



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

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

Propisochlor
SANCO/10190/2011 final
24 March 2011

Review report for the active substance **propisochlor**

in support of a decision concerning the non-inclusion of propisochlor 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 propisochlor, made in the context of a new application by the data submitter after the non-inclusion of this substance.

Propisochlor is a substance that was covered by the fourth 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.

Article 24(e) of Commission Regulation (EC) No 2229/2004 laying down detailed rules for the implementation of the fourth stage offered the possibility for the notifier to withdraw, under specific conditions, its support for the active substance. The notifier withdrew his support and propisochlor was not included through Commission Decision 2008/941/EC².

In accordance with Article 13 of Regulation (EC) No 33/2008³, Arysta Life Science S.A.S., the sole data submitter presented, on 29 May 2009 a request to Hungary, the rapporteur Member State, for a new application aiming at Annex I inclusion of the substance.

Hungary 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 30 November 2009.

¹ OJ L 230, 19.8.1991, p. 1.

² OJ L 335, 13.12.2008, p. 91.

³ OJ L 15, 18.1.2008, p. 5.

In accordance with the provisions of Article 19 of Regulation (EC) No 33/2008, the EFSA organised the consultation on the additional report by all the Member States as well as by Arysta Life Science S.A.S, being the sole data submitter, on 3 December 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 based on data submitted in accordance with Regulation (EC) No 33/2008. [Conclusions regarding the peer review of the pesticide risk assessment of the active substance propisochlor (issued on 9 September 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 24 March 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 2011/262/EU**⁵ concerning the non-inclusion of propisochlor 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 in accordance with Regulation (EC) No 33/2008 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 relevance of the impurities present in the technical material,

⁴ European Food Safety Authority; Conclusion on the peer review of the pesticide risk assessment of the active substance propisochlor. EFSA Journal 2010; 8(9):1769. [60 pp.]. doi:10.2903/j.efsa.2010.1769. Available online: www.efsa.europa.eu

⁵ OJ L 111, 30.4.2011, p. 19–21

- the toxicological relevance of several metabolites (M2⁶, M7⁷, M12⁸, M14⁹, M17¹⁰, M20¹¹, M22¹² and M35¹³) to perform a reliable consumer risk assessment and to conclude on a residue definition for propisochlor,
- the groundwater exposure assessment for major soil metabolite M9¹⁴
- the aquatic risk assessment of several metabolites (M1¹⁵, M2, M5¹⁶, M7¹⁷ and M9) could not be finalised.

- **concerns were identified with regard to**

- potential groundwater contamination of several metabolites (M1, M2, M5, M7 and M9) with unknown toxicological and ecotoxicological relevance with expected concentrations much greater than the parametric drinking water limit of 0,1 µg/l set in Annex VI of Directive 91/414/EEC in several scenarios in the FOCUS models for groundwater leaching,
- very high potential of groundwater exposure by non-relevant metabolite M4 over a wide range of geo-climatic conditions,
- the high acute risk to herbivorous birds,
- the high long term risk to herbivorous mammals,
- the risk to earthworm-eating mammals,
- the high chronic risk to earthworms for metabolite M2.

In conclusion from the assessments made on the basis of the information submitted in accordance with Regulation (EC) No 33/2008, 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.

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

⁶ 2-[(2-ethyl-6-methylphenyl) (isopropoxymethyl)amino]-2-oxoethane sulfonic acid

⁷ ({2-[(2-ethyl-6-methylphenyl) (isopropoxymethyl)amino]-2-oxoethyl} sulfinyl) acetic acid

⁸ unidentified compound in maize forage and sunflower seeds

⁹ 3-({2-[(2-ethyl-6-methylphenyl)amino]-2-oxoethyl} sulfinyl)-2-hydroxypropanoic acid

¹⁰ N-(2-ethyl-6-methylphenyl)-2-(hexopyranosyloxy)-N-[(propan-2-yloxy)methyl]acetamide

¹¹ methyl 3-[(2-[(2-ethyl-6-methylphenyl)](propan-2-yloxy)methyl]amino}-2-oxoethyl)sulfinyl]-2-hydroxypropanoate

¹² unidentified compound in maize grain, sugar beet root and sunflower seeds

¹³ unidentified compound in sunflower seeds

¹⁴ dimer of N-(2-ethyl-6-methyl phenyl)-N-(isopropoxymethyl)-2-(mercapto) acetamide

¹⁵ 2-[(2-ethyl-6-methylphenyl) amino]-2-oxoethane sulfonic acid

¹⁶ N-(2-ethyl-6-methylphenyl)-2-hydroxy-N-(isopropoxymethyl)acetamide

¹⁷ ({2-[(2-ethyl-6-methylphenyl) (isopropoxymethyl)amino]-2-oxoethyl} sulfinyl) acetic acid