdom, the original rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

The United Kingdom finalised in May 2008 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 15 May 2008 and included a recommendation as to include methomyl 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 Dupont de Nemours being the sole data submitter, on 23 June 2008 by making it available.

¹ OJ No L 2556, 29.9.2007, p.40.

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 methomyl (re-issued on 19 December 2008)²]. 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 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 June 2009

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 2009/115/EC³ concerning the inclusion of methomyl in Annex I to Directive 91/414/EEC, and to assist the Member States in decisions on individual plant protection products containing methomyl 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 *EFSA Scientific Report (2008) 222 – Conclusion regarding the peer review of the pesticide risk assessment of the active substance methomyl (re-issued on 19 December 2008).*

³ OJ L 228, 1.9.2009, p. 17–19.

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 methomyl 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 methomyl 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	0.0025 mg/kg bw/day
ARfD	0.0025 mg/kg bw/day
AOEL	0.0025 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; excluding water and products of animal origin) for a 70 kg adult is 6 % of the Acceptable Daily Intake (ADI), (WHO cluster B diet). 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 model, tomato: critical consumer - UK diet- = infant: 40%)

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 methomyl 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.

The review has established that for the active substance notified by the 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 methomyl

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:

Member States should pay particular attention to:

- the operator safety: conditions of use shall prescribe the use of adequate personal protective equipment. Special attention shall be paid to the exposure of operators using knapsacks or other hand-held application equipment;
- the protection of birds;
- the protection of aquatic organisms: conditions of authorisation shall include risk mitigation measures, where appropriate, such as buffer zones, reduction of run-off and drift reduction nozzles;
- the protection of non-target arthropods, in particular bees: risk mitigation measures to avoid all contact with bees shall be applied.

Member States must ensure that methomyl-based formulations contain effective repelling and/or emetic agents.

Where appropriate, conditions of authorisation shall include further risk mitigation measures.

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 methomyl in Annex I under the current inclusion conditions.

8. Information on studies with claimed data protection

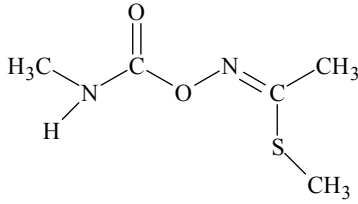
For information of any interested parties, the rapporteur Member State will keep available a document which gives information about the studies for which the data submitter has claimed data protection and which during the re-evaluation process were considered as essential with a view to annex I inclusion.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

APPENDIX I**Identity****METHOMYL**

Common name (ISO)	Methomyl
Chemical name (IUPAC)	S-methyl (EZ)-N-(methylcarbamoyloxy)thioacetimidate
Chemical name (CA)	Methyl N-[[[(methylamino)carbonyl]oxy]ethanimidothioate
CIPAC No	264
CAS No	16752-77-5
EEC No	240-815-0
FAO SPECIFICATION	980 g/kg [264/TC (2002)]
Minimum purity	980 g/kg
Molecular formula	C ₅ H ₁₀ N ₂ O ₂ S
Molecular mass	162.2 g/mol
Structural formula	

APPENDIX II
List of uses supported by available data
METHOMYL

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 a.s. (i)	method kind (f-h)	growth stage & season (j)	number min/max x (k)	interval between applications (min)	kg as/hl min/max	water l/ha min/max	kg as/ha max		
Cucumber/ Courgette Tomato/ aubergine (eggplant)	SEU	Lannate 20 SL	F	Biting and sucking insects	SL	200 g/L	MV/HV; foliar	Pre-harvest starting from BBCH 20	1-2	14	0.025	1000	0.25	7	

- 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
 - (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) 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