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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

Note by the Secretariat

1. Article 5 of the Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade provides that when the Secretariat has received at least one notification from each of two prior informed consent (PIC) regions regarding a particular chemical that it has verified meet the requirements of Annex I to the Convention it shall forward them to the Chemical Review Committee. The Committee shall review the information provided in such notifications and, in accordance with the criteria set out in Annex II, recommend to the Conference of the Parties whether the chemical in question should be included in Annex III and a decision guidance document drafted.

2. At its second meeting, the Chemical Review Committee reviewed one notification of final regulatory action related to alachlor from North America (Canada). The Committee concluded that the notification for alachlor from Canada met the requirements of the Rotterdam Convention. The rationale for the Committee's conclusion is set out in document UNEP/FAO/RC/CRC 4/8/Add.1.

3. The Secretariat has subsequently received one additional notification relating to alachlor that meets the information requirements of Annex I from one PIC region (Europe (European Community)). The summary of the notification was included in PIC Circular XXVI of December 2007.

4. The two notifications, as received from the notifying countries, are contained in the annex to the present note.

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

K0763650 041107

5. The supporting documentation provided by the European Community is set out in document UNEP/FAO/RC/CRC.4/8/Add.2.

6. A list of other notifications previously considered by the Chemical Review Committee is set out in document UNEP/FAO/RC/CRC.4/INF/5.

Annex

Notification of final regulatory action for alachlor for Canada

Notification of final regulatory action for alachlor from European Commission

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

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: CANADA

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	IDENTITY OF CHEMICAL	
1.1	**Common name**	alachlor
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: 2-chloro-2',6'-diethyl-N-methoxy-methylacetanilide C.A.:2-chloro-N-(2,6-diethylphenyl)-N-(methoxymethyl)acetamide
1.3	**Trade names and names of preparations**	- Lasso 4 Weed Killer Emulsifiable Concentrate - Lasso 10 Granular Herbicide - Lasso Emulsifiable Concentrate Weed Killer - Lasso Emulsifiable Herbicide - Lasso II Granule
1.4	**Code numbers**	
1.4.1	**CAS number**	15972-60-8
1.4.2	**Harmonized System customs code**	380830
1.4.3	**Other numbers (specify the numbering system)**	EINECS # 240-110-8 RTECS # AE1225000

1.5	**Indication regarding previous notification on this chemical, if any**
1.5.1	☐ This is a first time notification of final regulatory action on this chemical.

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals
11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5.2	☐ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ ☒ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: May 1, 1996

1.6	**Information on hazard classification where the chemical is subject to classification requirements**
International classification systems	**Hazard class**
WHO	1a - extremely hazardous
Other classification systems	**Hazard class**
EU	Xn - Harmful

1.7	**Use or uses of the chemical**
1.7.1	☒ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Herbicide for control of annual grasses and broadleaf weeds in corn and soybeans
1.7.2	☐ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8	**Properties**
1.8.1	**Description of physico-chemical properties of the chemical**

Form: yellow to white to wine red, odourless solid @ room temp;
yellow to red liquid @> 40°C;
Melting Point: 40.5-41.5 °C;
Boiling Point: 100 °C/0.0026kPa;
Vapour Pressure: 2.1 mPa (25°C);
Solubility: water 242 mg/l:
soluble in diethyl ether, acetone, benzene, chloroform, ethanol and ethyl acetate
slightly soluble in heptane;
Kow logP: 3.09.

REF: Tomlin, CDS, 1997, The Pesticide Manual 11th Addition, British Crop Protection Council, U.K. p 22-23

1.8.2	**Description of toxicological properties of the chemical**

The following toxicity values have been reported:

Study Type	Value
Oral rats LD_{50}	930-1350 mg/kg;
Dermal rat LD_{50}	>2000mg/kg;
percutaneous rabbits LD_{50}	13 300 mg/kg;
inhalation (4h), rats	1.04 mg/l air

	NOEL, rats (2y) ≤ 2.5 mg/kg b.w./day; dog (1y) ≤ 1 mg/kg b.w./day Oncogenic in rats but not mice; Non-irritating to skin or eyes; contact sensitisation in guinea pigs REF: Tomlin, CDS, 1997, The Pesticide Manual 11th Addition, British Crop Protection Council, U.K. p 22-23 Considered a potential human carcinogen by Agriculture Canada and Health & Welfare Canada (see Note to CAPCO C88-04)
1.8.3	**Description of ecotoxicological properties of the chemical** The following toxicity values have been reported: Study Type — Value oral LD_{50}s: bobwhite quail 1536 mg/kg bee 32 mg/bee LC_{50}: bobwhite quail and mallard duck (5d) >5620 mg/kg diet LC_{50} (96h): Rainbow trout 1.8 mg/L Bluegill sunfish 2.8 mg/L fathead minnow 5.0 mg/L channel catfish 2.1 mg/L LC_{50} earthworms (14d) 387mg/kg dry soil EC_{50} (48h): Crayfish >320 mg/L daphnia 10 mg/L TL_{50} *Selenastrum capricornutum* (72h) 12 µg/L REF: Tomlin, CDS, 1997, The Pesticide Manual 11th Addition, British Crop Protection Council, U.K. p 22-23

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**
2.1	**The chemical is:** ☒ **banned** **OR** ❑ **severely restricted**
2.2	**Information specific to the final regulatory action**
2.2.1	**Summary of the final regulatory action** • all uses banned Dec 31, 1985; low import tolerances set for corn, soybean, drybeans, meat and milk (1). • all product registrations cancelled due to carcinogenic potential, and existence of a lower risk alternative product, metolachlor (2). • manufacturer (Monsanto) requested review of regulatory action, as allowed by section 23 of PCPA. Alachlor Review Board formed Nov 13, 1985 (2). • final report (October 1987), Board recommended restoration of alachlor registrations, believing that the relative safety of the alternative product metalochlor did not support cancellation of alachlor registrations. (2). • the Minister maintained metolachlor safer than alachlor and ban upheld (3)

2.2.2	**Reference to the regulatory document**	
	(1) Minister's announcement of February 5, 1985; (2) The Report of the Alachlor Review Board, October 1987; (3) Note to Capco C88-04	
2.2.3	**Date of entry into force of the final regulatory action**	
	December 31, 1985	

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☒ Yes	☐ No
	If yes, give information on such evaluation • Determined to be animal carcinogen from review of feeding studies in rats and mice; deemed to have potential as human carcinogen • Primary concern was occupational exposure but presence of alachlor in ground water, with further potential of contamination, increased concerns of non-occupational exposure • Determined that use of alachlor represents an unacceptable risk of harm to public health		
	Reference to the relevant documentation (1) Note to Capco C88-04 (2) The Report of the Alachlor Review Board, Government of Canada Publication, 1987		

2.4	**Reasons for the final regulatory action**		
2.4.1	**Is the reason for the final regulatory action relevant to the human health?**	☒ Yes	☐ No
	If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers • Two long-term dietary studies in the rat, indicated an increase in the incidence of adenomas and adenocarcinomas in the nasal turbinates, and of stomach tumours at a number of doses (2). • A long-term dietary mouse study indicated a statistically significant number of lung tumours in females at the highest dose (2). • Based on the above results alachlor was deemed an animal carcinogen with potential as a human carcinogen (2) • The primary concern was occupational exposure but the presence of alachlor in ground water, with further potential of contamination, increased concerns of exposure (2) • Determined that use of alachlor represents an unacceptable risk of harm to public health (1)		
	Reference to the relevant documentation (1) Note to CAPCO C88-04 (2) The Report of the Alachlor Review Board, Government of Canada Publication, 1987.		
	Expected effect of the final regulatory action • Elimination of herbicide use of alachlor in Canada, thus eliminating hazard due to occupational exposure and exposure through contaminated ground water. • At the time, some costs to farmers were expected due to virtual monopoly for Ciba-Geigy and a decrease in performance in certain instances however due to the continued presence of metolachlor these effects are expected to be relatively minor. • No further effect anticipated as action was taken several years ago		

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☐ Yes	☒ No
	If yes, give summary of the known hazards and risks to the environment		
	Reference to the relevant documentation		

	Expected effect of the final regulatory action

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	❑ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Use or uses that remain allowed	

2.5.2	**Final regulatory action has been taken for the chemical category**	☒ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All uses and formulations are prohibited	
	Formulation(s) and use or uses that remain allowed	
	None	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.

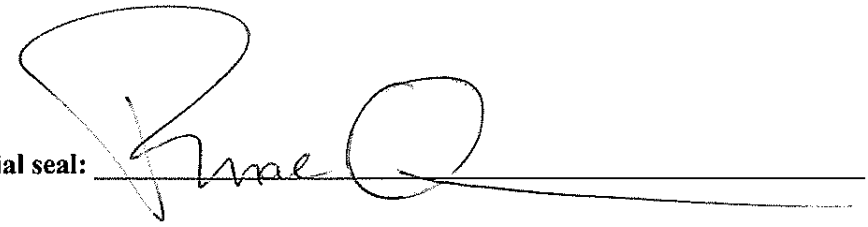
	Quantity per year (MT)	Year
Produced		
Imported		
Exported		
Used		

2.6	**Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions**
	• no further impact likely to take place as product was banned several years ago

2.7	**Other relevant information that may cover:**
2.7.1	**Assessment of socio-economic effects of the final regulatory action**
	• at the time, the two most widely used herbicides for control of annual grasses in corn and soybean were alachlor (Monsanto) and metolachlor (Ciba-Geigy). Keeping alachlor on the market would have provided the growers with choice thus insuring against monopolistic practices (e.g. price increases) (2). • on average crop yields and weed control for metolachlor and alachlor were equal. However, there was some concern that in specific circumstances there are significant differences in performance. This led to concern that, even though the overall impact would be small, some individuals would be very hard hit by the removal of alachlor from the market place (2). Ref: (2) The Report of the Alachlor Review Board, Government of Canada Publication, 1987
2.7.2	**Information on alternatives and their relative risks**
2.7.3	**Relevant additional information**

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish_MacQuarrie@hc-sc.gc.ca
Designated National Authority	
Institution	Pest Management Regulatory Agency, Health Canada
Address	2720 Riverside Drive Ottawa, Ontario K1A 0K9 Canada
Name of person in charge	Trish MacQuarrie
Position of person in charge	Director, Alternative Strategies and Regulatory Affairs Division
Telephone	+1 613-736-3660
Telefax	+1 613-736-3659
E-mail address	Trish_MacQuarrie@hc-sc.gc.ca

Date, signature of DNA and official seal: 

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

UNEP

FORM FOR NOTIFICATION OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

IMPORTANT: See instructions before filling in the form

COUNTRY: EUROPEAN COMMUNITY

(Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	alachlor
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: 2-chloro-2',6'-diethyl-N--methoxymethylacetanilide CA: 2-chloro-*N*-(2,6—diethylphenyl)-*N*-(methoxymethyl)acetamide
1.3	**Trade names and names of preparations**	Formulation types: Emulsifiable concentrate (EC) or microencapsulated (ME or MT) Trade names include: Alanex, Bronco, Cannon, Crop Star, Lasso, Lariat, Partner, Reneur, Traton
1.4	**Code numbers**	
1.4.1	**CAS number**	15972-60-8
1.4.2	**Harmonized System customs code**	2924 29 95
1.4.3	**Other numbers (specify the numbering system)**	EC: 616-015-00-6 EINECS: 240-110-8 CIPAC: 204 UN: 2588

PLEASE RETURN THE COMPLETED FORM TO:

Secretariat for the Rotterdam Convention
Plant Protection Service
Plant Production and Protection Division, FAO
Viale delle Terme di Caracalla
00100 Rome, Italy

Tel: (+39 06) 5705 3441
Fax: (+39 06) 5705 6347
E-mail: pic@fao.org

OR

Secretariat for the Rotterdam Convention
UNEP Chemicals

11-13, Chemin des Anémones
CH – 1219 Châtelaine, Geneva, Switzerland

Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

1.5	Indication regarding previous notification on this chemical, if any
1.5.1	X This is a first time notification of final regulatory action on this chemical.
1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ This notification replaces all previously submitted notifications on this chemical.
	Date of issue of the previous notification: _____

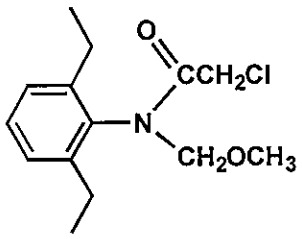
1.6 Information on hazard classification where the chemical is subject to classification requirements	
International classification systems	**Hazard class**
WHO Classification	Slightly hazardous (Class III) technical grade active ingredient in pesticides
EPA	B2 Probable human carcinogen
IARC	No assessment
UN	Hazard Class II – slightly hazardous
Classification of the EC in accordance with Council directive 67/548/EEC	Xn (Harmful) N (Dangerous for the environment) Carcinogen Category 3 R22; Harmful if swallowed R43; May cause sensitization by skin contact R40; Limited evidence of a carcinogenic effect R50/53; Very toxic to aquatic organisms. May cause long-term adverse effects in the aquatic environment
Other classification systems	**Hazard class**

1.7	Use or uses of the chemical
1.7.1	**X Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Alachlor is a herbicide that is absorbed from the soil primarily by the shoot of emerging seedlings. Following absorption it is translocated throughout the plant. The mode of action of alachlor appears to be inhibition of protein synthesis in susceptible plants. Alachlor produces a selective weed control in maize, sweet corn, soybean, sunflower and cotton, controlling annual grasses and small weed broadleaf species, killing off susceptible weed species and suppressing growth on some tolerant plants. Normally, one application to soil pre-emergence or early post-emergence (2-3 leaf stage) is carried out to control weeds. Generally, the dose is between 1.7 and 2.4 kg/ha.
1.7.2	θ **Industrial**
	Describe the industrial uses of the chemical in your country:

1.8 Properties

1.8.1 Description of physico-chemical properties of the chemical

Minimum Purity: 900 g/kg
FAO Specification: Not less than 900 g/kg (FAO, 1991)
Molecular Formula: $C_{14}H_{20}ClNO_2$
Molecular Mass: 269.77 g/mol
Structural Formula:



Appearance:
White crystalline solid. Munsell N9.5/90%R. (Sinon)
Odour:

Melting Point: 41.5°C (Sinon)
Boiling Point: -
Vapour Pressure: p (20°C) = 2.7×10^{-5} hPa
p (25°C) = 5.5×10^{-5} hPa

Volatility:
Henry's Law Constant: 9.129×10^{-7} Pa m^3 mol^{-1}
Solubility in Water: At 20°C (g/l)
pH 5: 0.188
pH 7: 0.170
pH9: 0.179

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

Density: 1.745 g/cm^3 at 20°C
1.87 g/cm^3 at 20°C (purified alachlor)
Dissociation Constant (pKa): Not measurable constant between pH 2.6 to pH 12.2
Log P_{ow}: 2.97 (20°C)
Hydrolysis Rate: pH5 – pH9: Half-life <1 year

Alachlor is **flammable, Flash point 51°C, not explosive**

1.8.2	**Description of toxicological properties of the chemical** **Absorption, distribution, excretion and metabolism in mammals:** Rat: fast and extensive oral absorption (range 79-96%) within 96 hours. Monkey: 90% absorption **Acute Toxicity:** LD_{50} (rat, oral) 1350 mg/kg bw LD_{50} (rat, dermal) 4982 mg/kg bw LD_{50} (rat, inhalation, 4 hour) >4.67 mg/l air (nose only) **Irritation & Sensitisation:** Alachlor is not irritating to the skin and eyes according to EU criteria. It is sensitizing to the skin (M&K test). **Subchronic Toxicity:** 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 **Chronic Toxicity:** Mice (18-months) (liver, bone, kidney and nasal olfactory mucosa) Rats (116-weeks) NOAEL = 14 mg/kg bw/day (nasal epithelium, liver, eye, stomach, thyroid) This figure is considered the lowest relevant NOAEL **Genotoxicity:** 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*. **Carcinogenicity:** Rats: Nasal turbinate tumours: mechanism 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 the 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.

Reproductive Toxicity:
Rat (3-generation reproduction study):
Critical effect: No effects on reproduction parameters. Body and organ weight changes 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)
Critical effect: rat - increased absorptions and decreases in the mean foetal body weight
Rabbit – no effects
Developmental NOAEL = 150 mg/kg bw/day

Endocrine disruption
Data indicating endocrine disruption are inconclusive. The relevance to risk assessment is open until formal tests for endocrine disruption are available.

Neurotoxicity:
No evidence of neurotoxicity

Safety Values:
EU Risk Assessment Acceptable Daily Intake (ADI) and Acceptable Operator Exposure Level (AOEL) = 0.0025 mg/kg bw/day

The ADI and AOEL can be established as a threshold value can be set (it has not been classified as a genotoxic carcinogen) and it is 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 $\geq$ 1000.

EU Risk Assessment Acute Reference Dose (ARfD) = Not allocated

1.8.3 Description of ecotoxicological properties of the chemical

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 cometabolism is the most important process by which alachlor is lost from most soils with some loss by photolysis.
Alachlor has Koc values ranging from 103.9 to 192, indicating high to medium mobility in soil.

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.

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.

Ecotoxicology
• Terrestrial birds
Acute toxicity: Chicken LD50: 916 mg/kg LC50: 28 mg/kg bw
Dietary toxicity: Bobwhite quail and mallard duck: >5620 ppm (active ingredient and formulation)
Reproductive: Mallard duck NOEC: 50 ppm ai (4.97 mg/kg bw/day)

• Honey bee
Acute oral toxicity: LD50 oral formulation: >100 µg/bee
Acute contact toxicity: LD50 contact formulation: >100 µg/bee
Acute oral toxicity: LD50 oral (ai): >94 µg/bee
Acute contact toxicity: LD50 contact (ai): >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

• Earthworm
Acute toxicity: LC50 technical: 267 mg/kg (applying factor of 2 = 133.5)
LC50 Formulation: 483 mg/kg (232 mg ai/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

• 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 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: 0.0019 mg/l
	Formulation: 0.0026->0.226 mg a.i./l
	Metabolites 65: 3.5 mg/l
	70: >123 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

1.9 References used in Part I

EU Draft Assessment Report and Addenda for alachlor (1999-2005) prepared in the context of the risk assessment under Directive 91/414/EEC

EU Draft Assessment & Addenda Endpoints (January 2005)

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**			
2.1	**The chemical is:**	**X banned**	**OR**	**θ severely restricted**
2.2	**Information specific to the final regulatory action**			
2.2.1	**Summary of the final regulatory action** 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 substances in Annex I to Directive 91/414/EEC. The authorizations for plant protection products containing alachlor have to be withdrawn by 18 June 2007. From 19 December 2006 no authorizations for plant protection products containing alachlor can be granted or renewed.			
2.2.2	**Reference to the regulatory document** Commission Decision 2006/966/EC 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 (Official Journal of the European Union L 397 of 30.12.2006, p.28-30) (copy attached and also available at: http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_397/l_39720061230en00280030.pdf)			
2.2.3	**Date of entry into force of the final regulatory action** 19 December 2006. 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.			

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	**X Yes**	**θ No**
	If yes, give information on such evaluation 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 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 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 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 has 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 alachlor was not demonstrated to fulfil the safety requirements laid down in Article 5 (1) (a) and (b) of Directive 91/414/EEC. In particular, 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 eco-toxicological concern; and its possible impact on operators, workers and bystanders.		

Reference to the relevant documentation

Review report for the active substance Alachlor (SANCO/4331/2000-final, 10 January 2007) and supporting background documents (e.g. dossier, monograph and the peer review report under the Peer Review Programme) (copy attached and also available at:
http://ec.europa.eu/food/plant/protection/evaluation/existactive/alachlor_en.pdf)

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 No EFSA-Q-2004-48) adopted on 28 October 2004, The EFSA Journal (2004), 111, 1-34 (copy attached and also available at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620774536.htm)

2.4 Reasons for the final regulatory action

2.4.1 Is the reason for the final regulatory action relevant to the human health? **X Yes** **θ No**

If yes, give summary of the known hazards and risks presented by the chemical to human health, including the health of consumers and workers

Exposure of operators, workers and bystanders has not been considered to be sufficiently addressed with the available information. Alachlor has been classified as carcinogenic category 3, R40. The 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. Though "extremely unlikely", it cannot be discarded that nasal tumors are relevant to humans.

The calculations based on the UK and German operator exposure assessment models gave values higher than the AOEL for all uses of Lasso EC and Reneur, even when adequate PPE is worn during the operation of mixing, loading and application. Therefore, these calculations indicate an unacceptable risk to the operator for all uses of alachlor for which data were submitted.

General exposure has also been assessed using values generated by a biomonitoring study in which absorbed dose of Lasso EC was as follows:

Table 1 Absorbed dose of Lasso EC obtained from Canadian biomonitoring study

Work load (ha/day)	**Absorbed dose (mg/kg bw/day)**
50	0.008
39	0.006
10	0.002

A workload of 39 and 50 ha/day, both give an absorbed dose of greater than the proposed AOEL of 0.0025 mg/kg bw/day.

Reference to the relevant documentation

Review report for the active substances Alachlor (SANCO/4331/2000 final, 10 January 2007) and supporting background documents (e.g. dossier, monograph and the peer review report under the Peer Review Programme) (copy attached and also available at:
http://ec.europa.eu/food/plant/protection/evaluation/existactive/alachlor_en.pdf)

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 No EFSA-Q-2004-48) adopted on 28 October 2004, The EFSA Journal (2004), 111, 1-34 (copy attached and also available at:
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620774536.htm

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products.

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	**X Yes** θ **No**
	If yes, give summary of the known hazards and risks to the environment	
	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 being 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 10 µg/l. The assessment of those soil metabolites by the PPR Panel 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 tested by the Panel, due to inadequate databases, meaning that 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 aquatic organism, fish, 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 long-term risk to terrestrial vertebrates (large birds eating grass, mammals) and acute risk to fish, algae and aquatic plants (acute and mesocosm).	
	Reference to the relevant documentation	
	Review report for the active substances Alachlor (SANCO/4331/2000-final, 10 January 2007) and supporting background documents (e.g. dossier, monograph and the peer review report under the Peer Review Programme) (copy attached and also available at: http://ec.europa.eu/food/plant/protection/evaluation/existactive/alachlor_en.pdf) 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 No EFSA-Q-2004-48) adopted on 28 October 2004, The EFSA Journal (2004), 111, 1-34 (copy attached and also available at: http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620774536.htm	
	Expected effect of the final regulatory action	
	Reduction of risk from the use of plant protection products.	

2.5	**Category or categories where the final regulatory action has been taken**	
2.5.1	**Final regulatory action has been taken for the chemical category**	θ **Industrial**
	Use or uses prohibited by the final regulatory action	
	Not relevant	
	Use or uses that remain allowed	
	Not relevant	

2.5.2	**Final regulatory action has been taken for the chemical category**	X **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All the applications as plant protection product	
	Formulation(s) and use or uses that remain allowed	
	Not relevant	

2.5.3 Estimated quantity of the chemical produced, imported, exported and used, where available.

	Quantity per year (MT)	Year
Produced		
Imported		
Exported		
Used		

2.6	Indication, to the extent possible, of the likely relevance of the final regulatory action 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.

2.7	Other relevant information that may cover:	
2.7.1	Assessment of socio-economic effects of the final regulatory action	
2.7.2	Information on alternatives and their relative risks	
2.7.3	Relevant additional information	

PART III : GOVERNMENT AUTHORITIES

Ministry/Department and authority responsible for issuing/enforcing the final regulatory action	
Institution	European Commission
Address	B-1049 Brussels Belgium
Telephone	+322 296 4135
Telefax	+322 296 7617
E-mail address	Paul.Speight@ec.europa.eu
Designated National Authority	
Institution	DG Environment European Commission
Address	B-1049 Brussels Belgium
Name of person in charge	Paul Speight
Position of person in charge	Deputy Head of Unit
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Date, signature of DNA and official seal: 23/11/07 Paul Speight