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

DECISION GUIDANCE DOCUMENTS

HCH (mixed isomers)

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

UNEP

United Nations Environment Programme

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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 have recommended that these chemical 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 point
bw	body weight
^{o} 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	ram microgram good agricultural practice guideline level
µg	microgram
GAP	good agricultural practice
GL	guideline level
ha	hectare
HEOD	
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) kilogram
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. (For difference between draft MRLs and Codex MRLs, see the introduction Annex I.)
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
ppm	parts per million (Used only in reference to concentration of a pesticide in an experimental diet. In all other contexts the terms mg/kg or are used).
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

HCH (mixed isomers)

PRIOR INFORMED CONSENT
DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

l.1 Common Name: BHC, HCH (Europe), 666 (Denmark) hexachlor (Sweden), hexachloran (USSR),

l.2 Chemical Type: Organochlorine

l.3 Use: Pesticide (insecticide)

l.4 Chemical Name: 1,2,3,4,5,6-Hexachlorocyclohexane

l.5 CAS No.: 608-73-1

l.6 Trade Names/Synonyms: Benzex (Woolfolk Chemical), Dol, Dolmix, Gammexane, Gexane, HCCH, Hexafor, Hexablanc, Hexamul, Hexapoudre, Hexyclan, Hillbeech, Kotol (Shell, UK), Lindacol (Shell, UK), perchlorobenzene, Soprocide, Submar (India Medical), FBHC (discontinued)

l.7 Mode of Action: Acts as an ingested and contact insecticide, and has some fumigant action.

l.8 Formulation Types: Dusts, wettable powders, oil solutions, emulsifiable concentrates (requires BHC of intermediate to high gamma isomer content (36-45%) in order to obtain solutions of sufficient gamma content to be effective).

l.9 Basic Producers: Hindustan Insecticides Ltd. (India); Inquinosa (Spain)

2. SUMMARY OF CONTROL ACTIONS

2.1 General: BHC has been banned or severely restricted in at least 11 countries and by the European Community. See Annex 1. (The gamma isomer, lindane, has been retained for a number of uses but is discussed in a separate decision guidance document.)

2.2 Reasons for Control Action: BHC use has been reported banned principally because of oncogenic effects detected in animal studies. When considered in combination with its persistence and bioaccumulation potential, the dietary cancer risk was considered unacceptable. In addition, exposures to workers and other persons applying BHC was of concern. Countries also noted persistence and bioaccumulation, high toxicity and environmental effects as reasons for control actions.

2.3 Uses Banned: All uses have been prohibited in most countries reporting control actions; although some countries reported a very few uses remaining which are noted below.

2.4 Uses Reported to be Continued in Effect: In countries reporting a severe restriction on the use of BHC, the following uses were reported still in effect: China-non-food uses; Mexico-maize and cotton.

2.5 Alternatives: No countries reporting control actions presented information on alternatives, except that lindane, which is 99% gamma isomer of BHC, was permitted to be substituted in products in place of the alpha and beta isomers in the US and its use is permitted in other countries (Argentina, Switzerland, EEC, Netherlands) for uses similar to those for which BHC was banned. Since lindane is the principal isomer in BHC exhibiting insecticidal activity this substitution should result in effective alternatives for all uses of BHC. See separate DGD for lindane for any limitations applied to its use.

2.6 Contacts for Further Information: FAO/UNEP Joint Data Base, IRPTC, Geneva and Designated National Authorities in countries reporting control actions (Annex 1.).

3. SUMMARY OF FURTHER INFORMATION ON BENZENE HEXACHLORIDE

3.l Chemical and Physical Properties: Technical BHC is comprised mainly of alpha, beta and gamma isomers with only the gamma isomer (lindane) exhibiting significant insecticidal activity. The isomeric composition of technical BHC is: 53-70% alpha-BHC; 3-14% beta-BHC; 11-18% gamma-BHC; 6-10% delta-BHC; and, 3-10% other isomers. BHC is soluble in solvents such as benzene, chloroform or ether but is almost insoluble in water. Physical properties are not precise, varying with isomeric ratios. See also FAO specifications for BHC.

3.2 Toxicological Characteristics:

3.2.1 Acute Toxicity: Oral LD_{50}, a.i. rats, 88-270 mg/kg varying with carrier; WHO uses value of 100 mg/kg for classification purposes.

WHO Classification: a.i. Class II-moderately hazardous; exposure route-oral.

Formulations: Class II for solid formulations over 200 g/kg, class III for lower concentrations; class II for liquid formulations over 5%, class III for lower concentrations.

3.2.2 Short-Term Toxicity: Studies in animals indicate the potential for BHC to induce fetotoxic effects and to adversely affect reproduction.

3.2.3 Chronic Toxicity: BHC is oncogenic in mice and rats given oral doses of BHC and its alpha, beta and gamma isomers. IARC concluded that BHC and its pure alpha, beta and gamma isomers are carcinogenic in mice, producing liver cell tumours following oral administration.

Two-year feeding study NOEL: 25 mg/kg/day (rats); 50 mg/kg/day (dogs).

3.3 Environmental Characteristics:

3.3.1 Fate: BHC is persistent but not as much so as DDT. Ten percent of original concentration in sandy soil reported remaining after 14 years.

In water, no measurable degradation after a period of 8 weeks.

It is liquid soluble and tends to bioaccumulate. The beta isomer is the most stable isomer and is also the most environmentally persistent and chronically toxic isomer. Beta-BHC has a 10-30 times greater ability to accumulate in fatty tissue than the gamma isomer.

Alpha-BHC in a complex food chain system showed bioconcentration as high as 267 times in algae and 140 times the ambient concentration in Daphnia.

3.3.2 Effects: Toxic to fish: LC_{50} (48h) 0.16 mg/l (male guppies); 0.3 mg/l (female guppies). Bob-white quail, LD_{50}, oral, 120-130 mg/kg.

3.4 Exposure:

3.4.1 Food: Dietary exposure must be considered a major source of exposure where BHC is used on food plants and animals, since it is absorbed from the gastrointestinal tract. In the USA residues of beta-BHC were estimated to be detectable in tissues of 99% of the population when its use was permitted, based on tissue sampling programmes.

3.4.2 Occupational/Use: No reported data.

3.4.3 Environment: Persistent and accumulates in body tissue.

3.4.4 Accidental Poisoning: No reported data.

3.5 Measures to Reduce Exposure: The principal method of reducing exposure is to prohibit the use of BHC on food crops, substituting lindane for the other isomers of BHC. This substitution of lindane retains insecticidal activity in products, but eliminates the alpha and beta BHC isomers. Since the presence of beta-BHC residues in almost 100% of the US population was estimated during the use of BHC, dietary and environmental exposure are the most likely sources. These cannot readily be reduced except by banning the use of BHC.

Protective equipment can reduce the exposure of workers and applicators, however, the general dietary and environmental exposures resulting from use will not be reduced.

3.6 Packaging and Labelling: Follow FAO Guidelines on Good Labelling Practice for Pesticides and Guidelines for the Packaging and Storage of Pesticides. However, this cannot be expected to reduce exposure arising from use on food crops and animals.

3.7 Waste Disposal Methods: Guidelines are under development. This section will be updated when guidelines are available.

3.8 Maximum Residue Limits. (mg/kg):

JMPR/Codex Maximum Residue Limits: None

US: All previous MRLs have been replaced by action levels sufficient to cover inadvertent residues but not those resulting from intentional application. Action levels for most commodities are 0.05 ppm; with 0.3 ppm for frog legs (edible portion), citrus fruits, fat of animals and poultry and milk (fat basis); 0.5 on cocoa beans (whole, raw); 1.0 ppm on processed animal feed; and, 1 ppm on paprika.

4. MAJOR REFERENCES

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ANNEX 1
SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR HCH, MIXED ISOMERS, AS REPORTED BY COUNTRIES

BANNED:

Argentina	(1980)	Banned.
Canada	(1971)	Banned.
Japan	(1988)	Banned as agricultural chemical.
Liechtenstein	(1986)	Banned.
Panama	(1987)	Banned as agricultural chemical.
Singapore	(1984)	Banned.
Switzerland	(1986)	Banned.
Yugoslavia	(1972)	Banned as agricultural chemical.
USA	(1978)	Alpha- and beta-isomers banned.

WITHDRAWN:

None reported.

SEVERELY RESTRICTED:

Mexico	(1988)	Restricted agricultural use for cotton and maize.

Only remaining uses allowed:

None reported.

Specific uses reported as not allowed:

China	(1982)	Prohibited to use on fruit trees, tea, vegetables, herbs, tobacco, coffee, pepper.
EEC-countries*	(1988)	HCH-mixed isomers containing less than 99% of the gamma-isomer are prohibited.

Use permitted only with special authorization:

None reported.

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