Rotterdam Convention

Operation of the prior informed consent procedure
for banned or severely restricted chemicals

Decision Guidance Document

ALACHLOR

**Secretariat of the Rotterdam Convention
on the Prior Informed Consent Procedure for
Certain Hazardous Chemicals and Pesticides
in International Trade**

Introduction

The objective of the Rotterdam Convention is to promote shared responsibility and cooperative efforts among Parties in the international trade of certain hazardous chemicals in order to protect human health and the environment from potential harm and to contribute to their environmentally sound use, by facilitating information exchange about their characteristics, by providing for a national decision-making process on their import and export and by disseminating these decisions to Parties. The Secretariat of the Convention is provided jointly by the United Nations Environment Programme (UNEP) and the Food and Agriculture Organization of the United Nations (FAO).

Candidate chemicals[1] for inclusion in the prior informed consent (PIC) procedure under the Rotterdam Convention include those that have been banned or severely restricted by national regulatory actions in two or more Parties[2] in two different regions. Inclusion of a chemical in the PIC procedure is based on regulatory actions taken by Parties that have addressed the risks associated with the chemical by banning or severely restricting it. Other ways might be available to control or reduce such risks. Inclusion does not, however, imply that all Parties to the Convention have banned or severely restricted the chemical. For each chemical included in Annex III of the Rotterdam Convention and subject to the PIC procedure, Parties are requested to make an informed decision whether they consent or not to the future import of the chemical.

At its fifth meeting, held in Geneva from 20 to 24 June 2011, the Conference of the Parties agreed to list alachlor in Annex III of the Convention and adopted the decision-guidance document with the effect that this group of chemicals became subject to the PIC procedure.

The present decision-guidance document was communicated to designated national authorities on 24 October 2011, in accordance with Articles 7 and 10 of the Rotterdam Convention.

Purpose of the decision guidance document

For each chemical included in Annex III of the Rotterdam Convention, a decision-guidance document has been approved by the Conference of the Parties. Decision-guidance documents are sent to all Parties with a request that they make a decision regarding future import of the chemical.

Decision-guidance documents are prepared by the Chemical Review Committee. The Committee is a group of government-designated experts established in line with Article 18 of the Convention, which evaluates candidate chemicals for possible inclusion in Annex III of the Convention. Decision-guidance documents reflect the information provided by two or more Parties in support of their national regulatory actions to ban or severely restrict the chemical. They are not intended as the only source of information on a chemical nor are they updated or revised following their adoption by the Conference of the Parties.

There may be additional Parties that have taken regulatory actions to ban or severely restrict the chemical and others that have not banned or severely restricted it. Risk evaluations or information on alternative risk mitigation measures submitted by such Parties may be found on the Rotterdam Convention website (www.pic.int).

Under Article 14 of the Convention, Parties can exchange scientific, technical, economic and legal information concerning the chemicals under the scope of the Convention including toxicological, ecotoxicological and safety information. This information may be provided directly to other Parties or through the Secretariat. Information provided to the Secretariat will be posted on the Rotterdam Convention website.

Information on the chemical may also be available from other sources.

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1 According to the Convention, the term “chemical” means a substance, whether by itself or in a mixture or preparation and whether manufactured or obtained from nature, but does not include any living organism. It consists of the following categories: pesticide (including severely hazardous pesticide formulations) and industrial.

2 According to the Convention, the term “Party” means a State or regional economic integration organization that has consented to be bound by the Convention and for which the Convention is in force.

Disclaimer

The use of trade names in the present document is primarily intended to facilitate the correct identification of the chemical. It is not intended to imply any approval or disapproval of any particular company. As it is not possible to include all trade names presently in use, only a number of commonly used and published trade names have been included in the document.

While the information provided is believed to be accurate according to data available at the time of preparation of the present decision-guidance document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may arise there from. Neither FAO nor UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of FAO or UNEP concerning the legal status of any country, territory, city or area or of its authorities or concerning the delimitation of its frontiers or boundaries.

STANDARD CORE SET OF ABBREVIATIONS	
<	less than
≤	less than or equal to
<<	much less than
>	greater than
≥	greater than or equal to
µg	Microgram
µm	Micrometre
ADI	acceptable daily intake
ADP	adenosine diphosphate
a.i.	active ingredient
AOEL	Acceptable Operator Exposure level
ARfD	acute reference dose
a.s.	active substance
ATP	adenosine triphosphate
b.p.	boiling point
bw	body weight
^{o}C	degree Celsius (centigrade)
CA	Chemicals Association
CAS	Chemical Abstracts Service
cc	Cubic centimetre
CHO	Chinese hamster ovary
CIPAC	Collaborative International Pesticides Analytical Council
cm	centimetre
CN	Combined Nomenclature
DNA	Deoxyribose Nucleic Acid
DT50	DT_{50} is the time taken for 50 percent of the parent compound to disappear from soil or water by transformation
E.C.	European Community
EC_{50}	Effect concentration, 50%
ED_{50}	Effect dose, 50%
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
FAO	Food and Agriculture Organization of the United Nations
g	Gram
h	hour
ha	Hectare
IARC	international Agency for Research on Cancer
IC_{50}	inhibition concentration, 50%;
ILO	international Labour Organisation
i.m.	intramuscular
i.p.	intraperitoneal
IPCS	international Programme on Chemical Safety
IUPAC	International Union of Pure and Applied Chemistry
JMPR	Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on

STANDARD CORE SET OF ABBREVIATIONS	
	Pesticide Residues)
k	Kilo- (x 1000)
kg	Kilogram
Koc	organic carbon-water partition coefficient
l	Litre
LC_{50}	lethal concentration, 50%
LD_{LO}	lowest lethal dose
LD_{50}	lethal dose, 50%
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m	Metre
mg	Milligram
ml	Millilitre
m.p.	melting point
mPa	MilliPascal
MTD	maximum tolerated dose
ng	Nanogram
NOAEL	no-observed-adverse-effect level
NOEC	No Observed Effect Concentration
NOEL	no-observed-effect level
NTP	National Toxicology Program
OECD	Organisation for Economic Co-operation and Development
PCM	Phase contrast microscopy
PEC	Predicted Environmental Concentration
Pow	octanol-water partition coefficient
PPE	Personal Protective Equipment
ppm	parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).
RfD	reference dose for chronic oral exposure (comparable to ADI)
SMR	standardized mortality ratio
STEL	short term exposure limit
TER	Toxicity Exposure Ratio
TLV	threshold limit value
TWA	time weighted average
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
UV	Ultraviolet
VOC	volatile organic compound
WHO	World Health Organization
wt	Weight

Decision guidance document for a banned or severely restricted chemical

Alachlor **Published: October 2011**

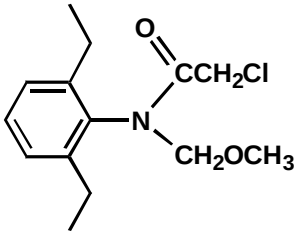
1. Identification and uses (see Annex 1 for further details)

Common name **Alachlor**

Chemical name and other names or synonyms
IUPAC: 2-chloro-2',6'-diethyl-N-methoxymethylacetanilide
CA: 2-chloro-*N*-(2,6-diethylphenyl)-*N*-(methoxymethyl)acetamide

Molecular formula $C_{14}H_{20}ClNO_2$

Chemical structure



CAS-No.(s) 15972-60-8

Harmonized System Customs Code
HS code for alachlor: 2924 29
HS code for preparations containing alachlor: 3808 93

Other numbers
CN code: 2924 29 98
EINECS: 240-110-8
CIPAC: 204
UN: 2588

Category Pesticide

Regulated category Pesticide

Use(s) in regulated category
Alachlor is a herbicide that is absorbed from the soil primarily by the shoots of emerging seedlings. Following absorption it is translocated throughout the plant. The mode of action appears to be inhibition of protein synthesis in susceptible plants.

European Community
Alachlor exerts selective weed control in maize, sweet corn, soybean, sunflower and cotton, controlling annual grasses and small weed broadleaf species, killing susceptible weed species and suppressing growth on some tolerant plants. One application to soil pre-emergence or early post-emergence (2-3 leaf stage) is enough to achieve effective weed control for 60-80 days after application. Generally the dose is between 1.7 and 2.4 kg/ha.

Canada
Herbicide for control of annual grasses and broadleaf weeds in corn and soybeans.

Trade names	Trade names include: Alanex, Bronco, Cannon, Crop Star, Lasso, Lariat, Partner, Reneur, Traton *This is an indicative list. It is not intended to be exhaustive.*
Formulation types	Formulation types: Emulsifiable concentrate (EC), granular (G) or microencapsulated (ME or MT)
Uses in other categories	No information available that would suggest use as an industrial chemical.
Basic manufacturers	Monsanto, Makhteshim-Agan, Phytorus, Shinung Corporation, RPG, Efthymiadis, EMV, Rallis, Cequisa (Pesticide Manual, 2006) *This is an indicative list of current and former manufacturers. It is not intended to be exhaustive.*

2. Reasons for inclusion in the PIC procedure

Alachlor is included in the PIC procedure as a pesticide. It is listed on the basis of the final regulatory actions taken by the European Community and by Canada to ban alachlor as a pesticide.

No final regulatory actions relating to industrial chemical uses have been notified.

2.1 Final regulatory action (see Annex 2 for further details)

European Community

It is prohibited to place on the market or use plant protection products containing alachlor. Alachlor is not included in the list of authorised active ingredients in Annex I to Directive 91/414/EEC.
The authorisations for plant protection products containing alachlor had to be withdrawn by 18 June 2007. From 19 December 2006 no authorisations for plant protection products containing alachlor could be granted or renewed.

Reason: Human Health and Environment

Canada

As of 31 December 1985 all uses banned and all product registrations were cancelled due to carcinogenic potential and existence of a lower risk alternative product (metolachlor). Subsequently the manufacturer requested a review of the regulatory action, under Section 23 of the Pest Control Products Act by an independent review board. The alachlor review board recommended restoration of alachlor registrations, however, the Minister of Agriculture upheld the ban citing appreciable health risk and the availability of an alternative.

Reason: Human Health (Environmental risk was not considered)

2.2 Risk evaluation (see Annex 1 for further details)

European Community

Directive 91/414/EEC provides for the European Commission to carry out a programme of work for the examination of existing active substances used in plant protection products which were on the market on 25 July 1993, with a view to their possible inclusion in Annex I to the Directive. Within this context, a number of companies notified their wish to secure the inclusion of alachlor as an authorised active ingredient. A Member State (Spain) was designated to undertake a hazard and risk assessment based on the dossier submitted by the notifiers.

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 main notifier, Monsanto SA. The results were then reviewed by the Member States and the Commission within the Standing Committee on the Food Chain and Animal Health (SCFCAH). Questions on Alachlor were also submitted to the Scientific Committee for Plants.

The evaluation was based on a review of scientific data generated for alachlor 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 recognised methods

were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognised scientific principles and procedures.

It was concluded that it had not been demonstrated that alachlor fulfilled the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC. Alachlor has been classified as carcinogenic category 3, R40, based on the observation that it caused nasal turbinate tumours in rats. Even though it was considered extremely unlikely, it could not be discarded that such nasal tumours are relevant to humans. Estimates of occupational exposure indicated that exposure would be greater than acceptable levels during the operations of mixing, loading and application even when personal protective equipment was worn. The calculations indicated an unacceptable risk to operators for all uses of alachlor.

Concerns were also 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 eco-toxicological concern.

Canada

The primary concern was occupational exposure. Alachlor was deemed an animal carcinogen with potential as a human carcinogen. Two long-term dietary studies in the rat indicated an increase in incidence of adenomas and adenocarcinomas in the nasal turbinates, and of stomach tumours at a number of doses. Tumours deemed to be biologically significant (though not statistically significant) occurred at dose levels that were within the range of potential occupational exposure estimates.

In addition the presence of alachlor in ground water and the potential of further contamination was also of concern.

Overall it was considered that under the conditions of use in Canada that alachlor represented an unacceptable risk of harm to human health.

3. Protective measures that have been applied concerning the chemical

3.1 Regulatory measures to reduce exposure

European Community	It is prohibited to place on the market or use plant protection products containing alachlor. Alachlor is not included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. The authorizations for plant protection products containing alachlor had to be withdrawn by 18 June 2007. From 19 December 2006 no authorizations for plant protection products containing alachlor could be granted or renewed.
Canada	All uses banned and all product registrations were cancelled as of 31 December 1985.

3.2 Other measures to reduce exposure

European Community
As the regulatory action was a complete ban of all uses of alachlor no further measures were taken.

Canada
As the regulatory action was a complete ban of all uses of alachlor no further measures were taken.

3.3 Alternatives

There are a number of alternative methods involving chemical and non-chemical strategies, including alternative technologies available, depending on the individual crop-pest complex under consideration. Countries should consider promoting, as appropriate, integrated pest management (IPM) strategies as a means of reducing or eliminating the use of hazardous pesticides.

Advice may be available through National IPM focal points, the FAO, and agricultural research or development agencies. Where it has been made available by governments, additional information on alternatives to alachlor may be found on the Rotterdam Convention website www.pic.int.

European Community

No information provided.

Canada

Metolachlor – an agricultural herbicide, was identified as alternative at the time of the final regulatory action.

3.4 Socio-economic effects

European Community

No information provided.

Canada

At the time of the final regulatory action, the two most widely used herbicides for control of annual grasses in corn and soybean were alachlor and metolachlor. Keeping alachlor on the market would have provided farmers with choice thus insuring against monopolistic practices. On average, crop yields and weed control for metolachlor and alachlor were equal. However, there were some concerns that in specific circumstances there were significant differences in performance. This led to concerns that, even though the overall impact would be small, some individuals would be very hard hit by the removal of alachlor from the market.

4. Hazards and Risks to human health and the environment

4.1 Hazard Classification

WHO / IPCS	Slightly hazardous (Class III) technical grade active ingredient
IARC	No assessment
European Community	Xn (Harmful) R22; Harmful if swallowed R43; May cause sensitization by skin contact Carcinogen Category 3 R40; Limited evidence of a carcinogenic effect N (Dangerous for the environment) R50/53; Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment
US EPA	Likely to be a human carcinogen at high doses, but not likely at low doses
UN	Hazard Class II – slightly hazardous

4.2 Exposure limits

EU Risk Assessment:

Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) = 0.0025 mg/kg bw/day

As alachlor has not been classified as a genotoxic carcinogen a threshold value can be established. The ADI and AOEL are based on the NOAEL of 0.5 mg/kg bw/day from the 2-year rat carcinogenicity study

(based on nasal turbinate adenoma in one female at 2.5 mg/kg bw/day) with a safety factor of 200. A safety factor of 200 is considered appropriate as the LOAEL (based on reversible effects at 2.5 mg/kg bw/day) / AOEL is greater or equal than 1000.

Acute Reference Dose (ARfD) = Not allocated

WHO: Drinking-water Guideline Value of 0.02 mg/l calculated by applying the linearized multistage model to data on the incidence of nasal tumours in rats. (WHO, 2004)

4.3 Packaging and labelling

The United Nations Committee of Experts on the Transportation of Dangerous Goods classifies the chemical in:

Hazard Class and Packing Group:	UN Packing Group III
International Maritime Dangerous Goods (IMDG) Code	Class 9 Environmentally hazardous substance, liquid N.O.S. alachlor 480 g/l Marine pollutant

4.4 First aid

NOTE: The following advice is based on information available from the World Health Organisation and the notifying countries and was correct at the time of publication. This advice is provided for information only and is not intended to supersede any national first aid protocols.

Inhalation – ***Fresh air, rest and refer for medical attention.***

Skin – ***Remove contaminated clothes. Rinse skin with plenty of water.***

Eyes – ***First rinse with plenty of water for several minutes (remove contact lenses if easily possible), then take to doctor.***

Ingestion – ***Rinse mouth, Rest. Refer for medical attention.***

(IPCS, 1994)

4.5 Waste management

Regulatory actions to ban a chemical should not result in creation of a stockpile requiring waste disposal. For guidance on how to avoid creating stockpiles of obsolete pesticide stocks the following guidelines are available: *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks* (1995), *The Pesticide Storage and Stock Control Manual* (1996) and *Guidelines for the management of small quantities of unwanted and obsolete pesticides* (1999).

In all cases waste should be disposed in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1996), any guidelines there under (SBC, 1994), and any other relevant regional agreements.

It should be noted that the disposal/destruction methods recommended in the literature are often not available in, or suitable for, all countries; e.g., high temperature incinerators may not be available. Consideration should be given to the use of alternative destruction technologies. Further information on possible approaches may be found in *Technical Guidelines for the Disposal of Bulk Quantities of*

Obsolete Pesticides in Developing Countries (1996).

Specific information for alachlor

Spillage disposal – Do not wash into sewer. Vacuum spilled material. Carefully collect remainder, then remove to a safe place.

Storage – Provision to contain effluent from fire extinguishing. Separated from food and feedstuff. Do not store near heat or open flame.
(IPCS, 1994)

Annexes

Annex 1 **Further information on the substance**

Annex 2 **Details on Final regulatory action**

Annex 3 **Address of designated national authorities**

Annex 4 **References**

Annex 1 Further information on the substance

Introductory text to Annex I

The information presented in this Annex reflects the conclusions of the two notifying parties: European Community and Canada. In a general way, information provided by these two parties on the hazards are synthesised and presented together, while the risk evaluation, specific to the conditions prevailing in European Community and Canada, are presented separately. This information is contained in the documents referenced in the notifications in support of their final regulatory actions to ban alachlor. The notification from Canada was first reported in PIC Circular XXII of December 2005 and the notification from European Community in PIC Circular XXVI of December 2007. The notification from Canada was first considered in the Second Meeting of the Chemical Review Committee in February 2006 and the notification from European Community at the Fourth Meeting of the Chemical Review Committee in March 2008.

The only major review of alachlor available to the Chemical Review Committee was the risk evaluation conducted by the European Community. The full report, Monograph on the Review of alachlor was produced by the European Community in 2005. Canada conducted a limited risk evaluation of alachlor prior to February 5, 1985. This risk evaluation reviewed in *The Report of the Alachlor Review Board* (1987) was also available to the CRC. The full risk evaluation was not available to the Chemical Review Committee. However, this risk evaluation had been reviewed by the Canadian Alachlor Review Board and extracts of the risk evaluation were included in the Report of the Alachlor Review Board (from 1987). This report was available to the Chemical Review Committee, which had found this sufficient to establish that the criteria of Annex II of the Convention had been met.

Other information has been taken from the WHO/FAO Data sheet on Pesticides, No. 86 on alachlor, the Pesticide Manual, Fourteenth Edition and the Bbckground document for the development of the WHO *Guidelines for Drinking-water Quality.* Alachlor has not been reviewed by the FAO/WHO Joint Meeting on Pesticide Residues (JMPR).

Annex 1 – Further information on notified chemical

1. Physico-Chemical properties

1.1	**Identity**	ISO: Alachlor IUPAC: 2-chloro-2',6'-diethyl-N-methoxymethylacetanilide CA: 2-chloro-*N*-(2,6—diethylphenyl)-*N*-(methoxymethyl)acetamide
1.2	**Formula**	$C_{14}H_{20}ClNO_2$
1.3	**Colour and Texture**	White crystalline solid. Munsell N9.5/90%R. (Sinon)
1.4	**Melting Point**	41.5°C (Sinon)
1.5	**Boiling Point**	100 °C/ 0.0026 kPa
1.6	**Vapour Pressure**	p (20°C) = 2.7 x 10^{-5} hPa p (25°C) = 5.5 x 10^{-5} hPa
1.7	**Henry's Law Constant**	9.129 x 10^{-7} Pa m^3 mol^{-1}
1.8	**Solubility in water**	At 20°C (g/l) pH 5: 0.188 pH 7: 0.170 pH9: 0.179
1.9	**Solubility in organic solvents**	At 20°C (g/l): Methanol >803 Acetone >827 Ethyl acetate >761 1,2 Dichloroethane >749 Xylene: >723 n-heptane 130
1.10	**Density (g/cm3)**	1.745 g/cm^3 at 20°C 1.87 g/cm^3 at 20°C (purified alachlor)
1.11	**Dissociation Constant**	Not measurable, constant between pH 2.6 to pH 12.2
1.12	**LogPow**	2.97 (20°C)
1.13	**Hydrolysis rate**	pH5 – pH9: Half-life <1 year

2 Toxicological properties

2.1	**General**	
2.1.1	**Mode of Action**	The main subchronic toxic effect of alachlor appears to be haematotoxicity. Turbinate tumours are seen in chronic animal studies and their relevance to humans cannot be ruled out. The mechanism of action is based on the production of iminoquinone species, which bind to tissue proteins causing disturbances in cell function and structure ultimately leading to cell death and regenerative cell proliferation. Although human nasal tissue is not capable of forming the iminoquinone precursor, it is considered that the mechanism of action could be relevant to humans. (EFSA, 2004)
2.1.2	**Symptoms of poisoning**	No reported cases, but symptoms of poisoning would probably include nausea, vomiting, dizziness. Collapse and coma may occur in severe poisoning. Dermal irritancy and allergic dermatitis may be seen in susceptible individuals following exposure to spray-mists, liquids or particulates (IPCS, 1996).

2.1.3 Absorption, distribution, excretion and metabolism in mammals

Rat: fast and extensive oral absorption (range 79-96%) within 96 hours.
Monkey: 90% absorption (EC, 2007)

2.2 Toxicology studies

2.2.1 Acute toxicity

LD_{50} (rat, oral)	930 to1350 mg/kg bw
LD_{50} (rat, dermal)	4982 mg/kg bw
LD_{50} (rat, inhalation, 4 hour)	1.04 mg/ l air to >4.67 mg/l air (nose only)
LD_{50} (rabbit, dermal)	13,300 mg/kg bw

Alachlor is not irritating to the skin and eyes according to EU criteria. It is sensitizing to the skin (M&K test). (EC, 2007)

2.2.2 Short term toxicity

Subchronic
Critical effect: haematotoxicity (RBC)
Dog (oral, 1 year): NOAEL = 1 mg/kg bw/day
Rabbit (dermal, 21 days): NOAEL = 200 mg/kg bw/day
Rat (inhalation, 28days): NOAEL = 0.06 mg/l/day

2.2.3 Genotoxicity (including mutagenicity)

There are some positive responses in *in vitro* assays especially with activation with olfactory mucosal S9 e.g. *Salmonella typhimurium* TA100 and a weak response in mouse lymphoma cells. Therefore target tissue bioactivation may lead to the formation of mutagenic metabolites, which may be critical in alachlor-induced rat nasal tumorigenesis.
There is no convincing evidence for genotoxicity *in vivo.* (EC, 2007)

Generally non-mutagenic in short-term tests. Positive result in hepatocyte DNA repair assay. (The Report of the Alachlor Review Board, 1987)

2.2.4 Long term toxicity and carcinogenicity

There have been a number of long-term studies on rats and mice.

CD-1 Mice were fed for 18-months at doses of 16.6, 65.4 and 262 mg/kg bw/day (males), 23.7, 90.3 and 399 mg/kg bw/day (females). Toxicity was observed in the liver, bone, kidney and nasal olfactory mucosa (EC, 2007).

Rats: the lowest relevant NOAELs were observed in rat studies.

A study on Long-Evans rats fed continuously for two years at doses of 14, 42 and 126 mg/kg bw/day gave a NOAEL = 14 mg/kg bw/day based on the absence of tumours at any site. Tumours were observed at higher concentrations in the nasal epithelium, stomach and thyroid together with liver changes and ocular lesions.(EC, 2007)

In another study, nasal turbinate tumours in Long-Evans rats, considered biologically significant but not statistically significant, were observed at concentrations higher than 2.5 mg/kg bw/day; they were statistically significant at concentrations higher than 15 mg/kg bw/day. Stomach tumours rats, considered biologically significant but not statistically significant, were observed at concentrations higher than 2.5 mg/kg bw/day; they were statistically significant at concentrations above 126 mg/kg bw/day. (Canada, 1987)

In a subsequent study, specifically on nasal turbinate tumours, Long-Evans rats were fed in the diet, 0.5, 2.5 or 15 mg/kg bw/day alachlor for 25 months. Based on a single nasal turbinate adenoma in a female animal at 2.5 mg/kg

bw/day, the NOAEL was set at 0.5 mg/kg bw/day (EC, 2007).

The following conclusions were drawn by the European Community on the significance of the tumours observed to humans:

Nasal turbinate tumours: The mechanism of action is based on the production of iminoquinone species, which bind to tissue proteins causing disturbances in cell function and structure and ultimately leading to cell death and regenerative cell proliferation. Iminoquinone protein adducts have not been observed in mice or monkeys. Human nasal tissue is not capable of forming the iminoquinone precursor (the p-hydroxy derivative).

It is considered that this mechanism of action could be relevant to humans, although it is unlikely that concentrations of the active metabolite would be achieved to initiate the chain of events leading to cancer. The evidence for a genotoxic mode of action is weak.

Gastric tumours: these are generated at very high dose levels through a gastrin-mediated mechanism that does not appear operative in primates at similar doses.

Thyroid tumours: At very high levels of alachlor, thyroid tumours are induced following chronic stimulation of the thyroid and increased thyroid hormone excretion including TSH. This mechanism is not considered relevant to humans. (EC, 2007)

The Canadian findings can be summarised as follows:

- Nasal turbinate tumours (rats) were considered biologically significant (i.e. not statistically significant) at ≥ 2.5 mg/kg bw/day and statistically significant at ≥ 15 mg/kg bw/day;
- Stomach cancers (rats) were considered biologically significant (i.e. not statistically significant) at ≥ 2.5 mg/kg bw/day and statistically significant at 126 mg/kg bw/day.

2.2.5 Effects on reproduction

Rat (3-generation reproduction study):
No effects on reproduction parameters. Body and organ weight changes were observed in F0, F2 and F3b generations at maternal toxic doses in rat.

Reproduction NOAELs = 30 mg/kg bw/day
Paternal NOAEL = 10 mg/kg bw/day
Developmental NOAEL = 10 mg/kg bw/day

Rat and rabbit (Teratology study)

Rabbit – no effects
Rat - increased absorptions and decreases in the mean foetal body weight
Developmental NOAEL = 150 mg/kg bw/day (EC, 2007)

Endocrine disruption

Data indicating endocrine disruption are inconclusive. The relevance to risk assessment is open until formal tests for endocrine disruption are available. (EC, 2007)

2.2.6	**Neurotoxicity/ delayed neurotoxicity, Special studies where available**	No evidence of neurotoxicity (EC, 2007)
2.2.7	**Summary of mammalian toxicity and overall evaluation**	WHO has classified alachlor as slightly hazardous (Class III). LD_{50} values are 1350 mg/kg bw (rat, oral), 4982 mg/kg bw (rat, dermal) and >4.67 mg/l air (nose only; rat, inhalation, 4 hour). Alachlor is not irritating to the skin and eyes according to EU criteria but it is sensitizing to the skin. There are no reported cases but symptoms of poisoning would probably include nausea, vomiting, dizziness. Collapse and coma may occur in severe poisoning. The main subchronic endpoint is haematotoxicity. There is no convincing evidence for genotoxicity *in vivo.* After chronic exposure, nasal turbinate tumours seen in rats have a mechanism of action based on the production of iminoquinone species, which bind to tissue proteins causing disturbances in cell function and structure ultimately leading to cell death and regenerative cell proliferation. This mechanism of action could be relevant to humans. Stomach and thyroid tumours seen in animals are not considered relevant to humans. Evidence for endocrine disruption is inconclusive at present and alachlor is not considered a reproductive or neural toxicant. **Safety Values:** EU Risk Assessment Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) = 0.0025 mg/kg bw/day As alachlor is not considered to be genotoxic, an ADI and AOEL can be established based on the NOAEL of 0.5 mg/kg bw/day from the 2-year rat carcinogenicity study (based on nasal turbinate adenoma in one female at 2.5 mg/kg bw/day) with a safety factor of 200. A safety factor of 200 is considered appropriate as LOAEL (based on reversible effects at 2.5 mg/kg bw/day) / AOEL greater than or equal to 1000. EU Risk Assessment Acute Reference Dose (ARfD) = Not allocated

3 Human exposure/Risk evaluation

3.1	**Food**	Food does not appear to be a major route of exposure for the general population as residues in food are usually below the detection limit. It is rapidly metabolised by crops after application and does not bioaccumulate. In tolerant plants it is detoxified by rapid conjugation with glutathione (WHO, 2003).
3.2	**Air**	Because of its low volatility, the occurrence of alachlor in air is not considered significant. (EC, 2007)
3.3	**Water**	Alachlor was detected in the surface and ground water of 10 states of USA between 1979 and 1987. In two more recent surveys, alachlor was detected in one of 750 and 38 of 1430 private wells sampled. US monitoring data indicate that alachlor is present in groundwater at levels less than 0.1 to 16.6 µg/l. It has also been detected in an Italian survey in Italy in 1987-88 in 3 out of 322

drinking-water supplies at a maximum level of 1.6 µg/l. (WHO, 2003)

In Canada (1984) 7 out of 60 selected (i.e. suspected to be contaminated) wells were positive for alachlor, with a range of 0.10 to 2.11 ppb. Data from 1979 to 1984 alachlor was detected in 13 out of 442 selected wells, with a highest concentration of 9.1 ug/L. For surface waters, 5 out of 317 samples taken between 1981 and 1984 were positive for alachlor.

3.4 Occupational exposure

European Community

Exposure of workers and bystanders has not been sufficiently addressed with the available information.

Calculations based on the UK and German operator exposure assessment models for the use patterns within the European Community, gave values higher than the AOEL for all uses of the products considered, even when adequate PPE is worn during the operation of mixing, loading and application. These calculations indicate an unacceptable risk to the operator for all uses of alachlor.

Alachlor has been classified as carcinogenic Cat.3, R40. The Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR Panel) considered that it was extremely unlikely that concentrations of an active metabolite, which was considered harmful, would be achieved to initiate the chain of events terminating in cancer. However, it concluded that although "extremely unlikely", it cannot be discarded that nasal tumours are relevant to humans.

Canada

At time of the decision to cancel registration of alachlor, exposures estimates were from patch tests on applicators when using the products as per the registered use pattern. Estimates of potential exposure ranged from 0.21 mg/kg bw/day with protective clothing, to 2.7 mg/kg bw/day without protective clothing. Estimates were based on treating 100 ha/day, at an application rate of 1.8 kg/acre and assumed 100% dermal absorption.

3.5 Medical data contributing to regulatory decision

European Community

No evidence of toxicological concern from medical surveillance of manufacturing plant personnel (EC, 2007).

3.6 Public exposure

European Community

No separate assessment. It was considered that risks for bystanders have not been sufficiently assessed with the available information.

Canada

Presence of alachlor in groundwater, with further potential of contamination was a cause for concern.

3.7 Summary-overall risk evaluation

European Community

Although unlikely, the relevance of rat nasal turbinate tumours to humans could not be discarded completely. Consideration of operator exposure scenarios indicates an unacceptable risk to the operator for all uses of alachlor. Exposure of workers and bystanders has not been considered to be sufficiently addressed with the available information.

Canada

Alachlor was deemed an animal carcinogen with potential as a human carcinogen. In rats, tumours deemed to be biologically significant (though not statistically significant) occurred at dose levels that were within the range of potential occupational exposure estimates. Exposure estimates ranged from 0.21 mg/kg bw/day to 2.7 mg/kg bw/day. Nasal and stomach tumours were noted in rats at 2.5 mg/kg bw/day.

Alachlor was considered to represent an unacceptable risk of harm to public health. The primary concern was occupational exposure, but the presence of alachlor in ground water, with further potential of contamination, increased concerns of exposure.

The appreciable cancer risk of alachlor, and the availability of metolachlor were principal factors in cancelling alachlor registrations.

4 Environmental fate and effects

4.1 Fate

4.1.1 Soil

Most degradation studies indicate that alachlor disappears relatively rapidly in soils. The DT_{50} under aerobic conditions is, generally under 30 days and in most field studies, 4-24 days. Biodegradation via co-metabolism is the most important process by which alachlor is lost from most soils with some loss by photolysis.
Alachlor also has a high to medium mobility in soil.

4.1.2 Water

Alachlor is not readily biodegradable and DT_{50} values in the range of 200-500 days in river water have been determined although these values can be decreased by the addition of soil or sediment reaching values of 23-206 days. Volatilisation is not a significant cause of losses.

4.1.3 Air

Alachlor is moderately stable in air ($t_{1/2}$ 2.544 hours). Partial removal of particulate alachlor may occur by dry deposition and its detection in rainwater suggests that it will be removed from air by wet deposition as well. Because of its low volatility, the occurrence of alachlor in air is not considered significant.

4.1.4 Bioconcentration

Bioconcentration Factor:
BCF = 50 in aquatic organisms. Not expected to bioconcentrate (EC 2007)
BCF = 6 in fish; not expected to bioconcentrate in aquatic organisms (USEPA, 2006).

4.1.5 Persistence

Alachlor disappears fairly rapidly in soil by biodegradation and photolysis. It does not degrade rapidly in water but this may be increased by the presence of soil and sediment. Its occurrence in air is not considered significant.

4.2 Effects on non-target organisms

4.2.1 Terrestrial vertebrates

<u>Terrestrial birds</u>

Acute toxicity: Chicken LD50: 916 mg/kg
Dietary toxicity: Bobwhite quail and mallard duck LC50: >5620 ppm (active ingredient and formulation)
Reproductive: Mallard duck NOEC: 50 ppm ai (4.97 mg/kg bw/day) (EC, 2007)

<u>Mammals</u>

The data used for the risk assessment of the European Community were from

the following rat studies
Acute toxicity: Rat LD50 930 - 1350 mg/kg bw
Long term toxicity: Developmental NOAEL 150 mg/kg bw/day
Reproductive NOAEL 10 mg/kg bw/day (3-generation)

Canada reports systemic NOAELs of ≥ 2.5 mg/kg bw/day in the rat and ≥ 1.0 mg/kg bw/day in the dog.

4.2.2 Aquatic species

Freshwater species

Extensive data are available for alachlor, thus the data reported below represent only a selection based on the lowest values for each species and ranges of results for the metabolites.

Fish: Acute 96-h LC50 Technical: 1.8 – 5.0 mg/l
Formulation: 1.5 mg a.i./l
Metabolite 65, 70, 54, 78: >100-127 mg/l
Metabolite 39: 55 mg/l(38-65)
Fish Chronic 96-day NOEC Technical: 0.19 mg/l
14-day NOEC Formulation: 0.25 mg/l

Daphnia Acute 48-h LC50 Technical: 10 mg/l
Formulation: 7.2 mg a.i./l
Metabolite 65, 70, 54: >95-126 mg/l
Daphnia Chronic 21-day NOEC Technical: 0.23 mg/l
Formulation: 0.23 mg/l
Metabolite 52: 7.4 mg/l

Algae (*Selenastrum capricornutum, Skeletonema costatum* and *Navicula pelliculosa*)
Acute 72-h EC50 Technical: 0.0012 - 0.0019 mg/l
Formulation: 0.0026->0.226 mg a.i./l
Metabolites 65: 3.5 mg/l
70: >132 mg/l
54: 46 mg/l
Acute 96-h EC50 Technical: 0,0029 mg/l
Metabolite 70, 54, 78: >116 mg/l
39: 55 mg/l
Algae Chronic 72-h NOEC Formulation: 0.0022 mg/l (0.001 a.i. mg/l)
120-h NOEC Technical: 0.00035 mg/l

Aquatic plants (*Lemna gibba*)
Acute EC50 7-days Formulation (Lasso EC): 0.0068 mg a.i./l
Formulation (Lasso MT): 0.119 mg a.i./l
Acute IC50 7-days Metabolites 65, 70, 54, 78: >203 mg/l
39: 68 mg/l
Aquatic plants (unspecified)
Acute IC50 14-days Technical: 0.0023 mg/l
Metabolite 65: >120

(EC, 2007)

4.2.3	**Honeybees and other arthropods**	Acute oral toxicity: LD50 oral formulation: >100 µg/bee Acute contact toxicity: LD50 contact formulation: >100 µg/bee Acute oral toxicity: LD50 oral (a.i.): >94 µg/bee Acute contact toxicity: LD50 contact (a.i.): >100 µg/bee Acute oral toxicity: LD50 oral formulation MT: >90 µg/bee Acute contact toxicity: LD50 contact formulation MT: >100 µg/bee Acute oral toxicity: LD50 oral formulation EC: >90 µg/bee Acute contact toxicity: LD50 contact formulation EC: >100 µg/bee (EC, 2007)
4.2.4	**Earthworms**	Acute toxicity: LC50 technical: 267 mg/kg (applying factor of 2 = 133.5) LC50 technical (14d): 387 mg/kg (dry soil) LC50 Formulation: 483 mg/kg (232 mg a.i./kg) LC50 (metabolites 70, 54, 69, 39: >1000 ppm LC50 (metabolite 65): >857 ppm Reproductive toxicity: NOEC Metabolite 70: 1.81 mg/kg dry soil NOEC Metabolite 78: 1.40 mg/kg dry soil NOEC Metabolite 65: 1.86 mg/kg dry soil NOEC Metabolite 54: 1.29 mg/kg dry soil (EC, 2007)
4.2.5	**Soil microorganisms**	For nitrogen and carbon mineralization, there were no relevant effects at approximately two times the application rate (2.4 kg/ha). (EC, 2007)
4.2.6	**Terrestrial plants**	No information

5 Environmental Exposure/Risk Evaluation

5.1 Terrestrial vertebrates

European Community

During the evaluation of this active substance, some areas of concern have been identified. This was especially the case for its environmental fate and behaviour, in particular with the formation of a large variety of degradation products, some of which were of toxicological and/or ecotoxicological concern.

Alachlor metabolites in groundwater are in this regard a concern since metabolites have been found in groundwater at concentrations higher than 1µg/l and are predicted in modelling scenarios at concentrations higher than 1 and 10 µg/l. Directive 2006/118/EC states that for groundwater quality, the standards which are acceptable in the European Community are 0.1 µg/l for individual active substances in pesticides, including their metabolites, degradation and reaction products and 0.5 µg/l for the total of all pesticides including their relevant metabolites, degradation and reaction products.

The assessment of those soil metabolites by the Scientific Panel on Plant Health, Plant Protection Products and their residues (PPR) of the European Food Safety Authority showed no evidence of toxicity for some of them. However, the toxicity and genotoxicity of others (85, 76, 51 and 25) could not be adequately assessed by the Panel, due to inadequate databases, meaning that uncertainty remains as to the danger of these metabolites.

The Toxicity Exposure Ratio (TER) is a measure of the risk: it is calculated by

dividing the no effect values of sensitive organisms by the predicted exposure to the substance. The Trigger value represents a value above which the TER is considered to represent an acceptable risk and may include a margin of precaution.

Using PEC values for the most sensitive birds and mammals, for various exposure scenarios for crop use in Europe, the Toxicity Exposure Ratios (TER) indicated a potential long-term risk to terrestrial vertebrates (large birds eating grass, mammals) as shown in Table 2.

Table 2 Critical TER (Toxicity Exposure Ratio) values for terrestrial vertebrates (all crops at application rate of 2.4 kg a.s./ha)

Organism	Timescale	TER	Trigger Value
Large birds eating grass	Long-term	0.19	5
Mammals	Long-term	1.86	5
		2.23	

5.2 Aquatic species

European Community

Alachlor has been proved to be very toxic for aquatic organisms, and may cause long-term adverse effects in the aquatic environment. Using PEC values for the most sensitive aquatic organisms for various exposure scenarios for crop use in Europe (different applications rates and buffer zones and run-off), the Toxicity Exposure Ratios (TER) indicated a potential acute risk to fish, algae and aquatic plants (acute and mesocosm) as shown in Table 3.

Table 3 Critical TER values for aquatic species (all crops at application rate of 2.4 kg a.s./ha)

Organism	Timescale	Distance	TER	Trigger Value
Fish	Acute	1	56.25	100
Algae	Acute	1	0.059	10
Algae	Acute	30	2.37	10
Algae	Acute	Run-off	0.71	10
Algae	Microcosm	1	0.03	1
Algae	Microcosm	Run-off	0.37	1
Aquatic plants	Acute	1	0.07	10
Aquatic plants	Acute	30	2.875	10
Aquatic plantsm	Acute	Run-off	0.86	10
Algae and Aquatic plants	Mesocosm	1	0.05	1

5.3 Honey bees and other arthropods

European Community

Using laboratory tests and the use of hazard quotients (reciprocal of TERs), it was assessed that there was no risk to honey bees.

Following an assessment of laboratory and extended laboratory tests on several species, the risk to other arthropods was considered as low.

5.4 Earthworms

European Community

Using LC50 and NOEC values for acute and reproductive toxicity respectively, the TERs indicated a low risk to earthworms.

5.5 Soil microorganisms

European Community

For nitrogen and carbon mineralization, there were no relevant effects at approximately two times the application rate (2.4 kg/ha).

5.6 Summary – overall risk evaluation

European Community

During the evaluation of this active substance, some areas of concern have been identified. It was especially the case for its environmental fate and behaviour, in particular with the formation of a large variety of degradation products, some of which were of toxicological and/or ecotoxicological concern.

Alachlor metabolites in groundwater are in this regard a concern since metabolites have been found in groundwater at concentrations higher than 1 and are predicted in modelling scenarios at concentrations higher than 1 and 10 µg/l. Uncertainty remains as to the danger of these metabolites.

Alachlor has been proved to be very toxic for aquatic organisms, and may cause long-term adverse effects in the aquatic environment. Using PEC values for the most sensitive organisms, for various exposure scenarios for crop use in Europe (different applications rates and buffer zones and run-off), the Toxicity Exposure Ratios (TERs) indicated a potential long-term risk to terrestrial vertebrates (large birds eating grass, mammals), and acute risk to fish, as well as acute and chronic (mesocosm) risk to algae and aquatic plants.

Annex 2 – Details on final regulatory actions reported

Country Name: European Community

1	**Effective date(s) of entry into force of actions**	18 June 2007. Any period of grace granted by the Member States under Article 4(6) of Directive 91/414/EEC shall be as short as possible and shall expire not later than 18 June 2008.
	Reference to the regulatory document	Commission Decision of 18 December 2006 concerning the non-inclusion of alachlor in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing this active substance http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_397/l_39720061230en00280030.pdf
2	**Succinct details of the final regulatory action(s)**	It is prohibited to place on the market or use plant protection containing alachlor. Alachlor is not included in the list of authorized active ingredients in Annex I to Directive 91/414/EEC. The authorizations for plant protection products containing alachlor had to be withdrawn by 18 June 2007. From 19 December 2006 no authorizations for plant protection products containing alachlor could be granted or renewed.
3	**Reasons for action**	An unacceptable risk to human health and the environment
4	**Basis for inclusion into Annex III**	Final regulatory action to ban alachlor based on a risk evaluation taking into account the normal pattern of use in the European Community and the effects caused by the application of the substance
4.1	**Risk evaluation**	Risk assessment calculations using potential exposure indicate an unacceptable risk to the operator for all uses of alachlor. Exposure of workers and bystanders has not been considered to be sufficiently addressed with the available information. Risk assessment calculations using potential exposure indicate a potential long-term risk to terrestrial vertebrates (large birds eating grass, mammals), acute risk to fish, and acute and chronic (mesocosm) risk to algae and aquatic plants.
4.2	**Criteria used**	Risk to human health and the environment during patterns of use relevant to the European Community
	Relevance to other States and Regions	Similar health and environmental problems are likely to be encountered in other countries where the substance is used, particularly in developing countries.
5	**Alternatives**	No information
6	**Waste management**	No specific measures outlined
7	**Other**	

Country Name: Canada		
1	**Effective date(s) of entry into force of actions**	31 December 1985. All Uses banned. All product registrations cancelled.
	Reference to the regulatory document	Minister's announcement of 5 February 1985
2	**Succinct details of the final regulatory action(s)**	All uses of alachlor banned. All product registrations cancelled.
3	**Reasons for action**	Carcinogenic potential of Alachlor and existence of a lower risk alternative.
4	**Basis for inclusion into Annex III**	Unacceptable risk to human health.
4.1	**Risk evaluation**	Alachlor was determined to be an animal carcinogen and was deemed to be a potential human carcinogen. Primary concern was occupational exposure but presence of alalchlor in ground water, with further potential of contamination, increased concerns of non-occupational exposure. It was determined that alachlor represents an unacceptable risk of harm to public health.
4.2	**Criteria used**	Risks to human health during patterns of use in Canada.
	Relevance to other States and Regions	Similar health problems are likely to be encountered in other countries where the substance is used, particularly in developing countries.
5	**Alternatives**	Metolachlor
6	**Waste management**	No information
7	**Other**	

Annex 3 – Addresses of designated national authorities

EUROPEAN COMMUNITY

DG Environment **European Commission** Rue de la Loi, 200 B-1049 Brussels Belgium *Paul Speight* Deputy Head of Unit	**Phone** +322 296 4135 **Fax** +322 296 7617 Paul.Speight@ec.europa.eu

CANADA

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C Industrial chemicals
CP Pesticides and industrial chemicals
P Pesticides

Annex 4 – References

Regulatory actions

European Community
Commission Decision of 18 December 2006 concerning the non-inclusion of alachlor in Annex I to Council Directive 91/414/EEC and the withdrawal of authorizations for plant protection products containing this active substance
http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_397/l_39720061230en00280030.pdf

Canada
Minister's announcement of February 5, 1985.

Other Documents

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