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Operation of the interim Prior Informed Consent procedure  
banned or severely restricted chemicals in international trade

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Decision Guidance Document

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Ethylene dichloride

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



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

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Rome - Geneva, February 2001

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## Mandate

The Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade was adopted at the Conference of Plenipotentiaries held in Rotterdam on 10 and 11 of September 1998. The same Conference also adopted a Resolution on interim arrangements in order to operate an interim PIC procedure between the time of the adoption of the Convention and its entry into force, and to prepare for its effective operation once it enters into force.

Paragraph 7 of this Resolution decided that all chemicals that have been identified for inclusion in the PIC procedure under the original PIC procedure but for which Decision Guidance Documents have not yet been circulated before the date on which the Convention is opened for signature will become subject to the interim PIC procedure as soon as the relevant decision guidance documents have been adopted by the Intergovernmental Negotiating Committee (INC).

At its 67th session, held in RomeGeneva on 12-16 July 199930 October to 3 November 2000, the INC thus adopted decision guidance documents for binapacryl and toxapheneethylene dichloride and ethylene oxide (Decision INC-67/23) with the effect that these chemicals became subject to the interim PIC procedure.

The present decision guidance documents for ethylene dichloride was communicated to the Designated National Authorities on 1 September 1999February 2001 with the request that they submit a response concerning the future import of the chemical to the Secretariat in line with Article 10, paragraph 2 of the Rotterdam Convention.

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## Disclaimer

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

While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, the Food and Agriculture Organization of the United Nations (FAO) and the United Nations Environment Programme (UNEP) disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP shall be liable for any injury, loss, damage or prejudice of any kind that may be suffered as a result of importing or prohibiting the import of this chemical.

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



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107-06-2

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## **ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT**

(N.B. Chemical elements and pesticides are not included in this list)

<u>&lt;</u>	<u>less than</u>
<u>≤</u>	<u>less than or equal to</u>
<u>&lt;&lt;</u>	<u>much less than</u>
<u>&gt;</u>	<u>greater than</u>
<u>≥</u>	<u>greater than or equal to</u>
<u>µg</u>	<u>Microgram</u>
<u>a.i.</u>	<u>active ingredient</u>
<u>ACGIH</u>	<u>American Conference of Governmental Industrial Hygienists</u>
<u>ADI</u>	<u>acceptable daily intake</u>
<u>ADP</u>	<u>adenosine diphosphate</u>
<u>ATP</u>	<u>adenosine triphosphate</u>
<u>BBA</u>	<u>Biologische Bundesanstalt für Land- und Forstwirtschaft</u>
<u>b.p.</u>	<u>boiling point</u>
<u>Bw</u>	<u>body weight</u>
<u>°C</u>	<u>degree Celsius (centigrade)</u>
<u>CA</u>	<u>Chemicals Association</u>
<u>CCPR</u>	<u>Codex Committee on Pesticide Residues</u>
<u>CHO</u>	<u>Chinese hamster ovary</u>
<u>D</u>	<u>Dust</u>
<u>EC</u>	<u>Emulsifiable concentrates</u>
<u>EC50</u>	<u>Effect concentration, 50%</u>
<u>ED50</u>	<u>Effect dose, 50%</u>
<u>EHC</u>	<u>Environmental Health Criteria</u>
<u>ERL</u>	<u>Extraneous residue limit</u>
<u>EU</u>	<u>European Union</u>
<u>FAO</u>	<u>Food and Agriculture Organization of the United Nations</u>
<u>g</u>	<u>Gram</u>
<u>GAP</u>	<u>Good agricultural practice</u>

## ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

<u>GL</u>	<u>Guideline level</u>
<u>GR</u>	<u>Granules</u>
<u>ha</u>	<u>Hectare</u>
<u>i.m.</u>	<u>Intramuscular</u>
<u>i.p.</u>	<u>Intraperitoneal</u>
<u>IARC</u>	<u>International Agency for Research on Cancer</u>
<u>IC50</u>	<u>Inhibition concentration, 50%;</u>
<u>IPCS</u>	<u>International Programme on Chemical Safety</u>
<u>IRPTC</u>	<u>International Register of Potentially Toxic Chemicals</u>
<u>IUPAC</u>	<u>International Union of Pure and Applied Chemistry</u>
<u>JMPR</u>	<u>Joint FAO/WHO Meeting on Pesticide Residues (Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and a WHO Expert Group on Pesticide Residues)</u>
<u>k</u>	<u>Kilo- (x 1000)</u>
<u>kg</u>	<u>Kilogram</u>
<u>Koc</u>	<u>Organic carbon-water partition coefficient</u>
<u>l</u>	<u>Litre</u>
<u>LC<sub>50</sub></u>	<u>Lethal concentration, 50%</u>
<u>LD<sub>50</sub></u>	<u>Lethal dose, 50%</u>
<u>LOAEL</u>	<u>Lowest observed adverse effect level</u>
<u>LD<sub>LO</sub></u>	<u>Lowest lethal dose</u>
<u>LOEL</u>	<u>lowest observed effect level</u>
<u>m</u>	<u>Metre</u>
<u>m.p.</u>	<u>melting point</u>
<u>mg</u>	<u>Milligram</u>
<u>ml</u>	<u>Millilitre</u>
<u>mPa</u>	<u>MilliPascal</u>
<u>MRL</u>	<u>maximum residue limit</u>
<u>MTD</u>	<u>maximum tolerated dose</u>
<u>NCI</u>	<u>National Cancer Institute</u>
<u>ng</u>	<u>Nanogram</u>
<u>NIOSH</u>	<u>National Institute of Occupational Safety and Health</u>

## ABBREVIATIONS WHICH MAY BE USED IN THIS DOCUMENT

<u>NOAEL</u>	<u>no-observed-adverse-effect level</u>
<u>NOEL</u>	<u>no-observed-effect level</u>
<u>OP</u>	<u>organophosphorus pesticide</u>
<u>PHI</u>	<u>pre-harvest interval</u>
<u>PIC</u>	<u>prior informed consent</u>
<u>Pow</u>	<u>octanol-water partition coefficient</u>
<u>POP</u>	<u>persistent organic pollutant</u>
<u>ppm</u>	<u>parts per million (used only with reference to the concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or mg/l are used).</u>
<u>RfD</u>	<u>reference dose for chronic oral exposure</u>
<u>SBC</u>	<u>secretariat for the Basel Convention</u>
<u>SC</u>	<u>Soluble concentrate</u>
<u>SG</u>	<u>water soluble granules</u>
<u>SL</u>	<u>soluble concentrate</u>
<u>SMR</u>	<u>standardized mortality ratio</u>
<u>STEL</u>	<u>short term exposure limit</u>
<u>TADI</u>	<u>temporary acceptable daily intake</u>
<u>TLV</u>	<u>threshold limit value</u>
<u>TMDI</u>	<u>theoretical maximum daily intake</u>
<u>TMRL</u>	<u>temporary maximum residue limit</u>
<u>TWA</u>	<u>time weighted average</u>
<u>UNEP</u>	<u>United Nations Environment Programme</u>
<u>USEPA</u>	<u>United States Environmental Protection Agency</u>
<u>UV</u>	<u>Ultraviolet</u>
<u>VOC</u>	<u>volatile organic compound</u>
<u>WHO</u>	<u>World Health Organization</u>
<u>WP</u>	<u>wettable powder</u>
<u>Wt</u>	<u>Weight</u>

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## PIC - Decision guidance document for a banned or severely restricted chemical

## Ethylene dichloride

Published: [February 2001](#)

	<b>Common name</b>	Ethylene dichloride (ISO)
<b>Formatted</b>	<b>Other names/ Synonyms</b>	1,2-Dichloroethane (IUPAC, CA); alpha,beta-dichloroethane; 1,2-bichloroethane dichloride; <u>ethane, 1,2-dichloro-</u> ; ethylene chloride; <u>EDC</u> ; 1,2-ethylenedichloride; sym-(metric)-dichloroethane.
<b>Formatted</b>	<b>CAS No.</b>	107-06-2
	<b>Use category</b>	Pesticide
<b>Deleted: both</b>	<b>Use</b>	Ethylene dichloride is <u>reported</u> used <u>as both</u> a pesticide and an industrial chemical.
<b>Formatted</b>		<b>Pesticide use:</b> A small fraction of the total production (approximately 0.1% in the USA in 1977) was used for pesticide solvent and as an insecticidal fumigant, mainly in agricultural products. When used as a fumigant, ethylene dichloride is usually mixed with tetrachloroethylene to reduce the fire hazard, and small portions of other fumigants are added (WHO, 1987). <u>It was also used as a rodenticide.</u>
<b>Deleted: as</b>		<b>Industrial use:</b> The major industrial use of the compound is in the synthesis of perchloroethylene (approximately 90% of the total production in Japan and approximately 50% of total production in the USA). Other chemicals produced from ethylene dichloride include 1,1,1-trichloroethane, ethyleneamines, vinylidene chloride, trichloroethylene, tetrachloroethylene <u>and ethylene glycol</u> . In 1977, 2 - 4% of the total production of ethylene dichloride in the USA was used for the synthesis of each of these chemicals. Another 2% was used in the USA as a lead scavenger in gasoline (WHO, 1987). <u>It was also used as laboratory solvent, as a drying agent in glues and for the fusion of polyethylene.</u>
<b>Formatted</b>		<b>Trade names</b>
<b>Deleted: s</b>		Borer-Sol, Brocide, Destruxol, Dichlor-emulsion, Dichlor-mulsion, Dutch Liquid, Oil, ENT 1656, Gaze Olefiant.
<b>Deleted: used</b>		<b>Formulation types</b>
<b>Formatted</b>		Liquid
<b>Formatted</b>		<b>Basic manufacturers</b>
<b>Deleted: s</b>		Dow Chemicals USA; Vulcan Materials Company, USA
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<b>Deleted: . This application will decline in importance with the worldwide conversion to unleaded fuel (WHO, 1987)</b>		

## Reasons for inclusion in the PIC procedure

Ethylene dichloride is included in the PIC procedure based on reported bans and severe restriction: use as a pesticide<sup>1</sup>. No control actions have been reported relating to its industrial uses. Inclusion is recommended at the eighth meeting of the FAO/UNEP Joint Group of Experts on Prior Informed Consent following detailed discussions during the sixth and seventh meetings.

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**Deleted: .** It is included in the procedure on the basis of the control actions reported by a number of Governments

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<sup>1</sup> Users of the DGD should be aware that the term "pesticides" may have different meanings in different jurisdictions

## Summary of control actions (see Annex 2 for details)

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Control actions were reported by 6 countries and the European Union. In 5 countries (Austria, Canada, Slovenia and the United Kingdom) and in the European Union, ethylene dichloride was reported as banned for use as an agricultural pesticide. No remaining uses in agriculture were reported. It reported that ethylene dichloride was totally banned for the fumigation of stored products. Concerning the carcinogenic properties of ethylene dichloride on human health is reported as a primary reason for control actions.

## Hazard classification by organization

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WHO	Gaseous or volatile fumigant, not classified under the WHO recommended classification of pesticides by hazard (IPCS, 1998-1999).
EPA	Group B2 (probable human carcinogen). (USEPA, 1991).
EU	F; R11 carc. Cat. 2; R45 Xn; R 22 Xi; R 36/37/38 (classification in accordance with Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances). (12 <sup>th</sup> ATP, 1991).
IARC	Group 2B (possibly carcinogenic to humans). (IARC, 1999).

## Protective measures that have been applied concerning the chemical

### Measures to reduce exposure

For the health and welfare of workers and the general public, the handling and application of this substance should be entrusted only to competently supervised and well-trained applicators who follow adequate safety measures and use the chemical according to good application practices. Re-exposed workers should receive appropriate monitoring and health evaluations. Protective clothing indicated in the *FAO Guidelines for Personal Protection when Working with Pesticides in Tropical Climates* (1990) is required.

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In view of the volatility of ethylene dichloride, particular attention should be given to control inhalation exposure.

### Packaging and labelling

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Follow the *FAO Revised Guidelines on Good Labelling Practice for Pesticides* (1995) and the *Guidelines for the Packaging and Storage of Pesticides* (1985). Unbreakable packaging required; put the product in unbreakable packaging into closed unbreakable container. Do not transport with food and feed stuff.

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

**Hazard class:** 3

**Packing group:** II

### Alternatives

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Only Austria reported that many alternatives for designated purposes were available. No alternative was reported by other notifying countries.

It is essential that before a country considers substituting any of the reported alternatives, it ensure the use is relevant to their national needs.

## Waste Disposal

Waste should be disposed of in accordance with the provisions of the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal, any guidelines thereunder (1994) and any other relevant regional agreements.

See the *FAO Guidelines on Prevention of Accumulation of Obsolete Pesticide Stocks (1995)*, or *Pesticide Storage and Stock Control Manual (1996)*.

Wear protective clothing and respiratory equipment suitable for hazardous materials. Sweep, scoop up spilled material. Vacuuming or wet sweeping may be used to avoid dust dispersal. Do not flush into surface water or sanitary sewer system. Dispose of empty containers in a sanitary landfill or incineration.

Waste must never be discharged into sewers or surface waters. Contaminated porous surfaces (vermiculite, etc) should be disposed of at a waste management facility. Recovered liquids must be reprocessed, incinerated or treated at a waste management facility (Environment Canada, 1992).

It should be noted that the methods recommended in the literature are often not suitable in a developing country. High temperature incinerators may not be available. Consideration should be given to the alternative destruction technologies.

## Exposure limits

	Type of limit	Value
Food	MRL's (Maximum Residue Limits in mg/kg) in specified products (FAO/WHO, 1999).	No MRL allocated.
	JMPR ADI (Acceptable Daily Intake) in mg/kg diet (WHO, 1992).	No ADI allocated.
Workplace	USA TLV-TWA (Threshold Limit Value: Time-Weighted Average) (ACGIH, 1999).	10 ppm (40 mg/m <sup>3</sup> )

## First aid

**First aid:** Move victim to fresh air. Call emergency medical care. Apply artificial respiration if victim is not breathing. Administer oxygen if breathing is difficult. Remove and isolate contaminated clothing and shoes. In case of contact with substance, immediately flush skin or eyes with running water for at least 15 minutes. Wash skin with soap and water. Keep victim warm and quiet. Effects of exposure (inhalation, ingestion or skin contact) to substance may be delayed. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves (U.S. Department of Transportation, 1996).

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**Deleted:** Precautions for "carcinogens": There is no universal method for disposal that has been proved satisfactory for all carcinogenic compounds. Ethylene dichloride is a candidate for liquid injection incineration, with a temperature of 650 to 1600 °C and a residence time of 0.1 to 2 seconds. (USEPA, 1987).

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**Deleted:** Persons who have been poisoned (accidentally or otherwise) should be transported immediately to a hospital and put under surveillance of properly trained medical staff. ¶  
Eyes: Immediately flush eyes with plenty of water for at least 15 minutes, occasionally lifting the upper and lower lids. Seek medical attention immediately. ¶  
Skin: Flush skin with plenty of soap and water for at least 15 minutes before removing contaminated clothing and shoes. ¶  
Ingestion: Do not induce vomiting. Have the victim rinse his or her mouth and then drink 2-4 cupsful of water, and seek medical advice. ¶  
Inhalation: Remove from exposure into fresh air immediately.

## **Annexes**

- Annex 1 **Further information on the substance**
- Annex 2 **Details on reported control actions**
- Annex 3 **List of designated national authorities**
- Annex 4 **References**

## Annex 1 - Further information on the substance

### 1 Chemical and physical properties

<b>1.1 Identity</b>	Clear colourless liquid; chloroform-like odour; sweet taste ( <i>Tomlin, 1994</i> ).
<b>1.2 Formula</b>	C <sub>2</sub> H <sub>4</sub> Cl <sub>2</sub>
<b>Chemical name</b>	1,2-dichloroethane (CA).
<b>1.3 Solubility</b>	<u>5-10 mg/ml at 19°C in water</u>
<b>logPow</b>	1.76
<b>1.4 Vapour pressure</b>	8.53 kPa (64 mmHg), 20 °C, highly volatile.
<b>1.5 Melting point</b>	-36°C
<b>1.6 Boiling point</b>	<u>83.5°C</u>
<b>1.7 Flammability</b>	<u>It is flammable. The flash point is 13°C</u>
<b>1.8 Reactivity</b>	This compound is incompatible with strong alkalis, strong caustics, oxidizing materials, active metals such as aluminium, magnesium, sodium or potassium. It reacts violently with nitrogen tetroxide, dimethylaminopropylamine or ammonia. A vigorous reaction also occurs when a mixture of this compound and propylene dichloride and o-dichlorobenzene comes into contact with aluminium. It can corrode iron, zinc and aluminium in the presence of moisture ( <i>Sax, 1986</i> ). Mixtures with <u>nitric acid</u> easily deteriorate ( <i>Bretherick, 1986</i> ).

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Deleted: 8.69 g/litre at 20 °C, miscible with alcohol, chloroform, ether (*IARC, 1979*).

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### 2 Toxicity

#### 2.1 General

- 2.1.1 Mode of action** Although only limited quantitative data are available, inhaled ethylene dichloride is likely to be adsorbed by the lungs in humans and experimental animals, based on its high vapour pressure and serum/air partition coefficient (*WHO, 1994*).
- 2.1.2 Uptake** Ethylene dichloride can be found in the blood of rodents, almost immediately after dermal, oral or inhalation exposure. Peak blood level in rat during continuous exposure for 24 hours is 135 mg/l (*Morton, 1991 in Richardson, 1993*).
- 2.1.3 Metabolism** Ethylene dichloride is metabolised in rat and mouse by two competing pathways, both of which involve glutathione (GSH). Oxidation to chloroacetaldehyde which is detoxified by GSH; it also reacts with GSH to form S-(2-chloroethyl)glutathione (*D'sruza, 1988 in Richardson, 1993*).
- Following intraperitoneal injection of mouse, the alkyl purines N<sup>6</sup>-carboxymethylguanine and 7-[S-(2-cysteinyl)ethyl]guanine were found in the urine. Chloroacetaldehyde and S-(2-chloroethyl)glutathione were found in haemoglobin (*Svensson, 1986 in Richardson, 1993*).
- Following intraperitoneal injection of 50-170 mg/kg <sup>14</sup>C-ethylene dichloride in mice, 10-42% was expired unchanged and 12-15% as carbon dioxide. No

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the remainder was excreted in the urine, primarily as chloroacetic acid (chloroacetaldehyde), S-(carboxymethyl)cysteine and thiodiacetic acid (1971 in Richardson, 1993).

Little dechlorination of ethylene dichloride was found to occur in rat and liver preparations in vitro (Rannug, 1978 in Richardson, 1993).

Metabolism of ethylene dichloride appears to have a significant role in the manifestation of the toxic, carcinogenic and mutagenic effects of this chemical.

## 2.2 Known effects on human health

### 2.2.1 Acute toxicity

**Symptoms of poisoning** Breathing ethylene dichloride can irritate the nose, throat and lungs causing coughing, shortness of breath and difficulty in breathing. Higher levels can cause a build-up of fluid in the lungs (pulmonary oedema). This can lead to death. Exposure can cause nausea, vomiting, headaches, increased drowsiness and then loss of consciousness. Over-exposure can also cause liver and kidney damage, and irritate the eyes. Contact can irritate the skin causing redness and a rash, and irritate the eyes (USEPA, 1987).

The lethal oral dose of ethylene dichloride in humans has been estimated to be between 20 and 50 ml (WHO, 1994).

### 2.2.2 Short and long term exposure

**Cancer Hazard:** Ethylene dichloride may be a carcinogen in humans as it has been shown to cause stomach, lung, breast and other types of cancer in animals.

**Other long term effects:** Ethylene dichloride can irritate the lungs. Repeated exposure may cause bronchitis to develop with cough, phlegm and shortness of breath. Repeated, prolonged contact can chronically irritate the skin causing dryness, redness and a rash. Repeated, prolonged exposure can cause loss of appetite, nausea and vomiting, trembling and low blood sugar (with weakness). It may damage the liver and kidneys (USEPA, 1987).

### 2.2.3 Epidemiological studies

Significant excess of deaths due to pancreatic cancer was found in a study of 278 men working in the chlorohydrin unit of a chemical production plant between 1941 and 1967 (Benson & Teta 1993 in WHO, 1995).

No significant difference was found compared with control in a case-control study on 21 employees at a petrochemical plant in USA (WHO, 1994).

In a cohort study of 6588 workers at the same plant, no significant excess of malignant brain tumours was observed (Austin & Schnatter, 1983 in WHO, 1995).

No association between ethylene dichloride spill and leukaemia in children was found in a small case-control study (Deschamps & Band, 1993 in WHO, 1995).

A statistically significant increase in colon and rectal cancer was observed in men aged  $\geq 55$  years and whose drinking water contained  $\geq 0.1$  mg/l ethylene dichloride, even if the authors did not suggest an association between ethylene dichloride and cancer but underlined the higher cancer incidence in populations consuming chlorinated water (Isacson in WHO, 1995).

Higher prevalence of subjective symptoms was observed in 10 male workers in an oil refinery exposed to 250-800 mg/m<sup>3</sup> than in those exposed to

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concentrations. However there was a co-exposure to benzene (*Cetnar 1959 in WHO, 1995*).

An increased morbidity for all disease categories was observed in a period (1951-55) in a group of workers at an aircraft factory exposed 30% of the working time to 80-150 mg/m<sup>3</sup> and to ≤ 5 mg/m<sup>3</sup> for the remainder (*Kozik, 1957 in WHO, 1995*).

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## 2.3 Toxicity studies with laboratory animals and *in vitro* systems

### 2.3.1 Acute toxicity

**oral** LD<sub>50</sub> for rats, mice, dogs and rabbits ranged from 413 to 2500 mg/kg (*WHO, 1995*).

**Dermal** LD<sub>50</sub> for rabbits ranged from 2800 to 4900 mg/kg bw (*Torkelson & 1981 in WHO, 1995*).

**Inhalation** LC<sub>50</sub> for rats exposed for 6 or 7.25 hours ranged from 4000 mg/m<sup>3</sup> to 10000 mg/m<sup>3</sup> (*WHO, 1995*).

**Irritation** Application of ethylene dichloride to the skin of experimental animals resulted in microscopic changes and moderate oedema (*Duprat et al., 1981 in WHO, 1995*).

### 2.3.2 Short-term exposure

Several short-term and subchronic studies in different experimental species indicate that liver and kidneys are the target organs. The documentation is considered inadequate to derive NOELs or LOELs. Some studies showed morphological changes in the liver in several species following subacute exposure to airborne concentrations as low as 800 mg/m<sup>3</sup>. Liver weight increase was observed in rats with subchronic oral administration of 400 mg/kg bw. Changes in serum parameters that indicate liver and kidney damage were observed in rats exposed to airborne concentrations as low as 800 mg/m<sup>3</sup> for 12 months (*WHO, 1995*).

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### 2.3.3 Long-term exposure

Studies on the chronic effects are related to the carcinogenicity of the substance and do not give sufficient information on non-neoplastic effects of the substance. Ethylene dichloride was carcinogenic in mice and rats administered by gavage or dermal application, while no increase in the incidence of tumours was noted in inhalation or in initiation/promotion bioassays (*WHO, 1994*).

### 2.3.4 Effects on reproduction

There is no evidence from a limited number of studies that ethylene dichloride is teratogenic in experimental animals. There is also little convincing evidence that ethylene dichloride induces reproductive or developmental effects at doses below those which cause other systemic effects (*WHO, 1995*).

### 2.3.5 Mutagenicity

Ethylene dichloride has been consistently positive in *in vitro* mutagenicity bioassays in *Salmonella typhimurium*. Response has been greater in the presence of an exogenous activation system (cytochrome P450 system) than in its absence, and mutagenicity was more than doubled in *S. typhimurium* expressing the human GSTA-1 gene. In cultured mammalian cells, ethylene dichloride forms DNA adducts. It also induces unscheduled DNA synthesis in primary cultures of rodents and human cells and gene mutation in several cell lines. Mutation frequency in human cell lines has been correlated with differences in glutathione-S-transferase activity. In *in vivo* studies ethylene dichloride induced somatic cell and sex-linked recessive lethal mutations in *Drosophila melanogaster* and the compound bound to DNA in all rodent studies in rats and mice. Although primary DNA damage in liver and

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chromatid exchange has been observed in studies in mice, there has been evidence for micronucleus induction (WHO, 1995).

### 2.3.6 Carcinogenicity

Carcinogenicity of ethylene dichloride was investigated in a few bioassays on experimental animals. Significant increases were not found for any type of tumour in Sprague-Dawley rats or Swiss mice exposed to 607 mg/m<sup>3</sup> for 78 weeks (a high mortality was observed in this study although it was not related to concentration). No significant increase in the incidence of mammary gland adenomas and fibroadenomas in Sprague-Dawley females exposed to 200 mg/m<sup>3</sup> for 2 years (WHO, 1995).

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Significant increased incidence of tumours was observed in two studies following ingestion; squamous cell carcinomas of the stomach in males and haemangiosarcomas in both sexes. Fibromas of the subcutaneous tissues in males, adenocarcinomas and fibroadenomas of the mammary glands in females were observed in Osborne-Mendel rats with Time-Weighted Average (TWA) daily doses of 45 to 95 mg/kg bw/day for 78 weeks. Similar increases in alveolar/bronchiolar adenomas in males and females, mammary adenocarcinomas in females and endometrial stromal polyp or endometrial stromal sarcoma combined in females and hepatocellular carcinoma in males were observed in B6C3F1 mice administered TWA of 97 or 195 mg/kg bw/day for males and 149 or 299 mg/kg bw/day for females by gavage for 78 weeks (WHO, 1995).

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A significant increase of lung tumours (benign papillomas) was found in female mice following repeated ethylene dichloride application for 440 days. A dose-related increase in the incidence of pulmonary adenoma was found in mice following repeated intraperitoneal injection of ethylene dichloride but was not significant. Concomitant exposure to inhaled ethylene dichloride and disulfiram in the diet resulted in an increased incidence of intrahepatic bile duct cholangiomas and cysts, subcutaneous fibrosarcomas, hepatic neoplastic nodules, interstitial cell tumours in the testes, mammary adenocarcinomas in rats compared to rats administered either ethylene dichloride alone or untreated controls. A further three bioassays did not show evident tumour development initiating or promoting properties (WHO, 1995).

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## 3 Exposure

- 3.1 **Food** Very little information is available on ethylene dichloride in food. Ethylene dichloride was found in Germany in milk products with added fruits. In Canada it was used as an extractant in samples of spice oleoresins. Residue studies show that ethylene dichloride can be found in fumigated grain (WHO, 1995).
- 3.2 **Occupational** Ethylene dichloride levels of up to 150 mg/m<sup>3</sup> and ranging from 40 to 800 mg/m<sup>3</sup> were detected in industrial plants using the chemical as a solvent (WHO, 1995). Time-weighted averages of 0.1 and 1 mg/m<sup>3</sup>, respectively, have been reported for two different jobs in an anti-knock agent blending plant in the USA. The maximum exposure level measured was 8.9 mg/m<sup>3</sup> (WHO, 1995).

- 3.3 Environment** Owing to the limited releases of ethylene dichloride, it is a rare environmental contaminant. It has been detected in both surface and groundwater unlike other volatile organic compounds (VOCs), higher levels were found in surface waters. USEPA estimates that 0.3% of all groundwater samples contain ethylene dichloride concentrations ranging from 0.5 to 5.0 g/l. Only 1 percent of surface waters are estimated to have concentrations from 0.5 to 5.0 g/l (*Howard, 1990; USEPA, 1987*).
- Ethylene dichloride commonly occurs in the air of urban and suburban areas at concentrations less than 0.2 ppb. The greatest source of ethylene dichloride exposure is from the air. Drinking water is the greatest source of exposure for populations with drinking water levels above 6 g/l (*Howard, 1990; USEPA, 1987*).
- 3.4 Accidental poisoning** Acute incidental exposure to ethylene dichloride by inhalation or ingestion can result in a variety of effects in humans, including effects on the central nervous system, liver, kidney, lung and cardiovascular system.

## 4 Effects on the environment

- 4.1 Fate** Ethylene dichloride released to the air slowly degrades over a period of a few months. Photo-oxidation with hydroxyl radicals, that results in the production of carbon dioxide and hydrochloric acid, is believed to be the predominant removal process. It is expected that ethylene dichloride is not transported over long distances and washed out during rainfall. Ethylene dichloride photolysis is not expected to occur (*Howard, 1990*).

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Ethylene dichloride released to surface waters will be removed primarily by evaporation within a few days or weeks. Adsorption to sediment and hydrolysis is not expected.

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Releases of ethylene dichloride on to soil will evaporate fairly rapidly. Migration to groundwater is expected for sandy soils (*Howard, 1990*).

- 4.1.1 Persistence** Biodegradation is not expected to occur under either aerobic or anaerobic conditions. The photo-oxidation of ethylene dichloride in air is expected to be a slow process. No significant bioaccumulation is expected to occur in aquatic organisms (*Howard, 1990*).

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- 4.1.2 Bioconcentration** Ethylene dichloride is not expected to bioconcentrate in fish due to its low K<sub>ow</sub>. The measured bioconcentration factor for bluegill sun fish is 1.5 (*Richardson, 1993*).

## 4.2 Ecotoxicity

- 4.2.1 Fish** Acute toxicity studies have been conducted on several species of freshwater fish. The most sensitive species was two to three-month old goldenfish (*Poecilia reticulata*), with a nominal 7-day LC<sub>50</sub> of 106 mg/l ethylene dichloride under static renewal test conditions. In three studies in 30-day fathead minnows (*Pimephales promelas*) over 96-hour LC<sub>50</sub> values ranged from 116 to 136 mg/l under flow-through conditions. The only available acute toxicity study in marine fish involved tidewater silversides (*Amblyopsys beryllina*) in which a nominal 96-hour LC<sub>50</sub> of 480 mg/l was reported under static test conditions (*WHO, 1994*).

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In a long-term flow-through study of the early life stages of fathead minnow (*Pimephales promelas*) a NOEL of 29 mg/l and a LOEL of 59 mg/l (re larval growth) were identified (WHO, 1994). The EC<sub>50</sub> for hatchability 27-day LC<sub>50</sub> for post-hatch survival both of 34 mg/l, resulted from ethylene dichloride flow-through assay on embryos and larvae of rainbow trout (*Onchorhynchus mykiss*) and the LOEL identified was 3.49 mg/l reduction in egg hatchability (WHO, 1994).

After 21 days of continuous exposure to 150 mg/l ethylene dichloride mortality of coho salmon (*Onchorhynchus kisutch*) eggs was 46%, while for alevins, 100% mortality occurred 9 days after hatching at 320 mg/l (WHO, 1994).

Teratogenic effects were observed in rainbow trout (*Onchorhynchus mykiss*). *Daphnia magna* appear to be the invertebrate species most sensitive to ethylene dichloride in chronic toxicity studies in freshwater. Under static conditions, the measured 48-hour LC<sub>50</sub> values for fed and unfed first instar *Daphnia* were 320 and 270 mg/l, respectively; the 48-hour LC<sub>50</sub> based on complete immobilization, were 180 and 160 mg/l for fed and unfed organisms, respectively (WHO, 1994).

In a 28-day flow-through study on *Daphnia magna* the LOEL and NOEL for reproductive success were respectively 20.7 and 10.6 mg/l, while the LOEL and NOEL for growth were 71.7 and 41.6 mg/l (WHO, 1994).

With regard to acute toxicity studies in marine invertebrates under static conditions, the nominal 24-hour EC<sub>50</sub> for immobilization of 30-hour post-hatched larvae of the brine shrimp, *Artemia salina*, was 93.6 mg/l (WHO, 1994). For marine adult shrimp, *Crangon crangon*, the measured 24-hour LC<sub>50</sub> was 100 mg/l, under static test conditions (WHO, 1994).

#### 4.2.2 Aquatic invertebrates

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#### 4.2.3 Birds

Significant reduction of the egg weight at 250 mg/kg and reduction of the number and weight of eggs at 500 mg/kg were observed in a study in which male and female leghorn chickens were fed mash which had been fumigated with ethylene dichloride (WHO, 1994).

#### 4.2.4 Bees

There are no adequate studies to permit an assessment of effects on bees.

#### 4.2.5 Other

##### Aquatic micro-organisms

The IC<sub>50</sub>s for *Nitrosomonas* and methanogens (29 and 25 mg/l, respectively) were considerably lower than for aerobic heterotrophs (470 mg/l). For bacteria, *Pseudomonas putida*, the nominal 16-hour EC<sub>50</sub> for the order of cell multiplication inhibition was 135 mg/l (WHO, 1994).

The freshwater blue-green algae, *Microcystis aeruginosa*, was seven times more sensitive to ethylene dichloride than green algae, *Scenedesmus quadricauda*, with a nominal 7-day ED<sub>50</sub>s for inhibition of cell multiplication at 27 °C of 105 and 710 mg/l, respectively (WHO, 1994).

Based on bioluminescence, the 5-minute IC<sub>50</sub> was 700 mg/l in a Microtox test with *Photobacterium phosphoreum* (WHO, 1994).

##### Aquatic vertebrates

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In a study in which embryos and larvae of the north-western salamander (*Ambystoma gracile*) and the leopard frog (*Rana pipiens*) were continuously exposed to ethylene dichloride from 30 minutes of fertilization (embryos maintained through four days posthatching (larvae), the resulting LC<sub>50</sub> for the salamander were 6.53 mg/l at the day of hatching (day 5) and 2.5 mg/l 4-day posthatching (day 9). LOEL was 0.99 mg/l for 23% reduction in hatching success.

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hatchability. The measured 5-day and 9-day LC<sub>50</sub> values for the frog 4.52 and 4.40 mg/l respectively, while the 5-day posthatch LOEL was 4.52 mg/l (WHO, 1994).

Terrestrial  
invertebrates

In an acute contact test, a 48-hour LC<sub>50</sub> for earthworms (*Esinia* sp.) exposed to ethylene dichloride-treated filter paper was 60 µg/m<sup>2</sup> (WHO, 1994).

Plants

Ethylene dichloride vapour was both lethal and mutagenic to barley k (two-rowed variety, *Bonus*) following exposure to 3 mg/m<sup>3</sup> for 24 hours



## Annex 2 - Details on reported control actions

### AUSTRIA

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**Effective:** 1992.

**Control action:** All agricultural uses banned.

**Reasons:** Carcinogenic and mutagenic properties. The substance has a potent reproductive effects in males and central nervous system effects.

**Alternatives:** Many alternatives for designated purposes.

### BELIZE

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**Effective:** 1985.

**Control action:** The substance is banned for agricultural use.

**Reasons:** Mixed with CCl<sub>4</sub>, a carcinogen.

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### CANADA

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**Effective:** 1984.

**Control action:** Suspended/banned for agricultural use.

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### EUROPEAN UNION

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**Effective:** 1989.

**Control action:** The placing on the market and the use of plant protection products containing 1,2-dichloroethane is prohibited. No remaining uses in agriculture allowed.

**Reasons:** The use of 1,2-dichloroethane as a plant protection product, in particular fumigate plants and soil, is likely to give rise to harmful effects on human and animal health as well as unreasonable adverse influence on the environment. 1,2-dichloroethane has been classified by the European Community as category 2 carcinogen (probably carcinogenic to humans).

(Member States of the European Union are: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain, Sweden, United Kingdom.)

### SLOVENIA

**Effective:** 1997.

**Control action:** Banned for use in agriculture.

**Reasons:** This chemical was banned from the use in agriculture due to the effect of its toxic properties to human health and the environment according to the opinion given by the Commission on Poisons.

**THAILAND****Deleted:** 1995.**Formatted****Formatted****Deleted:** All use categories have been banned.**Formatted****Formatted****Deleted:** y**Deleted:** ic in test animals**Effective:** 1995**Control action:** Ethylene dichloride was totally banned for the export, import, production, and use of Ethylene dichloride for fumigation of stored products was totally banned by the final regulatory action. Industrial use of Ethylene dichloride as a raw material in manufacture of vinylchloride remains allowed.**Reasons:** Possible carcinogen.**UNITED KINGDOM****Effective:** 1989.**Control action:** All agricultural uses revoked under the Control of Pesticides Regulations.**Reasons:** Evidence of carcinogenicity.**Deleted:** revoked**Formatted****Deleted:** c**Deleted:** p**Deleted:** r

## Annex 3 – List of Designated National Authorities

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### BELIZE

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#### C

Sanitation Engineer  
Public Health Bureau  
Ministry of Health  
Belize City

### CANADA

#### C

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**EUROPEAN UNION****CP**

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**P**

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**UNITED KINGDOM****CP**

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**CP** DNA Industrial Chemicals and Pesticides  
**P** DNA Pesticides  
**C** DNA Industrial Chemicals

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