EUROPEAN COMMISSION
DIRECTORATE-GENERAL
ENVIRONMENT
Directorate B - Protecting the Natural Environment
ENV.D.4 - Biotechnology, Pesticides and Health

Brussels, 6 October 2009
JH/ch Arès (09) 264710

Mr. Peter Kenmore
Secretariat for the Rotterdam
Convention, Plant Protection
Service
Plant Production and Protection
Division, FAO
Viale delle Terme di Caracalla
IT - 00100 Rome

Subject: Article 5 of the Rotterdam Convention - Trichlorfon

Dear Mr Kenmore,

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 trichlorfon. The referenced supporting documentation is also attached.

Yours sincerely,

Paul Speight

Paul SPEIGHT
Deputy Head of Unit

c.c.: UNEP Chemicals

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ROTTERDAM CONVENTION

SECRETARIAT FOR THE ROTTERDAM CONVENTION
ON THE PRIOR INFORMED CONSENT PROCEDURE
FOR CERTAIN HAZARDOUS CHEMICALS AND PESTICIDES
IN INTERNATIONAL TRADE

FORM FOR NOTIFICATION

OF FINAL REGULATORY ACTION TO BAN OR SEVERELY RESTRICT A CHEMICAL

Country:

European Community

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

SECTION 1 IDENTITY OF CHEMICAL SUBJECT TO THE FINAL REGULATORY ACTION

1.1	**Common name**	**Trichlorfon**
1.2	Chemical name according to an internationally recognized nomenclature (e.g. IUPAC), where such nomenclature exists	IUPAC: Dimethyl(RS)-2,2,2-trichloro-1-hydroxyethylphosphonate CA: Dimethyl-(2,2,2-trichlor-1-hydroxyethyl)phosphonate
1.3	Trade names and names of preparations	Cekufon 80 SP, a soluble powder (SP) formulation, registered under different trade names in Europe

1.4 Code numbers

1.4.1	CAS number	52-68-6
1.4.2	Harmonized System customs code	2931 00 95
1.4.3	Other numbers (specify the numbering system)	CIPAC No: 68 EEC No. (EINECS or ELINCS): 200-149-3

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 ☐ This notification replaces all previously submitted notifications on this chemical.
Date of issue of the previous notification: _____

SECTION 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

It is prohibited to place on the market or use plant protection products containing trichlorfon. Trichlorfon is not included in the list of authorised active substances in Annex I to Directive 91/414/EEC. Authorisations for plant protection products containing trichlorfon had to be withdrawn by 21 November 2007.

From 25 May 2007 no authorisations for plant protection products containing trichlorfon were allowed to be granted or renewed by the Member States and all uses of plant protection products containing trichlorfon were prohibited as from 21 November 2008.

2.2.2 Reference to the regulatory document, e.g. where decision is recorded or published

Commission Decision 2007/356/EC of 21 May 2007 concerning the non-inclusion of trichlorfon in Annex I to Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing that substance (notified under document number C(2007) 2096). Official Journal of the European Union.

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_133/l_13320070525en00420043.pdf

2.2.3 Date of entry into force of the final regulatory action

Complete entry into force of all provisions of Commission Decision 2007/356/EC of 21 May 2007 was 21 November 2008 since all uses of plant protection products containing trichlorfon were prohibited as from that date at the latest.

2.3 Category or categories where the final regulatory action has been taken

2.3.1 All use or uses of the chemical in your country prior to the final regulatory action

Trichlorfon is a plant protection product, used primarily as an insecticide for the control of lepidopteron insects in the protection of tomatoes. It also has some acaricidal properties.

2.3.2 Final regulatory action has been taken for the category ☐ Industrial

Use or uses prohibited by the final regulatory action

Non relevant

Use or uses that remain allowed (only in case of a severe restriction)

Non relevant

2.3.3 Final regulatory action has been taken for the category ☒ Pesticide

Formulation(s) and use or uses prohibited by the final regulatory action

All the applications as plant protection products.

Formulation(s) and use or uses that remain allowed
(only in case of a severe restriction)

Non relevant

2.4 Was the final regulatory action based on a risk or hazard evaluation?

☒ **Yes**

☐ **No** (If no, you may also complete section 2.5.3.3)

2.4.1 If yes, reference to the relevant documentation, which describes the hazard or risk evaluation

A risk assessment was carried out on the basis of Directive 91/414/EEC, which provides for the European Commission to issue a programme of work for the examination of existing active substances used in plant protection products with a view to their possible inclusion in Annex I to the Directive, and in accordance with the provisions of Article 8(7) of Regulation (EC) No 451/2000.

This resulted in several documents, including:

Review report for the active substance Trichlorfon (SANCO/10049/06 rev.0, September 2006)

http://ec.europa.eu/food/plant/protection/evaluation/existactive/list-trichlorfon_en.pdf

Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon, finalised 12 May 2006, EFSA Scientific Report (2006) 76,1-62, Conclusion on the peer review of trichlorfon

http://www.efsa.europa.eu/cs/BlobServer/PRAPER_Conclusion/praper_concl_sr76_trichlorfon_en1.pdf

2.4.2 Summary description of the risk or hazard evaluation upon which the ban or severe restriction was based.

2.4.2.1 Is the reason for the final regulatory action relevant to human health? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to human health, including the health of consumers and workers

It has not been demonstrated that it can be expected that, under the proposed conditions of use, plant protection products containing trichlorfon satisfy in general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC regarding risks for human health because available information is insufficient to perform a risk assessment regarding the operator, worker, bystanders and consumer exposure.

Moreover, according to the report of the European Food Safety Authority, trichlorfon is harmful during oral exposure and is a skin sensitizer. Notably, the most sensitive effect observed during short term exposure is reduction in acetyl cholinesterase (AChE) activity. Due to lack of data it was not possible to establish an AOEL (Acceptable Operator Exposure Level) and the risk assessment was performed on the basis of a provisional AOEL. In the absence of dermal absorption studies and taking into account physical and chemical properties, experts considered the default dermal absorption value of 100 % appropriate for the risk assessment. This resulted in exposure estimates that were much higher than the provisional AOEL for operators, workers and bystanders.

Expected effect of the final regulatory action

Reduction of risk for human health from the use of plant protection products.

2.4.2.2 Is the reason for the final regulatory action relevant to the environment? ☒ Yes ☐ No

If yes, give summary of the hazard or risk evaluation related to the environment

It has not been demonstrated that it can be expected that, under the proposed conditions of use, plant protection products containing trichlorfon satisfy in

general the requirements laid down in Article 5(1)(a) and (b) of Directive 91/414/EEC regarding risks for the environment. Due to a lack of supporting studies, available information is insufficient with regard to the fate and behaviour of the substance in the environment and its ecotoxicological properties. Concerns were identified with regard to the level of relevant impurities in the technical material and the risk to aquatic organisms.
The use of trichlorfon that was examined during the risk assessment includes the use of a permanent structure that protects the plants (e.g. a glasshouse). Therefore, the risk to birds and mammals was regarded as low based on limited exposure to tomatoes under protection. The risk to non-target arthropods, earthworms, other soil non-target macro-organisms and non-target plants was also considered to be low.
However, although the aquatic toxicity data are inadequate, the assessment on the existing study suggests that the risk to aquatic organisms can already be considered as high, and the risk to bees could not be assessed due to the lack of data.
Moreover, due to the lack of information, a sound assessment of the route and rate of degradation of trichlorfon in soil could not be concluded. For similar reasons, potential for contamination of surface and groundwater by trichlorfon could not be adequately assessed. There is also an outstanding data gap for a study on the effects of trichlorfon on sewage treatment plants.

Expected effect of the final regulatory action

Reduction of risk from the use of plant protection products.

2.5 Other relevant information regarding the final regulatory action

2.5.1 Estimated quantity of the chemical produced, imported, exported and used

	Quantity per year (MT)	Year
produced	No Information	
imported	No Information	
exported	No Information	
used	No Information	

2.5.2 Indication, to the extent possible, of the likely relevance of the final regulatory action to other states and regions

Similar health and environment problems are likely to be encountered in other countries where the substance is used, particularly in developing countries.

2.5.3 Other relevant information that may cover:

2.5.3.1 Assessment of socio-economic effects of the final regulatory action

No information

2.5.3.2 Information on alternatives and their relative risks, e.g. IPM, chemical and non-chemical alternatives

No information

2.5.3.3 Basis for the final regulatory action if other than hazard or risk evaluation

2.5.3.4 Additional information related to the chemical or the final regulatory action, if any

SECTION 3 PROPERTIES

3.1 Information on hazard classification where the chemical is subject to classification requirements

International classification systems **e.g. WHO, IARC, etc.**	**Hazard class**
IARC	Group 3

Other classification systems **e.g. EU, USEPA**	**Hazard class**
Classification of the EC in accordance with Council Directive 67/548/EEC	Xn; Harmful N; Harmful to the environment R22; Harmful if swallowed R43; May cause sensitisation by skin contact R50-53; Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment

Classification according to Regulation (EC) No 1272/2008 of the European Parliament and of the Council	Acute Toxicity (oral) 4 * - H302 Skin Sensitisation 1 - H317 Aquatic Acute 1 - H400 Aquatic Chronic 1 - H410

3.2 Further information on the properties of the chemical

3.2.1 Description of physico-chemical properties of the chemical

Minimum Purity: 980 g/kg

FAO Specification: AGP: CP/237 (1988)

Minimum purity 970 g/kg (980 ± 10 g/kg)

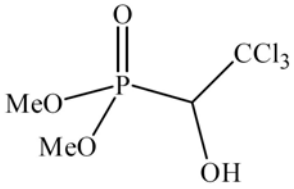
Water: 3 g/kg max.

Acetone insolubles: 5 g/kg max.

Molecular Formula: $C_4H_8Cl_3O_4P$

Molecular Mass: 257.44

Structural Formula:



Appearance: Between white and pink, waxy solid (90.1-94.1%*)

Odour:

Melting Point: Anomalous melting behaviour between 77-83°C (99.4%*)

Boiling Point: Decomposition before boiling (99.4%*)

Vapour Pressure: 2.1 x10-4 Pa at 20°C; 5.0 x10-4 Pa at 25°C (99.5%*)

Volatility:

Henry's Law Constant: 4.5 x10-7 Pa.m³/mole at 20°C

Solubility in Water: 120 g/l at 20°C, pH not stated (99.5%*)

Solubility in Organic Solvents:

Xylene:	21.5 g/l at 23°C (99.3%*)
Ethyl acetate:	363 g/l at 23°C (99.3%*)
Acetone:	707 g/l at 23°C (99.3%*)

	1,2-Dichloroethane	498 g/l at 23°C (99.3%*)
	Methanol	1346 g/l at 23°C (99.3%*)
	n-Heptane	0.66 g/l at 23°C (99.3%*)
Partition coefficient (logPOW):		0.43 at 20°C (99.5%*)
Hydrolytic stability (DT50):	(>98% radiochemical purity)	
	pH 5:	5.4 days (25°C)
	pH 7:	34 hours (25°C)
	pH 9:	31 minutes (25°C)

* = figures in brackets indicate the purity of the test substance

Reference

EFSA (2006). Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon finalised 12 May 2006. EFSA Scientific Report 76, 1-62.

http://www.efsa.europa.eu/cs/BlobServer/PRAPER_Conclusion/praper_concl_sr76_trichlorfon_en1.pdf.

3.2.2 Description of toxicological properties of the chemical

Absorption, Distribution, Excretion and Metabolism in Mammals:

Trichlorfon is rapidly and completely absorbed (80-90% within 24 hours). The highest plasma levels were reported 0.5 and 5 hours after administration, indicating enterohepatic recirculation. Trichlorfon is widely distributed, with the highest concentrations occurring in the liver and kidneys. The main metabolic pathway of trichlorfon involves glucuronidation and further dehydrochlorination. A minor pathway involving the conversion of trichlorfon to dichlorvos has also been identified. In rats, approximately 50% of an administered dose is excreted via the urine, 20% is excreted via the faeces, and 20% is expired as carbon dioxide. In rabbits, greater than 95% is excreted via the urine.

Acute Toxicity:

LD50 (rat, oral)	212 mg/kg bw
LD50 (rat dermal)	>5000 mg/kg bw

Irritation and Sensitisation:

Trichlorfon is non-irritating to the skin and eyes according to EU criteria. It is sensitising to the skin (Magnusson and Kligman's test).

Subchronic Toxicity:

Critical effect: Depression of plasma, RBC (Red Blood Cells) and brain acetylcholinesterase (AChE) activities and neurotoxicological signs.

Target organs: Increased weight, liver, kidney, spleen

Rat (oral, 90 days, male): NOAEL = 135 mg/kg bw/day (note: RBC and brain AChE levels were not determined)

Rat (oral, 90 days, female): LOAEL = 45 mg/kg bw/day (note: RBC and brain AChE levels were not determined)

Rabbit (dermal, 3 weeks): NOAEL = 100 mg/kg bw/day

Rat (inhalation, 3 weeks): NOAEL = 3.43 mg/kg bw/day

Chronic Toxicity:

Rat (oral, 2 years): NOAEL = 4.5 mg/kg bw/day (brain AChE depression, hypercholesterolemia and renal calcification (in males)).

Mouse (oral, 2 years): LOAEL = 49.21 mg/kg bw/day (AChE depression).

Inhalation toxicity:

LC50 active substance > 0.533mg/L (highest attainable concentration)

LC50 formulation (80% trichlorfon) > 1.564mg/L (~1.25 mg a.s./L)

Genotoxicity:

Equivocal results have been reported in *in vitro* gene mutation assays conducted in Chinese hamster lung cells. Positive results have been reported in *in vitro* chromosomal aberration assays conducted in human lymphocytes, with and without metabolic activation.

However the clastogenicity could not be confirmed *in vivo* for somatic cells (micronucleus test) or germ cells (dominant lethal assay) since the studies were considered as non acceptable due to major deviations from the guidelines.

Carcinogenicity:

Rat:

Incidences of adrenal pheochromocytomas and mononuclear cell leukaemia were

increased in male rats, however, incidences were not increased in females to the same extent, and were not increased in a second study at higher doses. Adrenal pheochromocytoma is reported to be common in this strain of rats.

Mouse:

No carcinogenic effects were observed.

Reproductive Toxicity:

Critical effect: No evidence of foetotoxicity in rats and rabbits.

Rabbit (teratology study): Maternal NOAEL 15 mg/kg bw/day

Developmental NOAEL 45 mg/kg bw/day

Neurotoxicity:

Rat (oral gavage, acute): NOAEL 10 mg/kg bw (clinical signs of toxicity, alterations in Field Observation Battery (FOB), decreased motor activity, and significant inhibition of plasma, RBC and brain AChE).

Rat (diet, 90 day): NOAEL 6.08 mg/kg bw/day (decreased bodyweight, motor and locomotor activity, inhibition of all types of AChE, myelin degeneration).

Hen (acute delayed neurotoxicity): LD50 167 mg/kg bw Typical signs of AChE inhibition were observed, however, no delayed neurotoxicity and no inhibition of neurotoxic esterase (NTE) were observed. This study is of poor quality, but is considered acceptable as additional information.

Hen (90 day delayed neurotoxicity): NOAEL 9 mg/kg bw/day (inhibition of whole blood AChE activity and associated clinical symptoms, slight axonal degeneration of the spinal cord).

Safety Values:

Due to the lack of certain studies, the reference values were not confirmed by Member State experts. Here are the provisional values proposed in the Draft Assessment Report:

EU Risk Assessment Acceptable Daily Intake (ADI): 0.045 mg/kg bw/day (based on a NOAEL of 4.5 mg/kg bw/day from a 2-year rat study with 100 safety factor).

EU Risk Assessment Acceptable Operator Exposure Level (AOEL): 0.09 mg/kg bw/day (based on a LOAEL of 45 mg/kg bw/day from a 90-day oral rat study with a higher safety factor of 500)

EU Risk Assessment acute Reference Dose (ARfD): 0.1 mg/kg bw (based on a NOAEL of 10 mg/kg bw/day from the acute oral neurotoxicity study in rats with a safety factor of 100).

Reference

EFSA (2006). Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon finalised 12 May 2006. EFSA Scientific Report 76, 1-62.

http://www.efsa.europa.eu/cs/BlobServer/PRAPER_Conclusion/praper_concl_sr76_trichlorfon_en1.pdf

3.2.3 Description of ecotoxicological properties of the chemical

Soil:

The available data from aerobic soil degradation studies, which were not completely accepted by experts (a new study was requested), suggested that degradation of trichlorfon in aerobic soil is pH dependent. In non-sterile aerobic soil at pH 5, following application of radiolabelled trichlorfon, approximately 30% of the applied radioactivity (AR) was present in soil as non-extractable residues after 67 days. Desmethyl-dichlorvos accounted for 37.55% AR and dichlorovinylphosphate accounted for 40.68% AR. At pH 7, 2-21% AR was present in soil as non-extractable residues after 33 days. In sterile aerobic soil at pH 5, 25% AR was present in the soil as non-extractable residues after 47 days. Due to the difficulty to derive experimentally a reliable Koc value for trichlorfon, a worst case value of zero was used in the risk assessment. The Koc value for two metabolites was set at zero due to missing data and for the metabolite dichlorvinyl phosphate the Koc was 10.2 mL/g.

Water:

The degradation of trichlorfon in water is pH dependent. In a sterile buffer solution at pH 5, following application of radiolabelled trichlorfon, approximately 80% of the applied radioactivity (AR) was identified as parent compound after 34 days. Approximately 10% AR was identified as desmethyl-DDVP, and 7.7% AR was identified as dichloroacetaldehyde (DCAA). At pH 7, after 48 hours, 40% AR was identified as trichlorfon, 25.5% AR was identified as DDVP, 22.7% AR as DCAA, 22.7% AR as DCAA and 12% AR as desmethyl-DDVP. At pH 9, 10.5% AR was present as parent compound after 45 minutes, 52.3% AR was detected as DDVP and 10.5% AR was detected as desmethyl-DDVP. DT50 values were calculated to be 117 days, 38 hours and 31 minutes at pH 5, 7 and 9, respectively. However, it should be noted that a data requirement for the accurate identification of the metabolites hydrolytically produced was established during the risk assessment. Trichlorfon is not expected to undergo photodegradation and is not readily biodegradable.

Air:

The half-life of trichlorfon in the troposphere due to the reaction with hydroxyl radicals has been calculated to be 1.73 days.

Ecotoxicity:

- Terrestrial birds:

None reported.

- Honey bee:

None reported.

- Earthworm

LC50 (Eisena foetida, 14 day, technical): 140 mg a.i./kg soil

- Arthropod:

Aphid parasitoid (Aphidius rhopalosiphi) LR50: 0.519 g a.s./ha

Predatory mite (Typhlodromus pyri) LR50: 90% mortality was observed at 1.2 kg a.s./ha

- Freshwater species:

Algae: Acute, 120 hour EC50

Green algae (Scenedesmus subspicatus): 10 mg/l (technical trichlorfon, 98.1%)

Fish: Acute static, 96 hour LC50

Rainbow trout (Oncorynchus mykiss): 0.7 mg/l (technical trichlorfon, 98.1% a.s.).

Reference

EFSA (2006). Conclusion regarding the peer review of the pesticide risk assessment of the active substance trichlorfon finalised 12 May 2006. EFSA Scientific Report 76, 1-62.

http://www.efsa.europa.eu/cs/BlobServer/PRAPER_Conclusion/praper_concl_sr76_trichlorfon_en1.pdf

SECTION 4 DESIGNATED NATIONAL AUTHORITY

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Date, signature of DNA and official seal: _____

PLEASE RETURN THE COMPLETED FORM TO:

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Definitions for the purposes of the Rotterdam Convention according to Article 2:

(a) '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;

(b) 'Banned chemical' means a chemical all uses of which within one or more categories have been prohibited by final regulatory action, in order to protect human health or the environment. It includes a chemical that has been refused approval for first-time use or has been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(c) 'Severely restricted chemical' means a chemical virtually all use of which within one or more categories has been prohibited by final regulatory action in order to protect human health or the environment, but for which certain specific uses remain allowed. It includes a chemical that has, for virtually all use, been refused for approval or been withdrawn by industry either from the domestic market or from further consideration in the domestic approval process, and where there is clear evidence that such action has been taken in order to protect human health or the environment;

(d) 'Final regulatory action' means an action taken by a Party that does not require subsequent regulatory action by that Party, the purpose of which is to ban or severely restrict a chemical.