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

DECISION GUIDANCE DOCUMENTS

Lindane

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

United Nations Environment Programme

UNEP

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

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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

Prior Informed Consent Decision Guidance Document

Lindane

1 Identification

1.1	Common Name	Lindane
	Other names/synonyms	gamma-HCH, gamma-BHC (refers to more than 99% gamma isomer), gamma-HKhTsH, ENT 7796, OMS17
1.2	Chemical Type	Chlorinated hydrocarbon
1.3	Use	Insecticide, Acaracide
1.4	Chemical Name	Gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane, 1-alpha, 2-alpha, 3-beta, 4-alpha, 5-alpha, 6-beta hexachlorocyclohexane
1.5	CAS No.	58-89-9
1.6	Trade Names	666; Aalindan; Africide; Agrocide; Agrocide III; Agrocide WP; Ameisenmittel Merck; Ameisentod; Aparasin; Aphtiria; Aplidal; Arbitex; BBH; Ben-Hex; Bentox; Bexol; Celanex; Chloresene; Codechine; DBH; Detmol-Extrakt; Devoran; Dol; Drill Tox-Spezial Aglukon; ENT 7796; Entomoxan; Exagamma; Forlin; Gallogama; Gamaphex; Gammalin; Gammalin 20; Gammex; Gammexane; Gammaterr; Gexane; Grammapox; Hecltox; Hexa; Hexachloran; y-Hexachloran; Hexachlorane; Hexaverm; Hexicide; Hexyclan; HGI; Hortex; Inexit; Isotox; Jacutin; Kokotine; Kwell; Lacca Hi Lin, Lacca Lin-O-Mulsion; Lendine; Lentox; Linafor; Lindafor; Lindagam; Lindagrain; Lindagam; Lindagram; Lindatox; Lindasep; Lin-O-Sol; Lindagranox; Lindalo; Lindamul; Lindapoudre; Lindaterra, Lindex; Lindust; Lintox; Lorexane; Milbol 49; Msycol; Neo-Scabicidol; Nexen FB; Nexit; Nexit-Stark; Nexol-E; Nicochloran; Novigam; Omnitox; Ovadziak;Owadizak; Pedraczak; Pflanzol; Quellada; Sang-gamma; Silvanol; Spritz-Rapidin; Spruehpflanzol; Streunex; TAP 85; Tri-6; Vitron
1.7	Mode of action as Pesticide	Insecticide with contact, stomach and respiratory action. Acts as stimulant to the nervous system causing epileptiform convulsions and death.
1.8	Formulation Types	Emulsifiable concentrates (0.45% to 40% with 11% or 12% & 20% common); flowable concentrates (0.5%, 1.0%, 30%, & 40%) wettable powders (3%, 6%, 9%, 10%, 25%, 75%); pressurized liquids (0.25%, 0.75%, 3%); dusts (0.5% to 75% with 1% common); smoke generators (10.2, 11.2, 20.0%); liquid ready-to-use (0.5% to 25% with 0.1% & 0.5% common); tech. grade (99%, 99.5%, 100%)

1.9	Basic Manufacturers	Agrolinz (Austria); All India Medical Corp. (India); Celamerck GmbH KG Ingelheim, (Fed. Rep. Germany); Drexel Chemical Co. (USA); Inquinosa (Spain); Mitsui, Inc. (Fukuoka, Japan); Rhône-Poulenc; Phytosanitaire (Lyons, France); Tianjin International Trust & Investment Corp. (Tianjin, China).

2 Summary of Control Actions

2.1 General

Actions to ban or severely restrict lindane have been taken by 11 countries. Seven countries have banned lindane.

The actions reported by governments to IRPTC/UNEP are listed in Annex I.

2.2 Reasons for the Control Actions

Control actions are reported by eleven countries. Eight (Australia, Austria, Cyprus, Finland, Indonesia, the Netherlands, New Zealand and Saint Lucia) indicated that lindane was being restricted or banned because of persistency in the environment, bioaccumulation in the food chain and toxicity to humans, aquatic and terrestrial species. One country (the Netherlands) indicated the impurities of lindane (other HCH isomers) as the environmental problem. Four countries (Austria, Republic of Korea, Sri Lanka and Sweden) referred to their concern over toxicity specifically to humans. Lindane has been associated with various human health concerns for several years.

2.3 Bans and restrictions

Eleven countries have partially or totally banned use on food or feed commodities. (*Refer to Annex 1 for details.)*

2.4 Uses Reported to be Continued in Effect

Seed treatment and soil treatment uses have been retained by several countries which have otherwise banned food/feed uses. Seven countries have retained a few remaining uses. (*Refer to Annex 1 for details*.)

2.5 Alternatives

Specific alternatives were suggested by some countries reporting control actions (Annex 2). It is important to remember that the effectiveness of any alternative pesticide needs to be established under conditions of use in specific crops and countries.

2.6 Contacts for Further Information

FAO/UNEP Joint Data Base, IRPTC, Geneva; Designated National Authorities (DNAs) in countries taking control actions may be a source of information on alternatives (Annex 3).

3 Summary of Further Information on Lindane

3.1 Chemical and Physical Properties

Technical lindane is a white crystalline solid with a melting point of 112.5-113.5^{0}C and boiling point of 323.4^{0}C. It is stable to light, heat, air and strong acids but decomposes to trichlorobenzenes and HCl in alkali. It is soluble in most organic solvents and is soluble in water at 10 parts per million (ppm) at 20^{0}C. Other chemical and physical properties include vapour pressure of 5.6 mPa at 20^{0}C (Pesticide Manual) and specific gravity 1.85.

3.2 Toxicological Characteristics

3.2.1 Classification

WHO	a.i. Class II (moderately hazardous)
IARC	Group 2B (possible carcinogen but inadequate evidence in humans)
EU	Toxic, irritant

3.2.2 General

No information

3.2.3 Acute Toxicity

Oral	LD_{50} rats 90-270 mg/kg; mice: 55-250 mg/kg; rabbit: 90-200 mg/kg (WHO, 1992)
Dermal	LD_{50} rat: 900-1000 mg/kg, rabbit: 200-300 mg/kg (WHO ,1992)
Inhalation	Rat LC_{50} 1500 mg/m^3/4 hrs (WHO, 1992)
Irritation	Eye irritation depends on the inert ingredients more than the active ingredient; lindane is not a primary dermal irritant; negative in the dermal sensitization test.

3.2.4 Short-term Toxicity

Lindane was reviewed by the JMPR a number of times between 1966 and 1979. An ADI of 0.01 mg/kg bw, based on liver enlargement observed in a long-term study in rats. Long-lasting, slowly reversible kidney damage was observed. The JMPR in 1989 established the NOAEL to be 10 ppm for rat, equal to 0.75 mg/kg bw/day, and 1.6 mg/kg bw/day for dog; the ADI for humans was estimated to be 0-0.008 mg/kg bw.

Teratogenicity	Foetotoxic and/or maternal toxic effects were observed after administration of lindane at 10 mg/kg bw
NOEL	Rat 0.2-0.5 mg/kg bw (WHO, 1991)

3.2.5 Chronic Toxicity

Carcinogenicity There was no increase in tumours to rats fed a maximum of 100 ppm (5mg/kg/day) of lindane throughout their lifespan. A two-year mouse oncogenicity study demonstrated increased incidences of liver tumours (male and female) when dosed at 400 ppm. The IARC (1987) concluded the evidence of carcinogenicity on humans to be inadequate.

Mutagenicity The mutagenicity of lindane has been adequately studied. Overall, lindane appears not to have mutagenic potential (WHO, 1991).

3.2.6 Epidemiological Data

It can be concluded, from a few acute and short-term studies on human beings, that a dose level of approximately 1.0 mg/kg bw will not induce poisoning but that a dose level of 15-17 mg/kg bw will result in severe toxic symptoms (WHO, 1991).

3.3 Environmental Characteristics

3.3.1 Fate

Lindane is mobile in sandy soils and non-mobile in clay soils; it is also retained more strongly where humus levels are high. However, the potential for lindane contamination of surface and ground water exists based on the results of a monitoring study conducted in south-eastern USA.

The half-life in soil ranges from 5 days (Kenya) to more than 400 days (temperate soils) depending on both temperature and microbiotic life of the soil (WHO, 1992).

In a series of dissipation studies with lindane, it was demonstrated that persistent pesticides such as lindane dissipate much faster in the tropics than in temperate climates, probably owing to a large extent to volatilization (WHO, 1992).

3.3.2 Effects

Fish LC_{50}: 0.02-0.09 mg/l (highly toxic) (WHO, 1991)

Bees Toxic to bees (Pesticide Manual, 1994)

Aquatic invertebrates Crustaceans: 0.005-0.88 µg/L (WHO 1991)

Birds LD_{50}: 120-210 for bobwhite quail; avian dietary toxicity: 882 ppm for bobwhite quail, 561 ppm for ring-necked pheasant (both moderately toxic); >5000 ppm mallard duck (minimal toxicity)

3.4 Exposure

3.4.1 Food

In the 1970s and 1980s lindane was found in many crops throughout the world as well as in honey and fish and shellfish. Levels of lindane being consumed with food varies from year to year in nations where it has been reported. Lindane concentrates in the fat of food animals and in milk and has been reported in a number of countries in such commodities. More than 90% of human intake of lindane originates from food. Monitoring studies have shown that residues of lindane

have been found in mother's milk. In several countries lindane has also been identified in blood serum, fat and adipose tissue (IARC, 1987; WHO, 1991).

3.4.2 Occupational/Use

Workers who are professionally exposed to lindane come into contact with the other HCH isomers present in lindane as impurities. A Japanese study reported levels of beta HCH in human blood plasma in 6 occupational groups who worked with lindane. The lowest mean levels were found in female farm workers (38 µg/l); the highest mean levels were found in male workers in pesticide factories (94 µg/l).

3.4.3 Environment

Monitoring outdoor air samples in the 1980s, the concentrations found in various continents ranged from 0.039 to 0.68 ng/m^3. Much higher lindane concentrations (51-61 µg/m^3) could be registered in houses after treatment with products containing lindane (WHO, 1991). Lindane has been detected in surface and drinking water and industrial effluent and sewage in Europe and the USA (WHO, 1991). Lindane (29-398 ng/l) has been found in rainwater in Tokyo (1975). It has also been located in soil in many parts of the world. In a Dutch study from 84 were analysed 96 samples from the upper 10 cm of soil from 38 natural reserves in the Netherlands. Fifty-nine samples contained less than 1 µg/kg, 7 contained 20-80 µg/kg. However, in the Ukraine, 36 of 136 soil samples taken at various locations contained lindane at levels of 0.1-5 mg/kg (WHO, 1991).

3.4.4 Accidental Poisoning

IARC reports that digestive tract inflammation, haemorrhaging, coma and death have been reported after lindane poisoning. Workers who were heavily exposed to lindane, DDT or both for periods ranging from 5-13 years, at time of liver biopsy showed cirrhosis and chronic hepatitis. Lindane is a central nervous system stimulant for which no specific antidote is available. A short-acting barbiturate should be used for alleviation of symptoms. Diazepam is the preferred treatment for convulsions (IARC, 1987).

3.5 Measures to Reduce Exposures

Protective clothing and gloves will reduce exposure of those handling and applying lindane. Additionally, goggles or a face shield should be worn.

3.6 Packaging and Labelling

Labels should include precautions and warnings related to applicator, handler and worker exposure, as well as hazards to aquatic organisms. Refer to the FAO Revised Guidelines on Good Labelling Practices for Pesticides (1995).

3.7 Waste Disposal Methods (WHO/IPCS, 1990)

In disposing of lindane, care should be taken to avoid contamination of natural waters and soil. Suggested methods of disposal are alkaline hydrolysis and high temperature incineration designed for organochlorine waste disposal. Detailed guidelines are under development. This section will be updated when guidelines are available.

3.8 Maximum Residue Limits (mg/kg)

Codex/JMPR ADI: 0.008 mg/kg bw (FAO, 1989)

Codex MRLs: (mg/kg) Apples, 0.5; beans (dry), 1 Po; Brussels sprouts, cabbage (head and Savoy), 0.5; cacao beans, 1.0; carrots, 0.2 E; cauliflower, 0.5; cereal grains, 0.5 Po; cherries, 0.5; cocoa (butter and mass), 1.0 cranberry, 3.0; currant (red and white), 0.5; eggs, 0.1 E; endives, 2.0; grapes, 0.5; kohlrabi, 1.0; lettuce (head), 2.0; meat of cattle, pigs and sheep 2.0 (fat) V; milks, 0.01 F V; pear, 0.5; peas, 0.1; plums (including prunes), 0.5; potato, 0.05; poultry meat, 0.7 E (fat); radish, 1.0; rape seed, 0.05; spinach, 2.0; strawberry, 3.0; sugar beet (beet, leaves or tops), 0.1; tomato, 2.0.(Codex Alimentarius Commission, 1986).

US Tolerances (ppm) Apples, apricots, asparagus, avocados, broccoli, Brussels sprouts, cabbage, cauliflower, celery, cherries, collards, 1.0; cucumbers, 3.0; eggplants, 1.0; fat of meat (cattle, horses, sheep), 7.0; fat of meat (hogs), 4.0; grapes, guavas, 1.0; kale, kohlrabi, 1.0; lettuce, 3.0; mangoes, 1.0; melons, mushrooms, 3.0; mustard (greens), nectarines, okra, onions (dry bulb only), peaches, pears, 1.0; pecans 0.01; peppers, pineapples, plums (fresh prunes), 1.0; pumpkins, 3.0; quinces, spinach, 1.0; squash, squash (summer), 3.0; strawberries, swiss chard, 1.0; tomatoes, 3.0.

4 Major References

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ANNEX 1

Summary of Control Actions and Remaining Uses as Reported by Countries

Actions taken and year effective

Bans

Finland	
Control Action	Total ban for use as a pesticide
Effective	1988
Uses still allowed	No remaining uses are allowed
Reasons for control action	High risk to human health and the environment
Date of notification	

Indonesia	
Control Action	Registration no longer
Effective	1985
Uses still allowed	No remaining uses are allowed
Reasons for control action	May induce adverse effects to environment and human health
Date of notification	

Korea, Republic of	
Control Action	Sale and use of the substance and its preparations are prohibited within the country
Effective	1986
Uses still allowed	No remaining uses are allowed
Reasons for control action	Harmful to human health
Date of notification	

Netherlands	
Control Action	It is prohibited to sell, stock or use all pesticides containing HCH (99% gamma isomer) as active ingredient
Effective	1979
Uses still allowed	No remaining uses are allowed
Reasons for control action	Persistence of impurities (aplha-, beta-, delta-, and epsilon-isomers of HCH which do not contribute to the activity of gamma-HCH); its high bioconcentration factor leads to biomagnification in the food chain
Date of notification	

New Zealand	
Control Action	Ban on all remaining products and uses
Effective	1990
Uses still allowed	No remaining uses allowed
Reasons for control action	Environmental reasons
Date of notification	

Saint Lucia	
Control Action	Registration refused; permitted for use as a pesticide
Effective	1987
Uses still allowed	No remaining uses allowed
Reasons for control action	High residual effects in soil water
Date of notification	

Sweden	
Control Action	Banned for use as pesticide
Effective	1988
Uses still allowed	
Reasons for control action	Suspected carcinogenic properties and persistence

Severely Restricted

Australia	
Control Action	Severely restricted; importation of the chemical is prohibited unless specifically approved by the Government
Effective	Varies from state to state
Uses still allowed	Control of white grub in pineapple
Reasons for control action	The persistence of the chemical makes it environmentally unacceptable

Austria	
Control Action	Severely restricted for use
Effective	1992
Uses still allowed	Lindane is only authorized as seed dressing against soil pests for crop farming applications
Reasons for control action	High persistence in the environment, its bio-accumulation in the food chain and in human tissues. Lindane is suspected to have carcinogenic properties. There is evidence that HCH-isomers act as a tumour promoter previously initiated by other chemicals

Cyprus	
Control Action	Severely restricted pesticide
Effective	1987
Uses still allowed	Only formulations of lindane containing less than 20% of gamma-HCH in gasoline or paints are registered for the protection of wood (control of termites and other insects). This use constitutes about 10% of all previously allowed uses.
Reasons for control action	Risk associated with human health and the contamination of the environment due to its persistence and accumulation of residues in mammalian tissues

Sri Lanka	
Control Action	Severely restricted
Effective	1986
Uses still allowed	Only permitted for pest control in coconut nurseries and for emergency use in spotted locust control. Use in shampoos allowed if approved by the Cosmetic Devices & Drugs Committee.
Reasons for control action	All regulatory decisions have been made on the basis of published toxicological and ecotoxicological data in relation both to the socio-economic conditions of the user and the benefits derived from using the pesticides.

ANNEX 2

Alternatives

The following alternatives were noted by countries reporting import decisions under the PIC procedure:

Country	
Austria	Many alternatives for designated purposes
Australia	Azinphos ethyl, carbaryl, chlorpyrifos, endosulfan, fenitrothion, methidathion, disulfoton, methamidophos, mevinphos, vamidothion, diazinon, malathion, permethrin, deltamethrin, bioresmethrin, cyfluthrin, cypermethrin, propoxur, pirimicarb, phonate, methomyl
Indonesia	Permethrin, decamethrin, phormothion
Sri Lanka	Carbamate pesticides have replaced lindane in agriculture

It is essential that before a country considers substituting any of these reported alternatives, it ensures that the use is relevant to its national needs. A first step may be to contact the DNA in the country where the alternative has been reported (see address: Annex 3). It will then be necessary to determine the compatibility with national crop protection practices.

ANNEX 3

List of Pesticide DNAs in Countries Reporting Control Actions or Alternatives

Australia	P	Mr. Ian Coleman Agricultural and Veterinary Chemicals Policy Section Dept. of Primary Industries and Energy GPO Box 858 Canberra ACT 2601	Tel.: 0061 6 271 6371 Fax.: 0061 6 272 5899 Email:icoleman@dpie.gov.au
	C	Assistant Secretary Environment Standard Branch Environment Protection Agency (EPA) 40 Blackall St. Barton ACT 2600 (Attn.: Ms. Kaye Dal Bon)	Fax: 616 274 1172 Tel: 616 274 1757
Austria	CP	Ministry of the Environment Department II/3 Stubenbastei 5 A - 1010 Vienna	Tel: (0043-1-51522 2701 Fax: (0043-1-51522 7744
Cyprus	P	The Chairman Pest Control Products Bd. Department of Agriculture,, Ministry of Agriculture & Natural Resources Nicosia	Tel: 30-2250/30-2254 Tlx: 4660 Minagri CY Cab: MINAGRI CYPRUS Fax: 361425 Nicosia
	C	Director Environment Service Ministry of Agriculture, Natural Resources & Environment Nicosia	Tel: 30-2883 Tlx: 4660 Minagri CY Cab: MINAGRI CYPRUS Fax: 363945 Nicosia
Finland	CP	Finnish Environment Agency Chemicals Division (Attn: Senior Advisor Magnus Nyström) SF - 00251 Helsinki	Tel: 358-0-403 005 45 s/b 403 000) Fax: 358-0-4-3-005 91
Indonesia	P	Chairman Pesticides Committee Direktorat Bina Perlindungan Tanaman Jln. AUP. Pasar Minggu Jakarta Selatan	Tel: 62 (21) 7805652/7806213 Fax: 62 (21) 7805652
	CP	Ms. Masnellyarti Hilman Bapedal Offices Arthaloka Bldg., 11th Floor Jl. Jend. Sudirman No. 2 Jakarta Pusat	Tel: (021) 583918 Tlx: 62 21 583918 Fax: (021) 5703365
Korea, Republic of	P	Director Sustainable Agriculture Division Agricultural Policy Bureau Ministry of Agriculture, Forestry and Fisheries Government Complex II Kwacheon 427-760	Tel: 82 2 5037284 Fax: 82 2 5073963

	CP	The Director Basic Chemicals Industry Division Basic Industry Bureau Ministry of Trade, Industry and Energy Government Complex II Kwacheon 427-760	Tel: 82 2 5002464 Fax:: 82 2 5039471
	C	Director Toxic Substances Management Division Ministry of Environment Government Complex II Kwacheon 427-760	Tel: 82 2 5049288 Fax: 82 2 5046068
Kuwait	P	The Director Plant Wealth Department The Public Authority for Agriculture Affairs & Fish Res. P.O. Box 21422 13075 Safat	Tel: (965) 2452790, 2456835/36 Tlx: 46408 EP CNCL KT Fax: (965) 2421993-2456836
Netherlands	CP	The Director Chemicals Division Ministry of Housing, Physical Planning and Environment Directorate for Chemicals, External Safety and Radiation Protection P.O. Box 30945 2500 GX The Hague (Attn: Dr. K.A. Gijsbertsen)	Tel: 31 70 - 3393939 Fax: 31 70 - 3391297
New Zealand	CP	Mr. D.W. Lunn Chief Scientist (Pesticides) Agricultural Compounds Unit Ministry of Agriculture & Fisheries P.O. Box 40-063 Upper Hutt	Tel: 064 4 528-6089 Fax: 064 4 528-4675
Saint Lucia	CP	The Chairman National Pesticides Control Board c/o Ministry of Agriculture Manoel Street Castries	*Tel: 809 4522526* *Fax: 809 4536314*
Sri Lanka	P	Registrar of Pesticides Pesticides Registration Office Royal Botanical Gardens P.O. Box 49 Peradeniya Getambe	*Tel: 94 08 88135* *Fax: 94 08 88206*
Sweden	CP	National Chemicals Directorate Attn.: Mr. Ule Johansson P.O. Box 1384 171 27 Solna	Tel: 46 (8) 730 6004 Tlx: 10460 AMS S Fax: 46 (8) 735 7698

	C	Industrial and consumer product chemicals
	P	Pesticides
	CP	Pesticides, industrial and consumer product chemicals