



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Methyl bromide
SANCO/10068/2011 final
28 January 2011

Review report for the active substance **methyl bromide**
finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
28 January 2011
in support of a decision concerning the non-inclusion of methyl bromide 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 methyl bromide, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Methyl bromide 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.

At the outcome of that evaluation, methyl bromide has not been included through Commission Decision 2008/753/EC² as, on the basis of the available information, there were clear indications that it may be expected that methyl bromide has harmful effects on human health and in particular on bystanders, because the exposure is greater than 100% of the AOEL and consumers, because the exposure is greater than 100% of the ADI and the ARfD. Moreover, other concerns which were identified by the rapporteur Member States in its assessment report were included in the relevant Commission Review Report (document SANCO/1059/2008 finalised on 20 May 2008).

In accordance with Article 13 of Regulation (EC) No 33/2008³, in agreement with the original notifier, Desclean Belgie N.V., the sole data submitter presented on 16 March 2009 a request to United Kingdom, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

¹ OJ No L 230, 19.8.1991

² OJ No L 258, 26.9.2008

³ OJ No L 15, 18.1.2008

The United Kingdom finalised in November 2009 its examination, in the form of an additional report to the original Draft Assessment Report. This Report was received by the Commission and the European Food Safety Authority on 26 November 2009.

The EFSA organised the consultation on the draft assessment report and, in accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, on the additional report by all the Member States as well as by Desclean Belgie N.V., being the sole data submitter, on 27 November by making it available.

The EFSA reviewed the additional report and the comments received thereon and in accordance with the provisions of Article 20 of Regulation (EC) No 33/2008 sent to the Commission its conclusion on the risk assessment [Conclusions regarding the peer review of the pesticide risk assessment of the active substance methyl bromide (issued on 3 November 2010)⁴]. 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 28 January 2011.

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 Decision **2011/120/EU**⁵ concerning the non-inclusion of methyl bromide in Annex I to Directive 91/414/EEC.

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.

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

The overall conclusion of this evaluation, 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 quantification of the bystander exposure;
- The indirect environmental exposure assessment;
- The estimated concentrations in air around the treated containers;
- The risk to non target organisms from indirect exposure.

⁴ **Error! Reference source not found.; Error! Reference source not found.** methyl bromide. **Error! Reference source not found.** [3 pp.]. doi:10.2903/j.efsa.2011.1893. Available online: www.efsa.europa.eu/efsajournal.

⁵ OJ L 47, 22.2.2011, p. 19–20

- **concerns were identified with regard to**

- The lack of reliable data on bystander exposure to allow a valid quantitative risk assessment;
- The uncertainties in the evaluation of the operator and worker risk assessment.

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.

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