



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Metam  
SANCO/206/2008 – final  
28 July 2009

Review report for the active substance **metam**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting  
on 26 February 2009

in support of a decision concerning the non-inclusion of metam in Annex I of Directive  
91/414/EEC and the withdrawal of authorisations for plant protection products containing  
this active substance

**1. Procedure followed for the re-evaluation process**

This review report has been established as a result of the re-evaluation of metam, 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<sup>(1)</sup> 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<sup>(2)</sup>, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Metam is one of the existing active substances covered by this Regulation.

In accordance with the provisions of Article 10 of Regulation (EC) No 451/2000, Taminco notified to the Commission of its wish to secure the inclusion of the active substance metam in Annex I to the Directive.

Under Annex I to Regulation (EC) No 1490/2002, Belgium has been designated by the Commission as rapporteur Member State to carry out the assessment of metam 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(1) of Regulation (EC) No

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<sup>1</sup> OJ No L 55, 29.02.2000, p.25. Regulation as last amended by Regulation (EC) No 1044/2003 (OJ L 151, 19.6.2003, p.32).

<sup>2</sup> 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).

1490/2002, as well as for other parties with regard to further technical and scientific information was 30 November 2003.

Taminco 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, Taminco was considered to be the main data submitter.

In accordance with the provisions of Article 10(1) of Regulation 1490/2002, Belgium submitted on 10 September 2007 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 metam 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 metam from the notifier.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, the EFSA organised the consultation on the draft assessment report by all the Member States as well as by Taminco being the main data submitter, on 4 October 2007 by making it available.

In accordance with the provisions of Article 11c (1) of Regulation (EC) No 1490/2002, 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.

In accordance with the provisions of Article 11c of Regulation (EC) No 1490/2002, 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 metam (finalised 26 November 2008)]<sup>3</sup>. 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 12 of Regulation (EC) No 1490/2002, the Commission referred on 26 February 2009 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 26 February 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 has been developed and finalised in the context of the Council Decision **2009/562/EC** concerning the non-inclusion of metam in Annex I to Directive 91/414/EEC.

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.

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<sup>3</sup> EFSA Scientific Report (2008) nr 203.

### 3. Overall conclusion in the context of Directive 91/414/EEC

The overall conclusion of this examination, based on the information available and the proposed conditions of use, is that:

- **the information available is insufficient** to satisfy the requirements set out in Annex II and Annex III Directive 91/414/EEC in particular with regard to:
  - the risk to consumers given the data gaps identified in the residue section and the possible impact of the relevant impurity DMTU; as a consequence, the consumers risk assessment could not be finalised;
  - the fate and behaviour in soil and water due to inadequate information on the major metabolite MITC and impurity DMTU. As a consequence, the risk to groundwater, could not be finalised;
  - MITC is volatile and long range transport and potential effects on the atmosphere need to be further addressed;
  - The risk assessment of acute effects of metam and its metabolite MITC to terrestrial vertebrates feeding on soil invertebrates
  - Further information is required to address the recovery potential of the non target arthropods, earthworms and non target soil macro-organisms.
  
- **concerns were identified with regard to**
  - the potential for contamination of groundwater by the major metabolite MITC in some scenarios
  - the risk assessment for operators and workers in greenhouses
  - risk to aquatic organisms.

In conclusion from the assessments made on the basis of the submitted information, no plant protection products containing the active substance concerned is expected to satisfy in general the requirements laid down in Article 5 (1) (a) and (b) of Council Directive 91/414/EEC.

Metam should therefore not be included in Annex I to Directive 91/414/EEC.