

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

DECISION GUIDANCE DOCUMENTS

Polychlorinated Biphenyls

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

United Nations Environment Programme

Food and Agriculture Organization
of the United Nations

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

**DECISION
GUIDANCE
DOCUMENTS**

Polychlorinated Biphenyls

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

Food and Agriculture Organization of the United Nations

United Nations Environment Programme

Rome – Geneva 1992

DISCLAIMER

The inclusion of these chemicals in the Prior Informed Consent Procedure is based on reports of control actions 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 bases 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 omission 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.

The designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of the Food and Agriculture Organization of the United Nations or the United Nations Environment Programme concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries.

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 point
bw	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 10 ³)
kg	kilogram

l	litre
LC ₅₀	lethal concentration, 50%
LD ₅₀	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 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

POLYCHLORINATED BIPHENYLS

PRIOR INFORMED CONSENT DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

1.1 Common Name: PCBs

1.2 Chemical Type: polyhalogenated organo compound

1.3 Use: different industrial uses in coolant systems and electrical industry (capacitors, transformers); as sealants for wood and cement surfaces; as hydraulic fluids, cutting oils.

1.4 Chemical Name: Polychlorinated biphenyls

1.5 CAS No: 1336-36-3

1.6 Trade Names/Synonyms:

Aroclor, Chlorentol, chlorinated biphenyl, chlorinated diphenyl, Clophen, chlorobiphenyl, Dykanol, Fenclor, Inerteen, Kanechlor, Noflamol, Phenoclor, polychlorobiphenyl, Pyralene, Pyranol, Santotherm, Sovol, Therminol

1.7 Mode of action:

Not relevant

1.8 Formulation Types: In pure form: colourless crystals. In commercial form: liquids (or liquid mixtures).

1.9 Basic Producers: Monsanto (USA); Caffaro (Italy); Kanegafuchi (Japan); Rhône-Poulenc (France); Atochem (France); Bayer (Germany); Chemko (Czechoslovakia).

2. SUMMARY OF CONTROL ACTIONS

2.1 General

PCBs are reported to be banned in two countries and severely restricted in 18 countries. Certain specified uses and specified concentrations are allowed in these countries. See Annex 1 for a summary of specific actions reported by governments.

2.2 Reasons for the control action

The control actions have been taken for the following reasons: persistence in the environment, bioaccumulation in the human food chain, extremely toxic impurities, formation of extremely toxic substances on thermolysis, harmful to human health, chronic toxicity, contamination of the environment.

2.3 Uses banned

The manufacture, supply, import, processing, distribution in commerce, advertisement, selling etc. generally is prohibited in Canada, USA, EEC, Sweden and Japan. In Algeria and Chile uses in electrical equipment are prohibited. In Algeria disposal in the natural environment is totally banned. See Annex 1 for a summary of specific actions reported by governments.

2.4 Uses reported to be continued in effect

Applications of the compound are allowed when below a certain concentration limit (EEC, Canada), in specified closed systems (USA), with permission of designated authorities (USA, Sweden, Japan). In the EEC the use of mono- and di-chlorinated biphenyls is not restricted.

2.5 Alternatives

No alternatives are suggested by those governments reporting control actions.

2.6 Contacts for further information

FAO/UNEP Joint Data Base, IRPTC, Geneva and the Designated National Authorities in countries taking control actions.

3. **SUMMARY OF FURTHER INFORMATION ON PBBs**

3.1 Chemical and Physical Properties

Chlorobiphenyls are thermally stable, resistant to oxidation, acids, bases and other chemical agents. In the pure form they are colourless crystals, but commercial products are liquids. Insoluble in water, soluble in oils and organic solvents.

3.2 Toxicological Characteristics

3.2.1 *Acute Toxicity:* oral LD₅₀ rat: 4 (Aroclor 1221) - 10 g/kg b.w. (Aroclor 1268).
LD₅₀ rabbit: 1 (Aroclor 1242) - 3 (Aroclor 1268) g/kg b.w.

3.2.2 *Short-term Toxicity:* effects on reproduction, teratogenicity, immune alteration, liver damage, increase of microsomal enzyme activity, interference with steroid metabolism.

3.2.3 *Chronic Toxicity:* carcinogenic to animals, probably carcinogenic for humans. IARC class II. ADI = 0.1 µg/kg b.w.

3.2.4 *Epidemiological data:* Human studies have shown that PCB exposure leads to skin abnormalities (acne- form), although there is strong evidence that this occurs only in combination with polychlorinated dibenzofurans (PCDFs). Accidental poisoning suggests that effects may be retardation of foetal growth and alteration on fetal

growth retardation and alteration of calcium metabolism related to hormonal disfunction. There is strong evidence from human mortality studies that PCBs produce cancer of liver, biliary tract and gall bladder.

3.3 Environmental Characteristics

3.3.1 *Fate:* PCBs with five or more chlorines are quite resistant to biodegradation, but photolysis may result in some breakdown of highly-chlorinated PCBs. The half life in soil is 5 years.

3.3.2 *Effects:* the bioconcentration factor in fish and crustacea is 270,000. LD₅₀ fish: 3-3000 µg/l, crustacea: 10-2400 µg/l (Aroclor 1254 very sensitive). Permissible concentration in water to protect aquatic life: 30 µg/l.

3.4 Exposure

3.4.1 *Food:* average dietary intake in industrialised countries is 5-100 µg/day, the major source being fish, PCBs are magnified in food chain.

3.4.2 *Occupational/Use:* inhalation is main route of absorption. Occupational Exposure Limit: 0.5 mg/m³ (8 h TWA). In the fatty tissue of occupationally exposed men concentrations up to 700 mg/kg have been found.

3.4.3 *Environment:* concentrations in ambient air 0.1-10 ng/m³, ocean water: 0.01-0.5 ng/l and in polluted rivers up to 500 ng/l have been reported.

3.4.4 *Accidental Poisoning:* mild effects of eye and skin irritation. Wash promptly, remove nonimpervious clothing promptly if wet or contaminated.

3.5 Measures to Reduce Exposures

Appropriate clothing to avoid skin contact, eye protection to prevent eye contact.

3.6 Packaging and Labeling

Suspected carcinogenic substance, hazardous to the environment, danger of cumulative effects. It should be stated on the label whether the substance is a specific isomer or a mixture of isomers.

3.7 Waste Disposal Methods

Incinerate for more than 2 seconds at 1200°C or higher. If PCB content of waste is less than 500 ppm incinerate for more than 0.5 sec at 800°C, Combustion of PCBs can produce dioxins.

3.8 Maximum Residue Limits (mg/kg)

Maximum Tolerated Concentration in food and food products 0.05 - 2 mg/kg, in fish and shell fish: 2 mg/kg (Sweden). In packaging materials for foods 10 mg/kg.

4. **MAJOR REFERENCES**

- WHO. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans, Vol. 18, IARC, Lyon (1978)
- WHO. Polychlorinated Biphenyls and Terphenyls. Environ. Health Criteria 2, WHO, Geneva (1976)
- WHO. PCBs, PCDDs and PCDFs. Environmental Health Series No. 23, WHO, Geneva (1987)
- Kimbrough, R.D. and A.A. Jensen. Halogenated biphenyls, terphenyls, naphthalenes, dibenzodioxins and related compounds. Topics in Environmental Health, Elsevier, Amsterdam, New York, Oxford (1989)

ANNEX 1

SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR POLYCHLORINATED BIPHENYLS, PCBs, AS REPORTED BY COUNTRIES

BANNED:

Liechtenstein (NS) Liechtenstein forms a customs and economic union with Switzerland, and the same laws concerning PCB apply.

Switzerland (1986) Manufacture, supply, import and use of PCB and products that contain the substance is prohibited, except for import of waste for disposal.

WITHDRAWN:

None reported.

SEVERELY RESTRICTED:

Only remaining uses allowed:

Canada (1977-85) Use of PCB's is restricted to use in any capacitor, transformer and associated switch-gear existing in Canada prior to July 1, 1980, and to use in the operation of other specified equipment existing prior to Sept. 1, 1977. (1977) It is prohibited to advertise, sell or import liquids containing PCB's for use in microscopy, including immersion oils, but not including refractive index oils. (1981) The maximum concentration of PCB's that may be contained in certain products is 50 ppm by weight. (1985)

EEC-countries * (1988) PCBs, except mono- and dichlorinated biphenyls, or preparations including waste oils, with a PCB-content higher than 0.01% by weight may not be used.

USA (1982) Manufacture, processing, distribution in commerce and use of PCB is generally prohibited. However, manufacture is permitted in closed manufacturing and controlled waste manufacturing processes where it is released in concentrations below specific, practical limits of quantitation.

* **EEC-countries-** Belgium, Denmark, France, Federal Republic of Germany, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Spain and United Kingdom.

Requirements concerning use, servicing, inspection, monitoring and record keeping are specified for certain electrical equipment using dielectric fluid containing PCB. Wastes containing PCB in concentrations over certain levels must be disposed of in qualified incinerator or approved landfill, or stored in a specific manner.

Specific uses reported as not allowed:

Algeria (1987) Prohibited for use in new electrical fittings. Repairing of electrical fittings using oils containing PCBs is banned. Control of electrical fittings which are in operation, stocked or rejected. Control of transport and stocking. Disposal in nature is totally banned.

Chile (1982) Use of PCBs in electrical equipment is prohibited.

Sweden (1973) Without permission from the Product Control board: - PCB may not be imported or handled; - transformers and capacitors which contain PCB with capacities of more than 2 kilovolt-ampere may not be offered for sale, transferred or taken into service; - PCB-products of the following kind may not be offered for sale, transferred or used professionally: paints, printing inks, caulking or sealing compounds, hydraulic oil, lubricating oil, cutting oil, heat transfer media, separate capacitors of 2 kilovolt-ampere or less.

Use permitted only with special authorization:

Japan (1981) Manufacture and import prohibited without authorisation by the Government. Uses other than those specified by Cabinet order are prohibited. Prohibition of import of specified products containing the substance.