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**Rotterdam Convention on the Prior Informed
Consent Procedure for Certain Hazardous
Chemicals and Pesticides in International Trade
Chemical Review Committee**

Fourth meeting

Geneva, 10–13 March 2008

Item 5 (b) (i) of the provisional agenda*

**Inclusion of chemicals in Annex III of the Rotterdam
Convention: review of notifications of final regulatory
action to ban or severely restricted a chemical:alachlor**

**Alachlor: Additional supporting documentation provided by the
European Community**

Note by the Secretariat

The Secretariat has the honour to provide, in the annex to the present note, additional supporting documentation provided by the European Community in support of its notification of final regulatory action on alachlor.

* UNEP/FAO/RC/CRC.4/1.



EUROPEAN COMMISSION
DIRECTORATE-GENERAL ENVIRONMENT
Directorate B – Protecting the Natural Environment
ENV.B.3 – Biotechnology, Pesticides & Health

**Documentation provided by
the European Community in support to the notification of a final regulatory
action to severely restrict**

ALACHLOR

in the framework of the

**Convention of Rotterdam
on the Prior Informed Consent procedure for certain hazardous
chemicals and pesticides in international trade**

11 February 2008

FOREWORD

Directive 91/414/EEC provides for the Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were already on the market on 25 July 1993, with a view to their possible inclusion in Annex I to the Directive.

Within this context, a company notified its wish to secure the inclusion of alachlor as an authorised active ingredient. A Member State was designated to undertake a hazard and risk assessment based on the dossier submitted by the notifier.

The assessment report was subject to peer review during which the Commission undertook extensive consultations with experts of the Member States as well as with the notifier. The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH). In addition, the Scientific Committee for Plants was consulted on specific questions.

The evaluation was based on a review of scientific data generated for alachlor and at least one representative formulation in the context of the conditions prevailing in the European Community (intended uses, recommended application rates, good agricultural practices).

Only data that have been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover data reviews were performed and documented according to generally recognized scientific principles and procedures.

The following excerpts of the documentation, which were drafted at an early stage of the review process, have where appropriate been updated in order to reflect subsequent discussions and conclusions.

ANNEX B

ALACHLOR

B - 5: TOXICOLOGY AND METABOLISM

B.5.14.4 Summary of predicted exposure

Predicted total systemic exposures from a representative sample of "worst-case" applications are summarised in Table 5.14.4-1c

Table 5.14.4-1: Estimated operator exposure from a representative sample of use conditions

Crop	Product Name	Application rate (product) (l/ha)	Application rate (as) (kg/ha)	Application volume (spray) (l/ha)	Pack size (l)	Total systemic exposure (mg/kg bw/day)			
						UK POEM		GERMAN	
						No PPE	PPE	No PPE	PPE
Field	Lasso EC	7.0	2.4	400	5	10.46	0.13	0.28	0.0096
Field	Renour	5.0	2.4	150	5	8.21	0.159	0.28	0.0096

PPE = Gloves for mixer/loader and applicator

The AOEL for alachlor has been proposed by the rapporteur at 0.01 mg/kg bw/day.

		UK POEM		German model	
		Total systemic exposure (mg/kg bw/day)	% AOEL	Total systemic exposure (mg/kg bw/day)	% AOEL
Lasso EC	No PPE	10.46	104600	0.28	2800
	PPE	0.13	1300	0.0096	96
Renour	No PPE	8.21	82100	0.28	2800
	PPE	0.159	1590	0.0096	96

In conclusion, based on estimates by the German operator exposure model, all uses of Alachlor result in exposures below the AOEL proposed for alachlor when adequate personal protective equipment is worn during the operations of mixing, loading and application.

Based on estimates by the UK operator exposure model, all uses result in exposures over than the AOEL proposed for alachlor.

Updated information

The final outcome of the peer review on alachlor is reported in the document "End point list-Alachlor-January 2005" and an excerpt of this document is provided below. This document was provided as supporting information together with the notification and is included in Document UNEP/FAO/RC/CRC.4/8/Add1.

The final conclusion of the operator risk assessment as outlined below was that applying the German and the UK operator exposure models, all supported uses result in exposure over the AOEL finally agreed for alachlor.

Excerpt of "End point list-Alachlor-January 2005":

Summary (Annex IIA, point 5.10)

	Value	Study	Safety factor
ADI:	0.0025 mg/kg bw/day	2-year, rat	200
AOEL	0.0025 mg/kg bw/day	2-year, rat	200
Drinking water limit	Not allocated		
ArfD (acute referenece dose)	Not allocated		

Acceptable exposure scenarios (including method of calculation)

Lasso EC Operator	Not accepted for proposed uses with UK POEM and German model
Workers	Accepted for proposed uses
Bystanders	Accepted for proposed uses
Estimation of exposure based on bio-monitoring data	Not accepted for proposed uses.