



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Asulam

SANCO/10240/2011 rev.3

14 July 2011

### Review report for the active substance **asulam**

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting  
on 14 July 2011  
in view of the non approval of asulam as active substance in accordance with Regulation  
(EC) No 1107/2009

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

This review report has been established as a result of the re-evaluation of asulam, made in the context of a new application by the data submitter after the non-inclusion of this substance to Annex I of Directive 91/414/EEC.

Asulam 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 market<sup>1</sup>, with a view to the possible inclusion of this substance in Annex I to the Directive.

Commission Regulation (EC) No 451/2000<sup>2</sup> and No 1490/2002<sup>3</sup> lay down the detailed rules for the implementation of the third stage of the programme. In particular, Article 11e of Regulation (EC) No 1490/2002 sets specific conditions for the notifier to withdraw its support. All notifiers withdrew their support and asulam was not included through Commission Decision 2008/934/EC<sup>4</sup>.

In accordance with Article 13 of Regulation (EC) No 33/2008<sup>5</sup>, United Phosphorus Limited, the sole data submitter presented, on 1 May 2009 a request to the United Kingdoms, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

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<sup>1</sup> OJ No L 230, 19.8.1991

<sup>2</sup> OJ No L 55, 29.2.2000

<sup>3</sup> OJ No L 224, 21.8.2002

<sup>4</sup> OJ No L 333, 11.12.2008

<sup>5</sup> OJ No L 15, 18.1.2008

The United Kingdoms 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 6 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 United Phosphorus Limited, being the sole data submitter, on 11 November 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 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 asulam (issued on 23 September 2010)<sup>6</sup>]. 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 14 July 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 Implementing **Regulation (EU) No 1045/2011**<sup>7</sup> concerning the nonapproval of asulam as active substances under Regulation (EC) No 1107/2009.

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 Regulation (EC) No 1107/2009**

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 Regulation (EC) No 544/2011 as regards the data requirements for active substances and

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<sup>6</sup> European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance asulam. EFSA Journal 2010,8(12):1822.. [71 pp.]. doi:10.2903/j.efsa.2010.1822. Available online: [www.efsa.europa.eu](http://www.efsa.europa.eu)

<sup>7</sup> OJ L 275, 20.10.2011, p. 23

Regulation (EC) No 545/2011 as regards the data requirements for plant protection products, in particular with regard to:

- the toxicological properties of the metabolite sulfanilamide
- the residue definition for risk assessment
- the processing studies
- the toxicological assessment of impurities.

- **concerns were identified with regard to**

- the risk to consumers
- the risk to birds
- the risk to terrestrial non-target plants

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.

Asulam should therefore not be approved in accordance with Regulation (EC) No 1107/2009.