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

DECISION GUIDANCE DOCUMENTS

Heptachlor

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

United Nations Environment Programme

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Food and Agriculture Organization
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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 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	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_{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 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

HEPTACHLOR

PRIOR INFORMED CONSENT
DECISION GUIDANCE DOCUMENT

1. IDENTIFICATION

1.1 Common Name: Heptachlor, heptachlore

1.2 Chemical Type: Chlorinated cyclodiene

1.3 Use: Pesticide (insecticide)

1.4 Chemical Name: 1,4,5,6,7,8,8-Heptachloro-3a,4,7,7a-tetrahydro-4,7-methanol-lH-indene

1.5 CAS No.: 76-44-8

1.6 Trade Names/Synonyms: Aahepta, Agroceres, Drinox, Heptaf, E 3314, ENT 15,152, GPKh, H34, Heptachlorane, Heptacur, Heptagran, Heptamul, Heptox, Rhodiachlor, Heptrex, Velsicol 104; 1, 4, 5, 6, 7, 8, 8 - heptachloro - 3a, 4, 7, 7a - tetrahydro - 4, 7 - methanoindene; Curasemillas

1.7 Mode of Action: Persistent, non-systemic contact and stomach poison with some fumigant action

1.8 Formulation Types: Emulsifiable concentrate (240 g/l), granular (250 g/kg), wettable powder (400 g/kg) and dusts

1.9 Basic Producer: Velsicol Chemical Corp. (USA)

2. SUMMARY OF CONTROL ACTIONS

2.1 General: Control actions to ban or severely restrict heptachlor have been taken by at least 28 countries beginning as early as 1958. In at least 21, heptachlor has been completely banned, and in seven others it is severely restricted. Specific actions reported by governments are summarized in Annex 1.

2.2 Reasons for Control Action: Control actions have been taken for various reasons including: heptachlor's toxicity to man, other mammals, birds, fish and other aquatic organisms, as well as a concern for bio-accumulation, persistence and environmental contamination. Of particular concern is its demonstrated carcinogenic response in laboratory rodents and its potential impact on human health from widespread environmental contamination in the food chain.

2.3 Uses banned: In most countries uses have been banned, particularly outdoor uses and general use in agriculture. In those countries that have severe restrictions, uses are limited

to seed treatment and/or termite control by public health officials or professional applicators only (see Annex 1).

2.4 Uses Reported to be Continued in Effect: Most, if not all temperate climate countries do not use heptachlor in any agricultural or widespread outdoor use. In those countries where uses are continued, the product is restricted to structural termite control and wood treatment. In tropical and subtropical countries that have retained seed treatment or pre-planting agricultural use, heptachlor is restricted to crops that form the edible portions above the ground and, in particular, to crops with longer growing seasons that are not direct-to-table foods. One country (Mexico) has restricted the use to only two crops, maize and sorghum, limited to pre-planting soil preparation.

2.5 Alternatives: Although many alternatives are known to be used, no specific alternative pesticide-use combinations have been suggested by countries taking control actions. These control actions have, however, resulted in the phasing out of heptachlor in preference for less environmentally persistent pesticides. For example, in the USA, chlorpyrifos, permethrin, cypermethrin, isofenphos, and fenvalerate have found increased usefulness as soil termiticides. Many alternatives are more acutely toxic to humans and domestic animals than heptachlor, or may require increased use and/or frequency rates to achieve the same degree of pest control.

2.6 Contacts for Further Information: FAO/UNEP Joint Data Base, IRPTC Geneva; Designated National Authorities in countries taking control actions.

3. SUMMARY OF FURTHER INFORMATION ON HEPTACHLOR

3.1 Chemical and Physical Properties: Pure heptachlor (99% pure) is a white crystalline solid, with a mild camphor-like odour. Technical grade heptachlor is a waxy solid, tan in colour, containing 72% heptachlor and 28% related compounds, practically insoluble in water, but readily soluble in most organic solvents (e.g xylene, carbon tetrachloride, acetone and benzene; weakly soluble in alcohol). Heptachlor is stable in daylight, air, moisture, moderate heat (160 °C) and weak alkali, and is oxidized biologically to heptachlor epoxide. It is photodegraded when volatilized or when exposed on environmental surfaces.

3.2 Toxicological Characteristics:

3.2.1 Acute Toxicity: Oral LD_{50}(rat), 100-162 mg/kg; dermal LD_{50}(rat), 195-250 mg/kg (in xylene), (rabbit) > 2000 mg/kg (dry powder); Inhalation LC_{50} (rat), > 2 mg/l and< 200 mg/l; 74% technical material is a mild dermal irritant. WHO Classification: ai Class-II - moderately hazardous. Formulations: Below 200 g/kg for solids - Class III.

3.2.2 Short-term Toxicity: On the basis of animal data, hepatotoxicity may be the most sensitive target organ effect for heptachlor/heptachlor epoxide. Signs of toxicity in animals following short- and long-term oral exposure include histologic evidence of severe

liver damage, increased liver weight, and increased levels of serum components indicative of hepatic damage. Rats and mice administered heptachlor in the diet for either eight months or 30 days, respectively, exhibited adverse effects on the liver. Effects observed included: increased liver weight, enlarged central hepatic lobule cells, and aggregation of the acidophilic cytoplasmic granules in the cell periphery. These effects were evident at 5 ppm, the lowest dose administered.

Heptachlor was administered daily to sheep, pigs and rats at 2 and 5 mg/kg bw for 78-86 days with hepatic necrosis reported in all three species.

3.2.3 Chronic Toxicity: Doses greater than 1 ppm in the diet of dogs resulted in increased pup mortality in F1 and F2 pups from a two-generation reproduction study; variable results on pup mortality were observed in several rat multi-generation reproduction studies at doses ranging from 0.3 to 10 ppm. Cataracts were also observed in rats given 6.9 mg/kg/day for three months prior to mating, and in their progeny. The effects of long-term administration of heptachlor in the diets of rats, mice and dogs are qualitatively similar to the effects produced by the administration of other chlorinated hydrocarbon pesticides. The liver is the target organ, undergoing alterations in the structure of the hepatic cells. These changes are characterized by swelling, homogeneity of the cytoplasm, and peripheral arrangement of the cytoplasmic granules of the hepatic cells in the central zones of the lobules. Also, an increase in rough and smooth endoplasmic reticulum and mitochondria.

NOEL: rat, 5 ppm (0.025 mg/kg bw); dog, 2.5 ppm (0.06 mg/kg bw); mice < 10 ppm (1.5 mg/kg bw).

JMPR ADI: 0.0001 mg/kg bw.

Heptachlor produced a significant increase in both benign and malignant liver tumours in both sexes of three separate strains of mice (C_3H, CF_1, and $B_6C_3F_1$). IARC concluded there is "sufficient evidence" that heptachlor is carcinogenic in mice, and "limited evidence" that heptachlor epoxide is carcinogenic in experimental animals. Overall IARC placed heptachlor in Group 3, "cannot be classified according to carcinogenicity in humans". The U.S. EPA considers heptachlor and heptachlor epoxide to be Group B2, "probable" human carcinogens, because of hepatocellular tumours in more than one strain of mouse, as well as in rats.

3.2.4 Epidemiological Studies: There has been no report of human poisoning by heptachlor. The clinical picture has been complicated by the presence of other toxic pesticides.

Twenty-five cases of blood dyscrasia associated with exposure to chlordane or heptachlor either alone or in combination with other drugs, in conjunction with three newly diagnosed cases of aplastic anaemia and three of acute leukaemia associated with prior history of exposure to technical grade chlordane containing 3-7% heptachlor were reviewed. During the period December 1974 to February 1976, five out of 14 children

with neuroblastoma admitted to one paediatric hospital had a positive of pre- or postnatal exposure to technical grade chlordane containing 3-7% heptachlor. History of exposure to chlordane had not yet been ascertained for the remaining nine cases.

In a study conducted in the United States, a group of 45 dairy farm family members consumed undiluted raw milk products known to be contaminated with heptachlor at concentrations up to 89.2 ppm (fat basis). The serum levels of heptachlor and its metabolites in the exposed individuals were elevated in comparison to 94 unexposed individuals of the same geographical region. There was no evidence of significant changes in liver enzyme levels or of related acute and/or subchronic hepatic effects in the exposed individuals.

No adverse effects on human foetal development were reported following ingestion of milk containing 0.12 to 5.0 ppm heptachlor for 27 to 29 months among women of child-bearing age in Oahu, Hawaii, USA.

A man with no previous medical problems had two documented exposures to an insecticide containing chlordane and heptachlor. Six months to one year later, he began to experience neurological symptoms which progressed until his death. At autopsy, his brain showed classic findings of multiple sclerosis and he had a severe peripheral neuropathy.

A retrospective mortality study was conducted on workers employed in the manufacture of heptachlor and chlordane between 1946 and 1976. The study group consisted of 1403 caucasian males who were employed for more than three months at either of two plants which produced heptachlor and chlordane in the USA. The results indicated an excess of deaths from cerebrovascular disease (17 observed, 9.3 expected).

3.3 Environmental Characteristics:

3.3.1 Fate: Heptachlor is less persistent in the soil than chlordane, although it may be detected in the soil for as long as 10 years after application. Heptachlor may vaporize slowly from the soil; it may be oxidized to form heptachlor epoxide, a substance more persistent and toxic than the parent compound; or it may be converted to less toxic metabolites by soil bacteria. Heptachlor incorporated into a silty loam soil dissipated from the surface with a half-life of 336-551 days; one author reports the half-life to be 9-10 months. Heptachlor is not expected to leach since it is insoluble in water and should adsorb to the soil surface. The majority of residues are found in the top few inches of the soil.

3.3.2 Effects: Heptachlor is potentially very highly toxic to both warm-water and cold-water fish species; acute LC_{50} to bluegill is 13 µg/l, and rainbow trout is 7.4 µg/l. It is also very highly toxic to freshwater invertebrates; acute 48 hr EC_{50} for *Daphnia pulex, Pteronarcys* sp. and *Orconectes* sp. is 42 µ/l, 1.1 µg/l and 0.5 µg/l, respectively. Heptachlor is potentially highly toxic to birds; dietary LC_{50} to bobwhite quail, pheasant, and mallard duck is 92 ppm, 24 ppm, and 480 ppm, respectively. The characteristic of heptachlor to

bio-accumulate could produce secondary chronic effects in exposed organisms and possible bio-magnification in the food chain.

3.4 Exposure:

3.4.1 Food: Since virtually all agricultural food uses have been banned or severely restricted, exposure via food is virtually nil. Extraneous Residue Limits (ERLs) have replaced previous Maximum Residue Levels (MRLs) to reflect this change in use pattern.

3.4.2 Occupational/Use: Dermal and inhalation routes are likely routes of exposure from occupational uses. 0.5 mg/m is the recommended threshold-limit value-time weighted average (TLV-TWA) for an 8-hr work shift. A short-term exposure limit (TLV-STEL, 15 minutes) of 2 mg/m has also been recommended. The acceptable ceiling concentration in the USSR is 0. mg/m . Airborne heptachlor in houses treated for termites should not exceed 2 μg/m .

3.4.3 Environment: Low levels of heptachlor have been found in air samples of several cities of the USA ranging from 2.3 to 19.2 ng/m . Heptachlor has been reported in drinking water, groundwater, plant effluent, river water, and sediments of lakes and rivers from 18 locations in USA and Europe (3 ng/l to 9 μg/l). Fish examined from the Pacific Ocean have shown detectable levels and oysters from the South Atlantic and Gulf of Mexico have demonstrated levels of heptachlor up to 10 ppb. Earthworms are able to absorb heptachlor from the soil resulting in detectable levels of fat in starlings. Heptachlor epoxide has also been found in the eggs of upland game and waterfowl.

3.4.4 Accidental Poisoning:

Acute symptoms: central nervous system effects (headache, blurred vision, dizziness, slight involuntary muscular movements, tremor, sweating, insomnia, nausea, and general malaise).

Severe poisoning: as in acute, plus epileptiform convulsions, loss of consciousness, urinary and faecal incontinence, disorientation, personality changes, psychic disturbances, and loss of memory. Abnormal encephalographic patterns.

The estimated dermal dose which is expected to produce symptoms is 1.2 g/day and an occupational intake of about 0.007 mg/kg/day has been estimated to be without measurable toxic effect.

The distribution of chlorinated pesticides in the plasma of pregnant women and in the milk of lactating women was compared with the amounts found in the plasma and tissues of stillborn or newborn infants. The concentration of heptachlor epoxide in the plasma and milk of pregnant or lactating women was found to be 0.003 and 0.0007 ppm, respectively. The organs of stillborn infants contained 0.8 ppm heptachlor epoxide and the blood of newborn infants contained 0.001 ppm. The possible health hazards of these levels was not demonstrated.

Antidote/First Aid: Treatment is symptomatic; use of gastric lavage and parenteral phenobarbital has resulted in reversal of neurologic signs for other cyclodiene pesticides. Drugs useful to control convulsions include: diazepam, lorazepam, barbiturates, and muscle-paralysing agents such as succinylcholine. Benzodiazepine drugs are currently anticonvulsants. Chloestyramine resin accelerates biliary-faecal excretion.

3.5 Measures to Reduce Exposure:

Handling: In handling heptachlor or its formulations care should be exercised to avoid skin contact, inhalation of dusts or mists, and ingestion. Protective gloves, overalls and boots should be water-resistant; an approved respirator should be worn for application in enclosed areas such as crawl spaces. Mixers/loaders should also wear goggles or a face shield when mixing, loading or handling the concentrate.

Avoid applying heptachlor in or around poultry houses, barns, silos, milk houses, or other structures or enclosures where livestock or poultry are held, or where food/feed is stored, prepared or processed. Heptachlor should not be applied to any crop when edible portions are present or to soil which will be planted with crops whose edible portion is in or on the ground.

Exposure of fish and aquatic organisms may be reduced by avoiding spraying near or over water bodies or by restricting or banning uses posing hazards of water contamination.

Effluents from manufacturing, formulating, storage, and equipment cleaning operation should be controlled to avoid water contamination.

3.6 Packaging and Labelling: Follow FAO Guidelines on Good Labelling Practice for Pesticides and Guidelines for the Packaging and Storage of Pesticides.

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

3.8 Maximum Residue Limits. (mg/kg):

JMPR/Codex Alimentarius: Codex has changed designation of limits for all commodities from MRLs (Minimum Residue Levels) to ERLs (Extraneous Residue Limits), recognizing the widespread banning of uses in agriculture and that most residues would be the result of previously authorized uses. Current ERL levels (in mg/kg) are: in carrots, meat, and poultry meat, 0.2; in soya bean oil (crude), 0.5; in cereal grains, cotton seed, soya bean (immature seeds), soya bean oil (refined), and tomato, 0.02; in citrus fruits and pineapple, 0.01; in eggs and vegetables (except carrot, soya bean, sugar beets and tomatoes), 0.05; and in milks, 0.006.

EEC: level in cereal grains is 0.01 mg/kg.

USA: all tolerances revoked; action levels recommended, 0.1, where all previous tolerances were established.

Some countries are reducing or revoking national limits to cover only environmental residues from previous uses. Food exporting countries using heptachlor should consider the MRLs in their market countries in making decisions on continued use of heptachlor.

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ANNEX 1
SUMMARY OF CONTROL ACTIONS AND REMAINING USES FOR HEPTACHLOR,
AS REPORTED BY COUNTRIES

BANNED:

Belize	(NS)		Banned as agricultural chemical.
Colombia	(1988)		Banned.
Cyprus	(NS)		Banned.
Ecuador	(1985)		Banned as agricultural chemical.
EEC-countries*	(1988)		Banned as agricultural chemical.
Kenya		(1987)	Banned as agricultural chemical.
Liechtenstein		(NS)	Banned.
Singapore	(1984)		Banned.
Switzerland	(1986)		Banned.
Yugoslavia	(1972)		Banned as agricultural chemical.

WITHDRAWN:

Canada (1970). Most food uses phased out in 1970. Most additional uses discontinued in 1976. Last product registration discontinued by registrant in 1985.

SEVERELY RESTRICTED:

Dominica (NS) Severely restricted pesticide.

Only remaining use allowed:

Bulgaria (NS) Used for seed treatment only.

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

Republic of Korea (1986) Sale and use prohibited except for production of industrial goods.

USA (1978) All uses cancelled except for subsurface ground insertion for termite control and dipping of roots or tops of non-food plants.

Venezuela (1983) Only permitted when intended for control of vectors for medical reasons by Ministry of health, control of agricultural pests by Ministry of agriculture.

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

Specific uses reported as not allowed:

Argentina (1968-72) Prohibited for use as tucuricide (glow-worm killer) (1968), as external parasiticide (1968) for use in treatment of natural and artificial meadows, in animal feed as external parasiticide (1969), and for use as antiweevil agent on seeds and their products intended for human or animal consumption (1972).

Chile (1983) Not allowed on natural or artificial meal directly or in concentrated form as animal feed. Prohibited on seeds, grain, etc.

Use permitted only with special authorization:

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

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