OPERATION OF THE PRIOR INFORMED CONSENT PROCEDURE FOR BANNED OR SEVERELY RESTRICTED CHEMICALS IN INTERNATIONAL TRADE

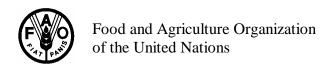
# DECISION GUIDANCE DOCUMENTS

**EDB** 

JOINT FAO/UNEP PROGRAMME FOR THE OPERATION OF PRIOR INFORMED CONSENT



United Nations Environment Programme



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Food and Agriculture Organization of the United Nations United Nations Environment Programme Rome - Geneva 1991; amended 1996

#### **DISCLAIMER**

The inclusion of these chemicals in the Prior Informed Consent Procedure is based on reports of control action submitted to the United Nations Environment Programme (UNEP) by participating countries, and which are presently listed in the UNEP-International Register of Potentially Toxic Chemicals (IRPTC) database on Prior Informed Consent. While recognizing that these reports from countries are subject to confirmation, the FAO/UNEP Joint Working Group of Experts on Prior Informed Consent has recommended that these chemicals be included in the Procedure. The status of these chemicals will be reconsidered on the basis of such new notifications as may be made by participating countries from time to time.

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 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 here.

This document is intended to serve as a guide and to assist authorities in making a sound decision on whether to continue to import, or to prohibit import, of these chemicals because of health or environmental reasons. While the information provided is believed to be accurate according to data available at the time of preparation of this Decision Guidance Document, FAO and UNEP disclaim any responsibility for omissions or any consequences that may flow therefrom. Neither FAO or UNEP, nor any member of the FAO/UNEP Joint Group of Experts 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 these chemicals.

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

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

ADI acceptable daily intake ai active ingredient

b.p. boiling pointbw body weight

°C degree Celsius (centigrade)

CCPR Codex Committee on Pesticide Residues

DNA Designated National Authority

EC emulsion concentrate

EEC European Economic Community

EPA U.S. Environmental Protection Agency

ERL extraneous residue limit

FAO Food and Agriculture Organization of the United Nations

g gram μg microgram

GAP good agricultural practice

GL guideline level

ha hectare

IARC International Agency for Research on Cancer

i.m. intramuscular i.p. intraperitoneal

IPCS International Programme on Chemical Safety

IRPTC International Register of Potentially Toxic Chemicals

JMPR 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)

k kilo- (x 103) kg kilogram

l litre

LC<sub>50</sub> lethal concentration, 50%

LD<sub>50</sub> lethal dose, median

m metre
mg milligram
ml millilitre
m.p. melting point

MRL Maximum Residue Limit. MTD maximum tolerated dose

ng nanogram

NOEL no-observed-effect level

NOAEL no-observed-adverse-effect level

NS Not Stated

OP organophosphorus pesticide

PHI pre-harvest interval ppb parts per billion

ppm parts per million (Used only in reference to the concentration of a pesticide

in an experimental diet. In all other contexts the terms mg/kg or mg/l are

used).

ppt parts per trillion

sp gr specific gravity

STEL Short Term Exposure Limit

TADI Temporary Acceptable Daily Intake

TLV Threshold Limit Value

TMDI theoretical maximum daily intake
TMRL Temporary Maximum Residue Limit

TWA Time Weighted Average

UNEP United Nations Environment Programme

WHO World Health Organization

WP wettable powder

wt weight

< less than

</ much less than
< less than or equal to

> greater than

≥ greater than or equal to

#### **EDB**

#### PRIOR INFORMED CONSENT DECISION GUIDANCE DOCUMENT

#### 1. **IDENTIFICATION**

- 1.1 <u>Common Name</u>: EDB
- 1.2 <u>Chemical Type</u>: Organobromide
- 1.3 Use: Pesticide (insecticide, nematicide)
- 1.4 <u>Chemical Name</u>: 1,2-dibromoethane
- 1.5 CAS No.: 106-93-4
- 1.6 <u>Trade Names/Synonyms</u>: Bromofume, Celmide, E-D-Bee, EDB, EDB-85, KopFume, Nephis (Discontinued products: Soilbrom 40, Soilbrom 85, Soilbrom 90, Soilbrom 90EC, Soilbrom 100, Dowfume)
- 1.7 <u>Mode of Action</u>: Fumigant insecticide, nematicide
- 1.8 <u>Formulation Types</u>: Mixed with an inert solvent for soil application; mixed with carbon tetrachloride and ethylene dichloride for mill, warehouse or household fumigation
- 1.9 Basic Producers: Excel Industries Ltd. (India), United Phosphorus Ltd. (India)

#### 2 SUMMARY OF CONTROL ACTIONS

- 2.1 <u>General</u>: Control actions to ban or severely restrict EDB have been taken by at least 10 countries, all in the 1980s. In four of these countries, EDB is severely restricted and in six countries it is completely banned. In countries which severely restrict use, permitted uses are primarily for special quarantine purposes. See Annex 1 for a summary of specific actions reported by governments.
- 2.2 <u>Reasons for Control Actions</u>: EDB has been subject to control actions due to health concerns and the persistence of the chemical in groundwater. EDB has been associated with reproductive, carcinogenic and genotoxic effects, in addition to high acute toxicity. Use as a soil fumigant has led to persistent contamination of groundwater aquifers.
- 2.3 <u>Uses Banned</u>: In most cases all pesticidal uses are banned.
- 2.4 <u>Uses Reported to be Continued in Effect</u>: Special quarantine uses. Other non-pesticidal uses continue, e.g. in leaded gasoline and as an industrial chemical.

- 2.5 <u>Alternatives</u>: Irradiation, phosphine gas and methyl bromide have been suggested as alternatives to commodity fumigation, although other nematicide such as 1,3-dichloropropene and nemacur have been suggested as alternatives for the soil fumigation use. (Note: Methyl bromide is being considered for category IA+.)
- 2.6 <u>Contacts for Further Information</u>: FAO/UNEP Joint Data Base, IRPTC Geneva; Designated National Authorities in countries taking control actions.

#### 3. SUMMARY OF FURTHER INFORMATION ON EDB

- 3.1 Chemical and Physical Properties: Colourless liquid. Soluble in all common organic solvents. EDB is non-flammable, volatile and resistant to degradation in water. Boiling point = 131.7 °C, specific gravity (25 °C) = 2.172. Solubility in water at 30 °C: 4.3 g/kg water.
- 3.2 <u>Toxicological Characteristics</u>:
- 3.2.1 <u>Acute Toxicity</u>: Rat (male) oral LD<sub>50</sub>; 146 mg ai/kg bw. WHO Classification: Not classified.
- 3.2.2 <u>Short-term Toxicity</u>: Atrophy of the testes and prostate was found in a 10-week inhalation study in the rat. The NOAEL in this study was 146 mg/m<sup>3</sup>. Reproductive effects have been observed in male workers exposed to EDB.
- 3.2.3 <u>Chronic Toxicity</u>: IARC (1987) has classified EDB as Group II A, a probable human carcinogen. IARC considered the evidence in humans to be inadequate and the evidence from animals to be sufficient regarding carcinogenicity. EDB is genotoxic in both *in vivo* and *in vitro* systems.
- 3.3 Environmental Characteristics:
- 3.3.1 <u>Fate</u>: EDB is mobile in air and water and has a half-life in water which ranges from days to years depending on environmental conditions. EDB binds to organic matter in soil and is subject to photo-degradation and volatilization. It is not readily bioacummulated.
- 3.3.2 Effects: No information available.
- 3.4 Exposure:
- 3.4.1 <u>Food</u>: Cessation of pesticidal use has presumably eliminated or significantly reduced dietary exposure. No recent reports of detection in food were found.
- 3.4.2 Occupational/Use: Both skin contact and inhalation can be significant routes of exposure. Occupational exposure had been estimated to be as high as 300 µg EDB/kg bw/day from fumigation use.

- 3.4.3 <u>Environment</u>: Low levels of EDB have been found in water as a result of pesticidal use. Levels reported in water have ranged from 0.05 to 5.0 ng EDB/1.
- 3.4.4 <u>Accidental Poisoning</u>: Some poisoning cases have been reported from pesticidal use. No specific antidotes are available. Induction of vomiting after ingestion or removal to fresh air after inhalation is recommended. Skin should be washed with soap and water after dermal contact, and contaminated clothes and shoes removed.
- 3.5 <u>Measures to Reduce Exposure</u>: EDB can be well-absorbed through all routes. Because most exposure during pesticide use is through inhalation, respirators and good ventilation will reduce exposure. Exposure to the environment and the general public can be reduced principally through controlling the use of EDB.
- 3.6 <u>Packaging and Labelling</u>: Signal word "Danger". Store in tightly closed container in a cool place away from dwellings. Follow FAO Guidelines on Good Labelling Practice.
- 3.7 <u>Waste Disposal Methods</u>: Guidelines are under development. This section will be updated when guidelines are available.
- 3.8 <u>Maximum Residue Limits (MRLs). (mg/kg)</u>: None recommended by JMPR/Codex. Various MRLs are recommended for inorganic bromide.

JMPR could not establish an ADI for EDB in 1965. The 1966 JMPR established an ADI of 1.0 mg/kg bw for bromide ion and recommended that EDB should only be used for fumigation of food on condition that no residue of the unchanged compound will reach the consumer.

#### 4. MAJOR REFERENCES

Farm Chemicals Handbook. Meister Publishing Company, Willoughby, Ohio, USA (Annual)

Food and Agriculture Organization. Guidelines for the packaging and storage of pesticides. FAO, Rome (1985)

International Agency for Research on Cancer. Monographs on the Evaluation of Carcinogenic Risks to Humans, Supplement 7, pp. 204-204, WHO, Lyons, France (1977)

International Register of Potentially Toxic Chemicals. IRPTC Legal File, Ethylene Dibromide. UNEP/IRPTC (1990)

U.S. Environmental Protection Agency. Ethylene Dibromide (EDB) Position Document. USEPA, Washington, D.C. (1983)

World Health Organization. The WHO Recommended Classification of Pesticides by Hazard. WHO, Geneva (1990)

World Health Organization. Evaluation of the toxicity of pesticide residues in food. Report of the Second Joint Meeting of the FAO Committee on Pesticides in Agriculture and the WHO Committee on Pesticide Residues, WHO, Geneva (FAO Meeting Report No. PL/1965/10; WHO/Food Add./26.65)

World Health Organization. Pesticide Residues in Food. Joint Report of the FAO Working Party on Pesticide Residues and the WHO Expert Committee on Pesticide Residues, WHO, Geneva (FAO Agricultural Studies No. 73; WHO Technical Report Series, No. 391)

## ANNEX 1 SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR ETHYLENE DIBROMIDE (EDB), AS REPORTED BY COUNTRIES

#### **BANNED:**

Belize	(NS)	Banned as agricultural chemical
Colombia	(1985)	Banned as agricultural chemical.
Cyprus	(1987)	Banned as agricultural chemical.
Ecuador	(1985)	Banned as agricultural chemical.
Kenya	(1985)	Banned as agricultural chemical.
Argentina	(1990)	Banned as agricultural chemical.

#### WITHDRAWN:

None reported.

#### **SEVERELY RESTRICTED:**

#### Only remaining uses allowed:

**USA** (1984) Cancellation of all registrations except for use in vault fumigation, aphis Japanese beetle control programme, as a quarantine fumigant for exported citrus and papaya. Special labelling required with directions for use.

#### Specific uses reported as not allowed:

**Chile** (1985) Use prohibited for fumigation of fruit and vegetables.

**United Kingdom** (1981-85) Withdrawal of use of EDB in combination with other liquid fumigants to disinfect cereal grains in food storage practice (1981), of use as a spot fumigant in food storage practice except for use by professional operators, and of all fumigant uses in food storage practice (1985).

#### Use permitted only with special authorization

**Sweden** (1985) Substance is severely restricted and may not be used without permission of the Labour Inspectorate.

Ed. 1, November 1991