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

Brussels, 22 August 2005
JF/ch D(05) 170035

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 a European Community notification concerning a final regulatory action relating to fenthion.

Yours sincerely,

p Klaus BEREND
Deputy Head of Unit

Cc. UNEP Chemicals

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BU-5 2/152 one: direct line (32-2) 299.48.60. Fax: (32-2) 299.85.58.
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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**	Fenthion
1.2	**Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists**	IUPAC: Thiophosphoric acid O,O'-dimethyl O"-(3-methyl-4-methylthio-phenyl) ester CA: Phosphorothioic acid, O,O-dimethyl O-[3-methyl-4-(methylthio)phenyl] ester
1.3	**Trade names and names of preparations**	Formulation types: dustable powder (DP), emulsifiable concentrate (EC), granule (GR); hot fogging concentrate (HN); PO; UL; wettable powder (WP) Selected trade names: Faster; Lebaycid; Pilartex.
1.4	**Code numbers**	
1.4.1	**CAS number**	55-38-9
1.4.2	**Harmonized System customs code**	
1.4.3	**Other numbers (specify the numbering system)**	EC: 015-048-00-8 EINECS: 200-231-9 CIPAC: 79 RTECS: TF9625000

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

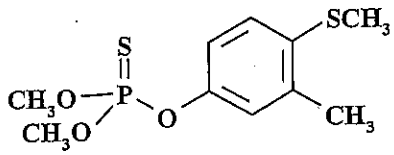
Tel: (+41 22) 917 8183
Fax: (+41 22) 797 3460
E-mail: pic@unep.ch

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: 6.1 UN Pack Group: III
Classification of the EC in accordance with Council Directive 67/548/EEC	Muta. Cat 3 (Mutagenic category 3) T (Toxic) Xn (Harmful) N (Dangerous to the environment) R68; 23,48/25;21/22; 50/53 (Possible risks of irreversible effects; Toxic by inhalation, Toxic: danger of serious damage to health by prolonged exposure if swallowed; Harmful in contact with skin and 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: Fenthion-containing plant protection products are cholinesterase inhibitors, acting by contact, inhalation and as a stomach poison. Used within the European Union in agriculture, horticulture and viticulture for the control of fruitflies, leafhoppers, leaf miners, leaf eating larvae, and other insect pests in fruit and olives.
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	930 g/kg

FAO specification	79/TC/S 1989
Molecular Formula	$C_{10}H_{15}O_3PS_2$
Molecular Mass	278.3
Structural Formula	
Appearance	Colourless/brown oily liquid.
Relative density	$D_4^{20} = 1.25$
Melting point	Not measurable.
Boiling point / decomposition	310°C at 1.013×10^5 Pa 120°C at 10 Pa 90°C at 1 Pa
Vapour pressure	7.4×10^{-4} Pa at 20°C 1.4×10^{-3} Pa at 25°C
Henry's law constant	5×10^{-2} Pa.m³. mol^{-1} at 20°C
Solubility in water	4.2 mg/l at 20°C

		At 20°C
Solubility in organic solvents (at 25°C)	n-heptane	100g/l
	xylene	>250g/l
	1,2 dichloroethane	>250 g/l
	2- propanol	>250g/l
	acetone	>250g/l
	ethylacetate	>250 g/l

Partition coefficient (log P_{ow}) 4.84

Hydrolytic stability (DT_{50})

pH	DT_{50} (days)	Temp
4	222.8	22
7	199.7	22
9	151.1	22
5	56	25
7	41	25
9	32	25

Photostability (DT_{50})

DT_{50} (min)	Temp	
4.5	-	under high pressure Hg vapour lamp
15	25	in distilled water
28.8	23	in aqueous buffer

Dossier, monograph and the peer review report under the Peer Review Programme (ECCO, January 1997)

1.8.2 Description of toxicological properties of the chemical

Absorption, distribution, metabolism and excretion in mammals
Fenthion was rapidly and almost completely absorbed after oral administration to rats and farm animals. In all animal species tested the excretion rate was high and the main route of elimination was via urine (88-107% at 72 hrs). None of the tracer radiocarbon from fenthion was eliminated in expired gases. Fenthion is distributed to the fat, liver and kidney after oral administration. It is almost completely metabolised through oxidation, hydrolysis and conjugation of phenolic hydrolysis products. Some of its oxidised metabolites (fenoxon, fenoxon sulfoxide, fenoxon sulfone, fenthion sulfoxide and fenthion sulfone) are considered as toxicologically significant.

Acute toxicity

LD50 oral rat	ca 250 mg/kg bw
LD50 oral male mouse	160 - 272 mg/kg bw
LD50 oral female mouse	160 - 273 mg/kg bw
LD50 oral hen	approx. 27 mg/kg bw
LD50 dermal rat	586 – 800 mg/kg bw
LC50 inhalation rat	454 - 507 mg/m^3

Skin and eye irritation
Not irritating (skin)
Slightly irritating (eye)

Not classified

Sensitisation
Not sensitising

Short-term toxicity
In subacute and subchronic studies, repeated oral, dermal or inhalative administration of fenthion mainly led to ChE activity inhibition.

- Rat (oral, 12 weeks): NOEL= 0.25 mg/kg bw/day (serum and RBC ChE activity inhibition)
- Dog (oral, 90 days): NOEL= 2 ppm / 0.05 mg/kg bw
- Rabbit (dermal, 15x 6h/day) NOEL= 5 mg/kg bw /day (plasma- and brain-ChE activity inhibition and skin effects)
- Rat (inhalation, 15x 7hrs/day) NOEL=1 mg/m^3 air (plasma-ChE activity inhibition)
- Dog (oral, 12 months) NOAEL/NOEL 0.1 mg/kg bw/day
- Rhesus monkeys (oral, 23 months) NOEL=0.07 mg/kg bw/day (plasma-ChE activity inhibition)

Lowest relevant oral NOAEL/NOEL: 0.1 mg/kg bw/day , 1 year dog
Lowest relevant dermal NOAEL/NOEL: 5 mg/kg bw/day , 21 day rabbit
Lowest relevant inhalation NOAEL/NOEL: 1 mg/ m^3 air /day , 21 day rat

Genotoxicity
Based on results form a battery of assays *in vitro* and *in vivo*, fenthion seems to have a slight genotoxic effect (DNA damage, clastogenicity) on mammalian cells.

Result from a in vivo genotoxicity testing (somatic cells) (April 2002):

Under the test conditions E 1752 did not produce any significant increases of chromosome aberrations and polyploidy in mice bone marrow cells *in vivo*.

Long-term toxicity

ChE activity inhibition was predominant in the long-term studies on rats, mice, dogs and monkeys, along with reduced food intake, body weight gain and a slight reduction of life expectation in rats, only at high doses.

- Rat (oral, 24 months): NOAEL= 3 ppm / 0.15 mg/kg bw/day (slight plasma- and RBC-ChE activity inhibition)
- Rat (oral, 24 months): NOEL: 0.09 ppm / 0.03 mg/kg bw/day (females, plasma- ChE activity inhibition; LOEL= 0.09 ppm/ 0.03 mg/kg bw/day (males, plasma- and RBC-ChE inhibition

Lowest relevant NOAEL: 0.25 mg/kg bw/day , 2 year rat

Carcinogenicity

No evidence of carcinogenic potential was found in long-term studies on fenthion in mice and rats.

Reproductive toxicity
No toxicological effects on reproduction were observed at doses below the range of maternal/paternal toxicity. No primary embryotoxic or teratogenic effects were observed in either rats or rabbits.

- Rat (2-generation study): NOEL (maternal)= <1 mg/kg bw/ day (ChE activity inhibition)
NOEL (foetal) = 4.2 mg/kg b.w./day (Increased resorptions)

Lowest relevant NOAEL/NOEL - Reproduction: 1.12 mg/kg bw/day , 2 generation rat (data from EC assessment)
Lowest relevant NOAEL/NOEL – Developmental toxicity: 4.2 mg/kg bw/day , rat (data from EC assessment)
Lowest relevant NOAEL/NOEL – Developmental toxicity: 2 mg/kg bw/day , rabbit (data from EC assessment)

Neurotoxicity
The Scientific Committee on Plants, which provides scientific advice to the European Commission, examined possible neurotoxicity of fenthion in 1998 and 2002 and concluded that fenthion is unlikely to pose a risk of delayed neurotoxicity in humans.

Safety values
EU Risk Assessment ADI = 0.007 mg/kg bw/day
EU Risk Assessment AOEL = 0.01 mg/kg bw/day (oral); 0.2 mg/kg bw/day (dermal); 0.02 mg/kg bw/day (inhalation).
EU Risk Assessment ARfD = 0.01 mg/kg bw/day

These values are both based on the results of a subacute human volunteer study and an uncertainty factor of 10 for the ADI.

1.8.3 Description of ecotoxicological properties of the chemical

Fate and behaviour

Soil

The aerobic degradation of fenthion is rapid and independent of the concentration used. The half-life in soil under aerobic conditions in the lab is low (less than 2 days at 22°C) and DT_{90} values do not exceed 10 days under these conditions. This implies that fenthion does not persist or accumulate in the soil.

Water

The half-life of fenthion in a natural pond water ranged from 1 to 1.5 days. The DT_{50} in a river water was about 7 days while the DT_{90} was 14 days. However there is no data about the fate of the metabolites. The DT_{50} value for fenthion in water/sediment systems was less than 7 days.

Water/sediment study:
DT50 water: about one day
DT90 water: about 10 days
DT50 whole system: about one week
DT 90 whole system: about two weeks

Air

Fenthion is only slightly volatile. On account of the relatively short chemical lifetime of fenthion in the air, it is not expected to be transported in gaseous phase over large distances or accumulate in the air.

Ecotoxicology

- Terrestrial vertebrates

Acute toxicity Rat LD50= ca 250 mg a.s./kg bw
Short term oral toxicity to mammals: NOEC 14 mg/kg diet or 1.12 mg a.s./kg bw/day (mammalian multigeneration study)

- Birds

Acute toxicity Bobwhite quail LD50 = 7.2 mg a.s./kg
Acute toxicity Mallard duck LD50 = 7.2 mg a.s./kg feed
Dietary toxicity to birds: 60 mg a.s./kg
Reproductive toxicity to birds: NOEC 10 mg as/kg bw

- Aquatic species:

- Fish

Acute toxicity (96hrs) Rainbow trout LC50 = 0.83 mg a.s./l
(96hrs) Bluegill sunfish LC50 = 0.83 mg a.s./l
(96hrs) Golden orfe LC50 = 0.83 mg a.s./l
Long term toxicity : NOEC = 0.013 mg a.s./l

- Invertebrates

Acute toxicity (48hrs) Water flea EC50 0.0057 mg a.s./l
(21 days) Water flea EC50= 0.1 µg/l
Chronic toxicity : NOEC based on formulation = 0.000042 mg a.s./l

- Earthworm

Eisenia foetida LC50= 750 mg/kg d.wt (14 days)
Acute toxicity: 375 mg a.s./kg dry weight soil

- Honey bee

Apis mellifera LD50= 0.31 µg/a.s./bee
Apis mellifera LD50= <2 µg/a.s./bee
Acute contact toxicity: 0.31 µg/a.s./bee

	Dossier, monograph and the peer review report under the Peer Review Programme (ECCO January 1997)

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**	Fenthion 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 fenthion had to be withdrawn by 11 August 2004. From 17 February 2004 no authorisations for plant protection products containing fenthion could be granted or renewed. For certain essential uses for specific Member States listed in the Annex to Commission Decision 2004/140/EC a prolonged period of withdrawal may be allowed until 30 June 2007 under specific conditions (see point 2.5.2).
2.2.2	**Reference to the regulatory document**	Commission Decision 2004/140/EC concerning the non-inclusion of fenthion 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 L46 of 17/02/2004, pp.32-34) (copy attached and also available at: http://europa.eu.int/eurlex/pri/en/oj/dat/2004/l_046/l_04620040217en00320034.pdf).
2.2.3	**Date of entry into force of the final regulatory action**	11/08/2004 (Authorisations for plant protection products containing fenthion had to be withdrawn by that date with the exception of certain essential uses as described in point 2.5.2).

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 to that Directive. Within this context, two companies notified their intention to support the inclusion of fenthion in the list of authorised active substances (Annex I to Directive 91/414/EEC) by submission of the necessary data and information. However, only one notifier submitted a dossier. A Member State was designated to undertake a risk assessment based on this dossier. The dossier and the assessment report were subject to peer review during which the Commission consulted with experts from Member States as well as with the notifier, Bayer CropScience. The Scientific Committee on Plants (SCP) was consulted twice (1998 and 2002) in order to give scientific advice on specific questions that could not be resolved in the peer review process. These questions were related to the possible risks of fenthion to human health and the environment. Taking into account all available data and information and also the modified GAP, which had been changed in the course of the evaluation from aerial and full cover application to spot application with a bait formulation, the SCP concluded that risks to birds from the proposed uses of fenthion are very uncertain and therefore could not be excluded. Finally, the Member States and the Commission within the Standing Committee on Food and Chain and Animal Health (SCFCAH) reviewed all results and decided not to include fenthion in Annex I to Directive 91/414/EEC because the 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 fenthion satisfy in general the requirements laid down in Article 5(1) (a) and (b) of Directive 91/414/EEC, in particular with regard to its possible impact on birds. The evaluation was based on a review of scientific data generated for fenthion and Lebaycid 500 EC in

	the context of the prevailing conditions in the European Community (intended uses, recommended application rates, good agricultural practices). Only data that have been generated according to scientifically recognized methods were validated and used for the evaluation. Moreover, data reviews were performed and documented according to generally recognized scientific principles and procedures.
	Reference to the relevant documentation
	Review Report for the active substance Fenthion SANCO/485/00-Final of 3 July 2003 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme (ECCO January 1997). Opinion of the Scientific Committee on Plants SCP/FENTHI/007-Final – adopted on 2 October 1998 Opinion of the Scientific Committee on Plants SCP/FENTHION-BIS/002 Final – adopted on 17 December 2002.

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	
	The final regulatory action was taken in order to protect the environment. However, fenthion is considered harmful owing to its acute oral toxicity value LD50 in rats being within the range 343-556 mg/kg bw. Results of the evaluation indicated a high risk to operators when applying fenthion. Based on an assessment using the German operator exposure model, this risk can be reduced to an acceptable level if personal protective equipment is worn during mixing/loading and application of the substance for the representative uses that were evaluated. However, it should be noted that missing or inappropriate personal protective equipment in violation of the product label and uses other than those evaluated might pose considerably higher risks to operators.	
	Reference to the relevant documentation	
	Review Report for the active substance Fenthion SANCO/485/00-Final of 3 July 2003 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme (ECCO January 1997).	
	Expected effect of the final regulatory action	
	Reduction of risk 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	
	The risk evaluation carried out by the Member States identified a high risk to birds by application of fenthion in orchards (citrus, olives, cherries, peaches). These concerns were confirmed by the Scientific Committee on Plants, which concluded that risks to birds from the proposed uses of fenthion are very uncertain. Therefore, the risks to birds could not be excluded and consequently no acceptable use of fenthion was identified. The risks to other relevant species (mammals, non-target arthropods, earthworms, aquatic organisms) were considered acceptable for the proposed uses, i.e. spot application of bait formulation in olives and citrus. However, it should be noted that fenthion is highly toxic to bees and risk mitigation measures were considered indispensable. It should also be noted that uses other than those evaluated might pose considerably higher risks to the environment.	
	Reference to the relevant documentation	

	Review Report for the active substance Fenthion SANCO/485/00-Final of 3 July 2003 (copy attached) and supporting background documents (dossier, monograph and the peer review report under the Peer Review Programme (ECCO January 1997). Opinion of the Scientific Committee on Plants SCP/FENTHI/007-Final – adopted on 2 October 1998 Opinion of the Scientific Committee on Plants SCP/FENTHION-BIS/002 Final – adopted on 17 December 2002.
	Expected effect of the final regulatory action
	Reduction of risks to the environment.

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**	√ **Pesticide**
	Formulation(s) and use or uses prohibited by the final regulatory action	
	All applications of plant protection products containing fenthion, 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 relabeled in order to match the restricted use 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 11 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 11 August 2005. For essential uses that can continue to be authorised until 30 June 2007, the grace period for disposal, etc of existing stocks is 6 months (i.e., up to 31 December 2007).

List of essential uses that may continue to be authorised

Member States	Use
Spain	Bait application in citrus and peaches
Greece	Bait application in olives
Italy	Bait application in olives
Portugal	Bait application in citrus and olives
Cyprus*	Bait application in citrus and olives

* As provided for in Commission Regulation 1335/2005 amending Decision 2004/140/EC

2.5.3 **Estimated quantity of the chemical produced, imported, exported and used, where available.**		
	Quantity per year (MT)	**Year**
Produced	Not available	
Imported	Not available	
Exported	Not available	
Used	Not available	

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 are likely to be encountered in other countries where 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	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
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E-mail address	klaus.berend@cec.eu.int

Date, signature of DNA and official seal: p/K Berend 22/8/05

Commission Européenne
D.G. ENV