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Conclusion on the focussed peer review of chlorthal-dimethyl

CONCLUSION ON PESTICIDE PEER REVIEW

Conclusion regarding the focussed peer review of the pesticide risk assessment of the active substance chlorthal-dimethyl

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Chlorthal-dimethyl is one of the 79 substances of the third stage Part A of the review programme covered by Commission Regulation (EC) No 1490/2002[1]. This Regulation requires the European Food Safety Authority (EFSA) to organise upon request of the EU-Commission a peer review of the initial evaluation, i.e. the draft assessment report (DAR), provided by the designated rapporteur Member State.

Chlorthal is the ISO common name for tetrachloroterephthalic acid (IUPAC). Due to the fact that chlorthal-dimethyl, a variant of chlorthal, is used in the formulated product, it should be noted that the evaluated data belong to the variant chlorthal-dimethyl, unless otherwise specified.

Greece being the designated rapporteur Member State submitted the DAR on chlorthal-dimethyl in accordance with the provisions of Article 10(1) of the Regulation (EC) No 1490/2002, which was received by the EFSA on 31 October 2006. The peer review was initiated on 6 July 2007 by dispatching the DAR for consultation of the Member States and the sole applicant AMVAC Chemical UK Limited. Subsequently, the comments received on the DAR were examined and responded by the rapporteur Member State in the reporting table. On 3 April 2008 the EFSA received an addendum to the DAR for the section on mammalian toxicology prepared by Greece, summarising studies, which had been available before the DAR was sent to the EFSA. Greece sent a copy of the addendum to the notifier on 21 July 2008 inviting the submission of comments by 15 September 2008.

In accordance with Article 11c of the Commission Regulation (EC) No 1490/2002[1], instead of requesting the organisation of a full peer review the EU-Commission asked the EFSA in a letter dated 4 June 2008 to focus on specific points including points related to criteria set out in Annex VI. These specific points were:
The toxicology and in particular the proposed classification as a carcinogen category 3
The relevance of the metabolite MPA
The amount of the metabolite MPA found in groundwater

[1] OJ No L 224, 21.08.2002, p. 25, as amended by Regulation (EC) No 1095/2007 (OJ L 246, 21.9.2007, p. 19)

On 18 July 2008 the EFSA started the focussed peer review on the specific points by distributing the addendum of March 2008 to Member States and inviting comments. Comments were submitted by Sweden, Austria, Germany, the United Kingdom, Denmark and France taking into account the evaluation of the studies summarised in the addendum of March 2008. These comments have been taken into consideration and were evaluated by the EFSA as summarised in the last column of the discussion table of the report of the focussed peer review.

A discussion of the outcome of the consultation of Member States took place during a written procedure in August 2008 leading to the conclusions as laid down in this report.

The notifier's comments were only available after the legal deadline for the EFSA to issue the conclusion. By letter received on 31 October 2008 the EU Commission asked the EFSA to consider the notifier's comments and to amend the EFSA conclusion if necessary by 30 November 2008.

The notifier submitted several comments, which were distributed to all Member States and discussed during a written procedure. Comments were submitted by France, Hungary and Greece and EFSA provided comments as well, as set out in Appendix 2 of the report on the focussed peer review.

Conclusion:

In agreement with the majority of the commenting Member States and the evaluation of the rapporteur Member State the EFSA concludes that

- the proposed classification is agreed. and
- the metabolite MPA must be considered relevant, and
- the metabolite MPA leaches to groundwater above 0.1 µg/L in all scenarios.

The information presented in the addendum and the comments presented by the notifier do not change the overall conclusion drawn by the rapporteur Member State in the DAR on the section of mammalian toxicology, as the majority of Member States confirmed that the studies presented (from 1963) are not adequate for the purpose of clarifying the carcinogenic properties of the active substance. For the section on fate and behaviour in the environment no additional data were submitted in the addendum.

According to the conclusions of the DAR, the active substance is proposed to be classified as Carc. Cat. 3. No convincing evidence has been provided that the metabolite MPA will not lead to any risk of carcinogenicity, therefore it must be considered relevant. According to the evaluation presented in

the DAR for the section on fate and behaviour the metabolite MPA exceeds the concentration in the groundwater of 0.1 µg/L in all scenarios.

Chlorthal-dimethyl clearly fulfils the Annex VI criteria of Commission Regulation (EC) No 1490/2002 as amended by Commission Regulation (EC) No 1095/2007.

The conclusion was reached on the basis of the evaluation of the representative uses as a herbicide to control grasses and annual dicotyledonous weeds on strawberry and ornamentals as proposed by the notifier.

Key words: chlorthal-dimethyl, peer review, risk assessment, pesticide, herbicide