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

DECISION GUIDANCE DOCUMENTS

Polybrominated Biphenyls

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

United Nations Environment Programme

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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 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/1 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

POLYBROMINATED BIPHENYLS

PRIOR INFORMED CONSENT
DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

1.1 Common Name: PBBs

1.2 Chemical Type: polyhalogenated organo compound

1.3 Use: fire retardants for synthetic fibres and moulded thermoplastic parts, plastics, coatings and lacquers

1.4 Chemical Name: Hexabromobiphenyl, Octabromobiphenyl, Decabromobiphenyl

1.5 CAS No: 36355-01-8 (hexa-), 27858-07-7 (octa-), 13654-09-6 (deca-)

1.6 Trade Names/Synonyms:
Firemaster BP-6, Firemaster FF-1, hexabromobiphenyl, Bromkal 80, Flammex B-10, HFO 101, Adine 0102, hbb, obb, BB-8, Berkflam B_{10}

1.7 Mode of action:
Not relevant

1.8 Formulation Types: Technical grade PBBs are white solids or brown flakes depending on the various isomers of the different biphenyls.

1.9 Basic Producers: Atochem (France); Dead Sea Bromines/Eurobrome (The Netherlands); Ethyl Corporation, Great Lakes Chemical Corporation (USA); Tosoh, Matsunaga, Nippo (Japan).

2. SUMMARY OF CONTROL ACTIONS

2.1 General
All PBBs have been banned in one country (Canada). In another country (USA) the use of hexabromobiphenyls, the main isomer used in industry has been forbidden. In the EEC the use of PBBs is severely restricted. Specific actions reported by governments are summarized in Annex 1.

2.2 Reasons for the control action

The control actions have been taken because PBBs accumulate in food chains, evidence exists of chronic toxicity to various species, and because they are embryotoxic and teratogenic. Furthermore the use has been discontinued because of the hazard to human health discovered after accidental use in Michigan in 1973.

2.3 Uses banned

In one country all isomers of PBB are banned, in one other country the use of hexabromobiphenyl, the main isomer, is banned. In the EEC PBBs may not be used in textile articles intended to come in contact with the skin.

2.4 Uses reported to be continued in effect

In the EEC all other uses than the use in textile articles intended to come in contact with the skin are continued. In the USA all uses except the use of hexabromobiphenyl are allowed to be continued.

2.5 Alternatives

Not presented in government reports.

2.6 Contacts for further information

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

3. SUMMARY OF FURTHER INFORMATION ON PBBs

3.1 Chemical and Physical Properties

Insoluble in water, soluble in fat and slightly to highly soluble in various organic solvents. Relatively stable and chemically unreactive.

3.2 Toxicological Characteristics

3.2.1 *Acute Toxicity:* oral LD_{50} rats: 21.5 g/kg bw (Firemaster BP-6), oral LD_{50} rats: > 17 g/kg bw (tech. octabromobiphenyl), dermal LD_{50} rabbit: 5 g/kg bw (hexabromobiphenyl).

3.2.2 *Short-term Toxicity:* PBBs cause weight loss, liver damage, porphyria, effects on central nervous system, skin, eyes and immune system, effects on reproduction, they are weakly teratogenic (embryotoxic) in cattle and laboratory animals. NOEL (Fire-master BP) < 0.5 mg/kg bw (teratogenic effects, weight loss).

3.2.3 *Chronic Toxicity:* IARC: inadequate evidence for carcinogenicity to humans, sufficient evidence for carcinogenicity in animals. ADI: no value estimated.

3.2.4 *Epidemiological data:* A retrospective study was conducted in persons living in Michigan after accidental use of PBB in cattle feed. Symptoms were not correlated with PBB body burden. In lactating Michigan women PBB concentrations in milk were positively correlated with fat content.

3.3 Environmental Characteristics

3.3.1 *Fate:* persistent in water and soil, degrades in ultraviolet light.

3.3.2 *Effects:* PBBs are readily bioconcentrated in fish (magnification factor: 10,000).

3.4 Exposure

3.4.1 *Food:* No data available, other than following the accidental feed contamination in Michigan (1973) when levels in milk and meat products were collected.

3.4.2 *Occupational/Use:* blood levels up to 85 µg/l have been detected in employees.

3.4.3 *Environment:* concentrations in river water: 3.2 µg/l (near effluent discharge), sediment > 250 mg/kg (IACR 1978), 77 mg/kg (IARC 1986), fish: 1.33 mg/kg.

3.4.4 *Accidental Poisoning:* mild effects of eye and skin irritation. Wash promptly when skin is wet or contaminated, if swallowed give large quantities of salt water and induce vomiting.

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.

3.7 Waste Disposal Methods

Incinerate for more than 2 seconds at 1200^{o}C or higher. If PBB content of waste is less than 500 ppm incinerate for more than 0.5 sec at 800^{o}C.

3.8 Maximum Residue Limits

0.3 mg/kg in the fat of meat, milk and dairy products, 0.05 mg/kg in eggs and animal feeds (US-FDA).

4. MAJOR REFERENCES

- WHO. IARC monographs on the evaluation of the carcinogenic risk of chemicals to humans Vol 41 (1986), 18 (1978), IARC, Lyon
- Safe, S. Polychlorinated biphenyls (PCBs) and the polybrominated biphenyls (PBBs): Biochemistry, toxicology and mechanism of action. CRC Reviews in Toxicology 13, 319-395 (1984)
- Sittig, M. Handbook of toxic and hazardous chemicals and carcinogens, Noyes publications, second edition, 1985
- Fries G.F. The PBB episode in Michigan: an overall appraisal. CRC Critical Reviews in Toxicology 16, 106-156 (1985)

ANNEX 1

SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR POLYBROMINATED BIPHENYLS, PBBs, AS REPORTED BY COUNTRIES

BANNED:

Canada (1979) Banned for all commercial, manufacturing and processing uses.

USA (1980) All use of hexabromobiphenyl, the main PBB isomer used in industrial processes was discontinued in 1974 after discovery of hazard to human health through accidental use in 1973. EPA has since required notification of any manufacture or importation of PBBs, to control that there are no significant sources of PBBs and to investigate any resumption of production.

WITHDRAWN:

None reported.

SEVERELY RESTRICTED:

Only remaining uses allowed:

EEC-countries * (1988) PBBs may not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.

Specific uses reported as not allowed:

None reported.

Use permitted only with special authorization:

None reported.

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