



EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate D - Food Safety: Production and distribution chain
Unit D.3 - Chemicals, contaminants and pesticides

Alachlor
SANCO/4331/2000 - final
10 January 2007

Review report for the active substance alachlor

finalised in the Standing Committee on the Food Chain and Animal Health at its meeting on
4 April 2006

in support of a decision concerning the non-inclusion of alachlor 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 alachlor, 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 (EEC) No 3600/92⁽¹⁾ laying down the detailed rules for the implementation of the first stage of the programme of work referred to in Article 8(2) of Council Directive 91/414/EEC, as last amended by Regulation (EC) No 2266/2000⁽²⁾, has laid down the detailed rules on the procedure according to which the re-evaluation has to be carried out. Alachlor is one of the 90 existing active substances covered by this Regulation.

In accordance with the provisions of Article 4 of Regulation (EEC) No 3600/92, Phytorus SA on 26 July 1993, Monsanto SA on 19 July 1993, I.Pi.Ci. Industria Prodotti Chimici on 30 July 1993, ACI International on 30 July 1993, Makhteshim Agron on 20 July 1993, Industrias Químicas del Vallés on 28 July 1993, Pilar Ibérica SL on 23 July 1993, Helm AG on 23 July 1993, Calliope SA on 21 July 1993, SA John & Stephen B. on 29 July 1993, Tradi-Agri SA on 29 July 1993 and B.V. Luxan on 21 July 1993 notified to the Commission of their wish to secure the inclusion of the active substance alachlor in Annex I to the Directive.

In accordance with the provisions of Article 5 of Regulation (EEC) No 3600/92, the Commission, by its Regulation (EEC) No 933/94⁽³⁾, as last amended by Regulation (EC) No 2230/95⁽⁴⁾, designated Spain as rapporteur Member State to carry out the assessment of alachlor on the basis of the dossiers submitted by the notifiers. In the same Regulation, the Commission specified furthermore the deadline for the notifiers with regard to the submission to the

¹ OJ No L 366, 15.12.1992, p.10.

² OJ No L 259, 13.10.2000, p.27.

³ OJ No L 107, 28.04.1994, p.8.

⁴ OJ No L 225, 22.09.1995, p.1.

rapporteur Member States of the dossiers required under Article 6(2) of Regulation (EEC) No 3600/92, as well as for other parties with regard to further technical and scientific information; for alachlor this deadline was 31 October 1995.

Monsanto SA, SA John & Stephen B, Sabachem International LTD, Phytorus SA and Makhteshim Agan submitted each in time a dossier to the rapporteur Member State. However, according the Spanish Regulation (Article 4 of Orden del Ministerio de la Presidencia de 28 de Marzo de 1996 – BOE 3.04.96) Phytorus SA, as notifier of the active substance Alachlor should have paid the fees for doing the assessment of its dossier, as Phytorus SA did not pay these fees, Phytorus SA must not be considered as notifier. In May 1998 Dow AgroSciences informed the Commission and Member States that Dow AgroSciences would deal in future with all matters concerning the reviews of the dossiers submitted on behalf of Sanachem. In November 1999 Dow AgroSciences informed the Commission, The Regulatory Authorities of the Member States and the Joint Research centre of the European Chemicals Bureau that Dow agroSciences does not wish to proceed any further with its support of the review of Alachlor.

Monsanto SA submitted in time a dossier to the rapporteur Member State which did not contain substantial data gaps, taking into account the supported uses. Therefore Monsanto SA was considered to be the main data submitter.

In accordance with the provisions of Article 7(1) of Regulation (EEC) No 3600/92, Spain submitted on 20 July 1999 to the Commission the report of its examination, hereafter referred to as the draft assessment report, including, as required, a recommendation concerning the possible inclusion of alachlor in Annex I to the Directive. Moreover, in accordance with the same provisions, the Commission and the Member States received also the summary dossier on alachlor from Monsanto SA, on 27 June 2000.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the Commission forwarded for consultation the draft assessment report to all the Member States on 28 January 2000 as well as to Monsanto SA being the main data submitter, on 08 February 2000.

The Commission 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 (peer review), in particular on each of the following disciplines:

- identity and physical /chemical properties ;
- fate and behaviour in the environment ;
- ecotoxicology ;
- mammalian toxicology ;
- residues and analytical methods ;
- regulatory questions.

The meetings for this consultation were organised on behalf of the Commission by the Pesticide Safety Directorate (PSD) in York, United Kingdom, from January to July 2001.

The report of the peer review (i.e. full report) was circulated, for further consultation, to Member States on 27 June 2001 and the main data submitter on 25 August 2001 for comments and further clarification.

In accordance with the provisions of Article 6(4) of Directive 91/414/EEC concerning consultation in the light of a possible unfavourable decision for the active substance the

Commission organised a tripartite meeting with the main data submitter and the rapporteur Member State for this active substance on 19 December 2003.

In accordance with the provisions of Article 7(3) of Regulation (EEC) No 3600/92, the dossier, the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications on the remaining issues, received after the peer review were referred to the **Standing Committee on the Food Chain and Animal Health**, and specialised working groups of this Committee, for final examination, with participation of experts from all Member States. This final examination took place from December 2004 to April 2005, and was finalised in the meeting of the **Standing Committee** on 4 April 2006.

These documents were also submitted to the Scientific Committee for Plants for separate consultation. The report of this Committee was formally adopted on 28 October 2004 (Question N° EFSA-Q-2004-48⁵). The review of alachlor revealed a number of open questions which were addressed by the Scientific Panel on Plant health, Plant protection products and their Residues (PPR). The Scientific Panel was asked to comment on two questions: Is the occurrence of nasal turbinate tumours observed in the rat carcinogenicity study relevant to humans and, if so, is a genotoxic mechanism involved? The second question was whether the information presented for the metabolites 65, 85, 54, 25, 76 and 51, which exceed the level of 0,1 µg/l, sufficient to demonstrate that they are not relevant? In its Opinion⁶ to the first question, the Scientific Panel concludes that the strength of the evidence suggests that a mode of action other than genotoxicity is involved in the occurrence of nasal turbinate tumours observed in the rat carcinogenicity studies. While the mode of action could be relevant to humans, it is extremely unlikely that concentrations of the active metabolite would be achieved to initiate the chain of events terminating in cancer. On the second question, the Scientific Panel concluded that metabolites 65, 54 and 25 have been adequately tested for toxicity, but the toxicity database is inadequate in the case of the soil metabolites 85, 76 and 51. The genotoxicity database is also inadequate for soil metabolites 85, 76 and 51. For metabolite 25 the Scientific Panel was unable to conclude that genotoxicity testing was adequate. It is concluded that whether the information presented for metabolites 65 and 54 is sufficient to demonstrate that they are not relevant, a similar conclusion cannot be reached for metabolites 85, 76, 51 and 25.

The present review report contains the conclusions of the final examination; given the importance of the draft assessment report, the peer review report (i.e. full report) and the comments and clarifications submitted after the peer review as basic information for the final examination process, these documents are considered respectively as background documents A, B and C to this review report and are part of it.

2. Purposes of this review report

This review report including the background documents has been developed and finalised in support of Commission Decision 2006/966/EC concerning the non-inclusion of alachlor in Annex I to Directive 91/414/EEC.

⁵ Opinion of the Scientific Committee on Plants regarding the inclusion of alachlor in Annex I to Council Directive 91/414/EEC concerning the placing of plant protection products on the market.

⁶ Opinion of the Scientific Panel on Plant health, Plant protection products and their Residues on a request from the Commission related to the evaluation of alachlor in the context of Council Directive 91/414/EEC (Question N° EFSA-Q-2004-48) adopted on 28 October 2004

In accordance with the provisions of Article 7(6) of Regulation (EEC) No 3600/92, 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. Moreover the Commission will send a copy of this review report (not including the background documents) to all operators having notified for this active substance under Article 4(1) of this Regulation.

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 environmental fate and toxicology/ecotoxicology of the substance and its metabolites
 - the exposure of operators, workers and bystanders.
- **concerns were identified with regard to**
 - the fate and behaviour of the substance in the environment, in particular the formation of a large variety of degradation products, some of which are of toxicological and/or ecotoxicological concern;
 - its possible impact on operators, workers and bystanders.

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.

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