EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Protecting the Natural Environment
ENV.B.4 - Biotechnology & Pesticides

Brussels, 23/11/04.
ENV.B.4 D(04) 342122

Mr. N. Van der Graaff
Interim Secretariat for the
Rotterdam
Convention, Plant Protection
Service
Plant Production and Protection
Division, FAO
Viale delle Terme di Caracalla
IT- 00100 Rome

Dear Mr Van der Graaff,

In line with Article 5 of the Rotterdam Convention, I am pleased to send you herewith European Community notifications concerning final regulatory actions relating to amitraz and atrazine respectively..

Yours sincerely,

Klaus BEREND

Cc. Mr Willis, UNEP

Rue de la Loi 200, B-1049 Bruxelles / Wetstraat 200, B-1049 Brussel - Belgium. Telephone: (32-2)299 11 11.
Office: BU5 2/152. Telephone: direct line (32-2) 299.48.60. Fax: (32-2) 296. 76.17.

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, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, The Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden and United Kingdom)

PART I: PROPERTIES, IDENTIFICATION AND USES

1.	**IDENTITY OF CHEMICAL**	
1.1	**Common name**	Amitraz
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: N-methylbis(2,4-xylyliminomethyl)amine CA: N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethylphenyl)imino]methyl]-N- methylmethaniminamide
1.3	**Trade names and names of preparations**	Formulation types: emulsifiable concentrate (EC), oil dispersible powder (OP), wettable powder (WP). Selected trade names: Akaroff, Byebye, Bumetran, Cekutraz, Edrizar, Mitac, Narval, Ovasyn, Parsec, Rotraz, Sender, Taktic, Trazam, Vapcozin.
1.4	**Code numbers**	
1.4.1	**CAS number**	33089-61-1
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	EINECS: 251-375-4 CIPAC: 362 RTECS: ZF0480000 EC: 612-086-00-2

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

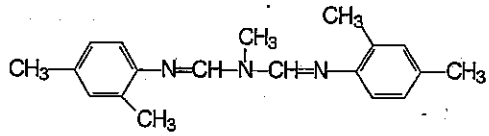
1.5	Indication regarding previous notification on this chemical, if any
1.5.1	☑ This is a first time notification of final regulatory action on this chemical.
1.5.2	θ This is a modification of a previous notification of final regulatory action on this chemical. The sections modified are: _____ θ This 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**
UN Classification	UN Hazard class: 3 UN Pack Group: III
Classification of the EC in accordance with Council directive 67/548/EEC	Xn (Harmful) N (dangerous for the environment) R22; 43; 48/22; 50/53 (harmful if swallowed; may cause sensitization by skin contact; harmful: danger of serious damage to health by prolonged exposure if swallowed; 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	☑ **Pesticide**
	Describe the uses of the chemical as a pesticide in your country:
	Amitraz containing plant protection products are used as selective insecticides and broad spectrum acaricides, amongst others, on pome fruits (apples and pears) and hops. Uses within the European Community included plant protection uses in apples, pears, stone fruits, strawberries, tomatoes, aubergines, peppers, hops, ornamentals, empty glasshouses, tree nurseries and public green in northern Europe and citrus fruits, apples, pears, stone fruits, bananas, grapes, strawberries, tomatoes, aubergines, peppers, cucurbits, cotton and ornamentals in Southern Europe, respectively.
1.7.2	θ **Industrial**
	Describe the industrial uses of the chemical in your country:
	Animal Health Uses: Amitraz is also used on mammalian domestic pets where it controls ticks, mites, lice and other animal pests.

1.8 Properties

1.8.1 Description of physico-chemical properties of the chemical

Minimum purity	970 g/kg (>99.4%)
FAO specification	-
Molecular Formula	$C_{19}H_{23}N_3$
Molecular Mass	293.4
Structural Formula	
Appearance	White/pale yellow crystalline solid
Melting point	86-88°C
Boiling point / decomposition	Not relevant. Decomposes with heat.
Vapour pressure	0.34 mPa at 25°C
Henry's law constant	1.0 Pa m^3mol^{-1}
Solubility in water	pH 6.5 9.4×10^{-5} g/l at 25°C pH 7.74-7.82 1.03×10^{-4} g/L at 25°C pH 10.8 0.22×10^{-3} g/L at 27°C
Solubility in organic solvents	Amitraz purity 99.4%

-At 25°C (g/L)

Acetone	300-600
Acetonitrile	60-75
Dichloromethane	>600
Dimethylsulfoxide	120-150
Ethanol	35.1
Ethylacetate	300-600
Hexane	21-25
Methanol	20.1
Isopropanol	21.5
Toluene	300-600

-At 20°C

Acetone	315
Dichloromethane	505
Ethylacetate	258
n-Heptane	36.6
Isopropanol	18.2
o-xylene	318

Density	1.128 at 20°C
Dissociation constant (pka)	4.2±0.1 at 20°C

Partition coefficient (log P_{ow})

pH	log P_{ow}	Temp (°C)
9	5.6	40°C
7	5.6	40°C
5.8:	5.5	25°C
6.14	5.96	22°C
5.51	5.98	22°C
5.29	6.00	22°C
5.25	6.01	22°C

Hydrolytic stability (DT_{50})

pH	DT_{50} (hrs)	Temp (°C)
4.99	0.97	22
7.05	15.5	22
9.2	32	22
5	2	25
7	22	25
9	26	25

Photostability(DT_{50})

-At pH 7.13, 28°C
11.8h hrs (light)
15.9hrs (dark)
46.5 hrs (corrected for hydrolysis)

1.8.2	Description of toxicological properties of the chemical

Absorption, distribution, excretion and metabolism in mammals:
Amitraz is readily absorbed via the gastrointestinal tract in rats, mice, dogs, baboons and humans. It is rapidly excreted via the urine (82% after 72 hrs in man) and to a lesser extent via the faeces. Amitraz is less readily absorbed via the skin with up to 1 % as concentrate and 2% as spray dilution based on in vivo rat study and comparative in vitro hman skin/rat skin .

Acute toxicity:
LD50 (rat, oral) approx. 600 mg/kg bw
LD50 (mouse oral) >1600 mg/kg bw
LD50 (rat, dermal) >1600 mg/kg bw
LC50 (rat, inhalation) approx. 65 mg/L air (6 hrs)

Skin and eye irritation:
Not irritating

Sensitisaton:
Sensitising (according to OECD Guideline 406)

Short term toxicity:
The respiratory, circulatory, digestive and nervous systems were affected by exposure to Amitraz, with clear evidence of CNS effects. Additionally, signs of liver toxicity were seen with oral exposures.

-Rat (oral gavage, 90 day): NOAEL 3 mg/kg bw, LOAEL, 12 mg/kg bw (minimal growth, irritability and excitability).
- Dog (oral capsule, 90 day): LOAEL = 0.25 mg/kg bw (increased blood sugar)
- Rabbit (dermal, 21 day): LOAEL = 50 mg/kg bw (sedation, body weight loss)
- Rat (inhalation, 21 day): NOEC = 0.01 mg/L air (irritation, ataxia, body weight loss)

Genotoxicity:
There is no evidence to suggest that technical Amitraz is of mutagenic potential.

Long term toxicity:
In chronic studies, Amitraz produced signs of neurotoxicity and, in mice, effects on the liver, pituitary, uterus and ovaries.

-Rat (oral, 2 yrs): NOAEL = 2.5 mg/kg bw/day, LOAEL = 10 mg/kg bw/day (decreased body weight gain, behavioral disturbances).
- Mouse (oral, 2 yrs): NOAEL = 2.3 mg/kg bw (male mice) and 2.6 mg/kg bw (female mice),LOAEL = 10 mg/kg bw/day (growth retardation, decreased food consumption, effects on behaviour, liver, pituitary and ovaries)
- Dog (oral capsule, 2 yrs): NOAEL = 0.25 mg/kg bw/day, LOAEL = 1 mg/kg bw/day (CNS depression)

Carcinogenicity:
Increase in liver tumours in mice (oral, 2 year study). Possibly non-genotoxic, species specific, relating

to disturbance in hormonal balance.

Reproductive toxicity:
Maternally toxic (languor, polypnoea and squinting) at all doses. Foetal effects noted in rats were dilated ureters and renal pelvic cavitation.

- Reproduction: NOAEL= 1.6 mg/kg bw/day (impaired lactation in dams due to impaired parental care) for leading to increased litter loss)
- Development: NOAEL = 7.5 mg/kg bw/day (increased dilated ureter, renal pelvic cavitation); NOAEL 6 mg/kg bw (total litter loss). No teratogenic potential, but foetotoxic at maternal toxic dose.

Neurotoxicity:
No specific studies of adequate quality available. Results indicate intoxication with weight loss, hyperactivity and increased aggressiveness.

Endocrine effects
Inconclusive evidence of oestrus cycle disturbance in mice.

Amitraz is an α2-receptor agonist and a number of the action of amitraz are due to central and peripheral α2adrenergic activity.

Safety values
EU Risk Assessment ADI = 0.0025 mg/kg bw/d
EU Risk Assessment AOEL = 0.0025 mg/kg bw/d (systemic)

These values were both based on a long-term oral toxicity study in dogs with a NOAEL of 0.25 mg/kg/day and an uncertainty factor of 100.

1.8.3 Description of ecotoxicological properties of the chemical

Soil: Amitraz is broken down rapidly in soil containing oxygen. The half-life in soil is <0.33 day and DT90 values between 1 and 6 days. Degradation occurs more rapidly in acidic soils than in alkaline or neutral soils.

Water: Amitraz remained in the water column and was rapidly degraded with a half-life of 1.7–3.4 hours at 25°C.

Air: Neither amitraz or its degradation products are significantly released into the air from soil.

Ecotoxicology

- Terrestrial vertebrates

Acute toxicity	Rat	LD_{50} = 600 mg/kg bw
Acute toxicity	Mouse	LD_{50} = 100 mg/kg bw (metabolite)
Reproduction	Rat	NOAEC = 50 ppm
Subchronic	Rat	NOAEC = 45 ppm

- Birds

Acute toxicity	Bobwhite quail	LD_{50} = 788 mg/kg bw
Acute toxicity	Bobwhite quail	LD_{50} = 1827 mg/kg bw (metabolite)
Acute toxicity	Bobwhite quail	LD_{50}= 71 mg/kg bw (metabolite)
Dietary toxicity	Bobwhite quail	LC_{50} = 1800 ppm
Dietary toxicity	Bobwhite quail	LC_{50}= >5200 ppm (metabolite)
Dietary toxicity	Bobwhite quail	LC_{50} = 1362 ppm
Reproduction	Mallard duck	NOAEC= 40 ppm
Reproduction	Bobwhite quail	NOAEC= 100 ppm (metabolite)
Reproduction	Mallard duck	NOAEC = 25 ppm (metabolite)

- Aquatic species

- Fish

(96hrs)	Bluegill sunfish	LC_{50} = 0.45 mg ai/L
(96hrs)	Bluegill sunfish	NOEC = 0.15 mg ai/L

- Invertebrates

(48hrs)	*Daphnia magna*	EC_{50} = 1.05 mg ai/L (immobilization)
28d	*Daphnia magna*	NOEC = 0.2 mg ai/L (reproduction)
28d	*Daphnia magna*	NOEC = <0.025 mg ai/L (mortality)
28d	*Chironomus sp.*	NOEC = 2 mg ai/L

- Earthworm: *Eisenia foetida* — LC_{50} = 20 mg as/kg soil (14 days)
- Honey bee: *Apis mellifera* — LD50 = 20µg form/l (96h, acute oral)
  Apis mellifera — LD50 = 27µg form/l (96h, acute contact)

PART II: FINAL REGULATORY ACTION

2.	**FINAL REGULATORY ACTION**	
2.1	**The chemical is:**	θ **banned** **OR** ☑ **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 amitraz. Amitraz 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 amitraz had to be withdrawn by 12 August 2004. From 17 February 2004 no authorisations for plant protection products containing amitraz could be granted or renewed. For certain essential uses for specific Member States listed in the Annex to Commission Decision 2004/141/EC a prolonged period of withdrawal until 30 June 2007 may be allowed (see point 2.5.2).
2.2.2	**Reference to the regulatory document**	Commission Decision 2004/141/EC concerning the non-inclusion of amitraz in Annex I to Council Directive 91/414/EEC and the withdrawal of the authorisations for plant protection products containing this active substance (Official journal of the European Union L46 of 17/02/2004, pp.35-37) (copy attached and also available at : http://europa.eu.int/eur-lex/pri/en/oj/dat/2004/l_046/l_04620040217en00350037.pdf)
2.2.3	**Date of entry into force of the final regulatory action**	12/08/2004 (Authorisation for plant protection products containing amitraz had to be withdrawn by then with the exception of certain essential uses as described in point 2.5.2 below).

2.3	**Was the final regulatory action based on a risk or hazard evaluation?**	☑ **Yes** θ **No**
	If yes, give information on such evaluation	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 of the Directive. Within this context, a number of companies notified their wish to secure the inclusion of amitraz as an authorised active ingredient. A Member State was designated to undertake a hazard 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. The results were then reviewed by the Member States and the Commission within the Standing Committee on Food Chain and Animal Health (SCFCAH). The evaluation was based on a review of scientific data generated for amitraz 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. Assessments made on the basis of the information submitted did not demonstrate that it may be expected that, under the proposed conditions of use, plant protection products containing amitraz satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC. In particular, concerns were identified with regard to the acceptability of acute exposure of consumers in view of the possible neurological effects of the active substance.
	Reference to the relevant documentation	Review report of the Standing Committee on the Food Chain and Animal Health at its meeting on 4 July 2003 for the active substance amitraz (10363/2003-final: 6 June 2003) (copy attached) and supporting background documents (dossier, monograph and the peer view report under the Peer Review Programme (ECCO, March 2000)

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 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	
	Final regulatory action was taken to protect consumers from the potential neurological effects of acute exposure to amitraz. It had not been demonstrated for the proposed uses that consumers might not be exposed to amitraz exceeding the Acute Reference Dose, i.e. the estimate of the amount of the substance that can be ingested over a short period of time without appreciable health risk to the consumer. A probabilistic risk assessment was prepared by the notifier. However it had to be taken into consideration that agreed criteria for the interpretation of such a probabilistic risk assessment are not yet established. It was concluded that it would not be appropriate, in view of the possible risks, to delay a decision further until such criteria are agreed.	
	Reference to the relevant documentation	
	Review report of the Standing Committee on the Food Chain and Animal Health at its meeting on 4 July 2003 for the active substance amitraz (10363/2003-final: 6 June 2003) (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme (ECCO, March 2000)	
	Expected effect of the final regulatory action	
	Reduction of risk to consumers from plant protection products	

2.4.2	**Is the reason for the final regulatory action relevant to the environment?**	☑ Yes θ No
	If yes, give summary of the known hazards and risks to the environment	
	During the evaluation of the risks to the environment some concerns were identified with regards to non-targets organisms, in particular birds and mammals eating treated insects. The final decision on the non-inclusion in Annex I of Directive 91/414/EEC, however, was not based on such concerns.	
	Reference to the relevant documentation	
	Review report of the Standing Committee on the Food Chain and Animal Health at its meeting on 4 July 2003 for the active substance amitraz (10363/2003-final: 6 June 2003) (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme (ECCO, March 2000)	
	Expected effect of the final regulatory action	
	Reduction of risk from plant protection uses.	

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	
	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 the applications as plant protection products, except the essential uses listed below

Formulation(s) and use or uses that remain allowed

Authorisations for essential uses may be maintained until 30 June 2007 by the EC Member States indicated, provided that they:

(a) ensure that such plant protection products remaining on the market are relabelled in order to match the restricted use and conditions;

(b) impose all appropriate risk mitigation measures to reduce any possible risks in order to ensure the protection of human and animal health and the environment; and

(c) ensure that alternative products or methods for such uses are being seriously sought, in particular by means of action plans.

For all non-essential uses, for which existing authorisations had to be withdrawn by 12 August 2004, the EC Member States may grant a period of grace for disposal, storage, placing on the market and use of existing stocks that must expire no later than 12 August 2005. For essential uses that can continue to be authorised until 30 June 2007, the grace period for disposal etc of the existing stocks is 6 months (*i.e.* up until 31 December 2007).

List of essential uses that may continue to be authorised

Member States	Use
Greece	Cotton
The Netherlands	Tree nursery
	Strawberry (only propagating material)
	Pear trees after harvest
United Kingdom	Pear trees after harvest
Portugal	Pear trees after harvest

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 concerns to those identified could arise in other countries where the substance is used, particularly 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	Rue de la Loi, 200 B-1049 Brussels Belgium
Telephone	+322 299 48 60
Telefax	+322 296 76 17
E-mail address	klaus.berend@cec.eu.int
Designated National Authority	
Institution	DG Environment European Commission
Address	Rue de la Loi, 200 B-1049 Brussels Belgium
Name of person in charge	Klaus BEREND
Position of person in charge	Deputy Head of Unit
Telephone	+322 299 48 60
Telefax	+322 296 76 17
E-mail address	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: 19.11.04