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Item 6 (d) of the provisional agenda*

Consideration of draft risk management evaluations: lindane

Draft risk management evaluation: lindane

Note by the Secretariat

1. At its second meeting, the Persistent Organic Pollutants Review Committee adopted decision POPRC-2/4 on lindane.[1] By paragraph 3 of the decision, the Committee decided to establish an ad hoc working group to prepare a risk management evaluation that includes an analysis of possible control measures for lindane in accordance with Annex F to the Convention.

2. The members of the ad hoc working group on lindane and its observers are listed in annex V of document UNEP/POPS/POPRC.2/17.

3. A standard workplan for the preparation of a draft risk management evaluation was adopted by the Committee at its second meeting.[2]

4. In accordance with decision POPRC-2/4 and the standard workplan adopted by the Committee, the ad hoc working group on lindane prepared the draft risk management evaluation set forth in the annex to the present note. The draft risk management evaluation has not been formally edited.

Possible action by the Committee

5. The Committee may wish:

(a) To adopt, with any amendments which it deems appropriate, the draft risk management evaluation set forth in the annex to the present note;

* UNEP/POPS/POPRC.3/1/Rev.1.

1 UNEP/POPS/POPRC.2/17, annex I.

2 Ibid., para. 39 and annex II-B.

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(b) To decide, in accordance with paragraph 9 of Article 8 of the Convention, based on the risk profile adopted at its second meeting (UNEP/POPS/POPRC/17/Add.4) and the risk management evaluation, whether the chemical should be recommended for consideration by the Conference of the Parties for listing in Annexes A, B, and/or C.

Annex

LINDANE

DRAFT RISK MANAGEMENT EVALUATION

Draft prepared by the ad hoc working group on
Lindane
under the Persistent Organic Pollutants Review Committee
of the Stockholm Convention

August 2007

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Executive summary

Mexico proposed that Lindane be added to Annex A of the Stockholm Convention on June 29, 2005. The POPs Review Committee evaluated Annex D information at its first meeting and concluded that "the screening criteria have been fulfilled for Lindane". The Review Committee at its second meeting evaluated the risk profile for Lindane in accordance with Annex E, and concluded that "Lindane is likely, as a result of its long range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted".

International initiatives on Lindane include the Protocol on Persistent Organic Pollutants of the Convention on Long-Range Transboundary Air Pollution; the Rotterdam Convention; and the OSPAR Commission for the Protection of the Marine Environment of the Northeast Atlantic.

Lindane is banned for use in 52 countries, restricted or severely restricted in 33 countries, not registered in 10 countries, and registered in 17 countries. Regional actions on Lindane include: The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane Isomers between Canada, United States and Mexico under the North American Commission for Environmental Cooperation; the Great Lakes Binational Toxics Strategy between the United States and Canada; the European Water Framework Directive 2000/60/EC; the European Union Regulation 850/2004/EC and the European Council Directive 850/2004/EEC, among others.

Lindane control measures currently implemented in several countries include: Production, use, sale and imports prohibition, registrations and use cancellations, clean-up of contaminated sites, and public health advisories and hazard warnings issuing for pharmaceutical uses.

The assessment of the efficacy and efficiency of control measures is country dependent; however, all countries consider that control measures currently implemented are technically feasible. There are several chemical alternatives for Lindane for seed treatment, livestock, and veterinary uses. Alternatives that are currently in use are considered, in general, technically feasible, efficient, available and accessible by the countries that are already using them. A different scenario exists for pharmaceutical alternatives for Lindane, where alternatives are available, but failures have been reported for scabies and lice treatments producing a big concern in relation to the limited number of available alternative products on the market. Non-chemical alternatives for Lindane agricultural uses have also been reviewed. Some information has been received about the cost of replacing Lindane with alternative pesticides in agricultural applications.

Lindane meets several internationally accepted criteria for persistence, bioaccumulation and toxicity. Therefore, the implementation of control measures is expected to reduce the risks from exposure of humans and the environment to Lindane. Implementation of control measures is expected to have positive impacts on biota due to the ease with which Lindane accumulates in wildlife, especially in Arctic wildlife. There are potential risks identified from dietary exposure, particularly to people in Alaska and the circumpolar Arctic who depend on traditional foods such as fish and marine mammals.

Several countries that have already prohibited or restricted Lindane use, consider the use of existing stockpiles for a set time period as feasible, leaving a limited amount of waste for disposal. Contaminated sites of former Lindane producers, old storages and dumps have to be addressed by several countries.

Canada, the United States, the Czech Republic, the Republic of Zambia and Brazil have mechanisms to monitor and control Lindane. Other countries also have programs to share information concerning Lindane uses, alternatives and regulations.

A thorough review of existing control measures that have already been implemented in several countries, shows that risks from exposure of humans and the environment to Lindane can be reduced significantly. Control measures are also expected to support the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

Having evaluated the risk profile corresponding to Lindane, and having prepared its risk management evaluation, the POPs Review Committee of the Stockholm Convention concludes that this chemical is likely, as a result of long-range environmental transport, to lead to significant adverse effects on human health and/or the environment, such that global action is warranted.

In accordance with paragraph 9 of Article 8 of the Convention, the Committee recommends the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of Lindane in Annex A. However, it should be noted there is some information provided by parties and observers pointing to an option for pharmaceutical use exemption.

1. Introduction

1.1 Chemical identity of the proposed substance

Lindane: gamma-hexachlorocyclohexane
Chemical formula: $C_6H_6Cl_6$
CAS number: 58-89-9
Molecular weight: 290.83
Physical and chemical properties are shown in Table 1-1.

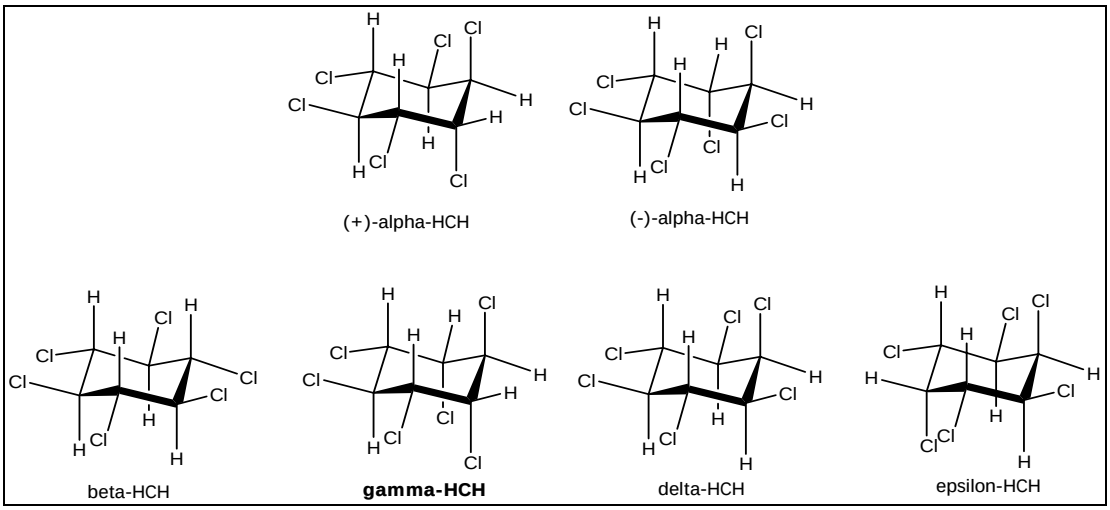
Table 1-1. Physico-chemical properties of Lindane

Physical state	**Crystalline solid**
Melting point	**112.5 °C**
Boiling point at 760 mmHg	**323.4 °C**
Vapor pressure at 20°C	**$4.2x10^{-5}$ mmHg**
Henry's Law constant at 25°C	**$3.5x10^{-6}$ atm m^3/mol**

ATSDR, 2005

Lindane is the common name for the gamma isomer of 1,2,3,4,5,6-hexachlorocyclohexane (HCH). Technical HCH is an isomeric mixture that contains mainly five forms differing only by the chlorine atoms orientation (axial or equatorial positions) around the cyclohexane ring (Figure 1-1). The five principal isomers are present in the mixture in the following proportions: alpha-hexachlorocyclohexane (53%–70%) in two enantiomeric forms ((+)alpha-HCH and (-)alpha-HCH), beta-hexachlorocyclohexane (3%–14%), gamma-hexachlorocyclohexane (11%–18%), delta-hexachlorocyclohexane (6%–10%) and epsilon-hexachlorocyclohexane (3%–5%). The gamma isomer is the only isomer showing strong insecticidal properties.

Figure 1-1. Structure of alpha, beta, gamma, delta and epsilon HCH isomers



Modified from Buser et al, 1995.

The term "benzene hexachloride (BHC)" is also commonly used for HCH, but according to IUPAC rules this designation is incorrect. Nevertheless the term is used and therefore, gamma-BHC also designates Lindane. In the present risk profile document, Lindane refers to at least 99% pure gamma-HCH and the BHC term is not used.

1.2 Conclusions of the Review Committee

Mexico proposed that Lindane be added to Annex A of the Stockholm Convention on June 29, 2005. The Persistent Organic Pollutants (POPs) Review Committee at its first meeting evaluated Annex D information and concluded that "the screening criteria have been fulfilled for Lindane" [3], and decided to establish an ad hoc working group to prepare a risk profile.

The POPs Review Committee at its second meeting evaluated the risk profile for Lindane[4] in accordance with Annex E, and concluded that "Lindane is likely, as a result of its long range environmental transport, to lead to significant adverse human health and environmental effects such that global action is warranted"[5].

1.3 Data sources

The following Parties and observers have answered the request for information specified in Annex F of the Convention: Brazil, Canada, Czech Republic, Germany, Japan, Mauritius, Mexico, Monaco, Republic of Zambia, Sweden, Switzerland, Thailand, United States of America, CropLife International and the International POPs Elimination Network. A more elaborated summary of the submissions is provided as separate **POPRC/INF** document.

1.4 Status of the chemical under international conventions

Lindane is listed as a "substance scheduled for restrictions on use" in Annex II of the 1998 **Protocol on Persistent Organic Pollutants of the Convention on Long-Range Transboundary Air Pollution**. This means that products in which at least 99% of the HCH isomer is in the gamma form (i.e. Lindane) are restricted to the following uses: 1. Seed treatment. 2. Soil applications directly followed by incorporation into the topsoil surface layer. 3. Professional remedial and industrial treatment of lumber, timber and logs. 4. Public health and veterinary topical insecticide. 5. Non-aerial application to tree seedlings, small-scale lawn use, and indoor and outdoor use for nursery stock and ornamentals. 6. Indoor industrial and residential applications. All restricted uses of Lindane shall be reassessed under the Protocol no later than two years after

[3] UNEP/POPS/POPRC.1/10

[4] UNEP/POPS/POPRC.2/10

[5] UNEP/POPS/POPRC.2/17

the date of entry into force. The Protocol entered into force on October 23th, 2003. There are currently 28 Parties to this Protocol. [6]

Lindane, as well as the mixture of HCH isomers, is listed in Annex III of the **Rotterdam Convention** on the Prior Informed Consent Procedure as "chemicals subject to the prior informed consent procedure". The Rotterdam Convention entered into force 24 February 2004. There are currently 116 Parties to this Convention. [7]

Hexachlorocyclohexane isomers, including Lindane, are included in the List of Chemicals for Priority Action (Updated 2005) under the **OSPAR Commission for the Protection of the Marine Environment of the Northeast Atlantic**. Under this initiative, the Hazardous Substance Strategy sets the objective of preventing pollution of the maritime area by continuously reducing discharges, emissions and losses of hazardous substances, with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances. The OSPAR Convention entered into force on 25 March 1998. [8]

HCH (including Lindane) is listed as a Level II substance in the **Great Lakes Binational Toxics Strategy** between the United States and Canada, which means that one of the two countries has grounds to indicate its persistence in the environment, potential for bioaccumulation and toxicity. [9]

1.5 Any national or regional control actions taken

Lindane is banned for use in 52 countries, restricted or severely restricted in 33 countries, not registered in 10 countries, and registered in 17 countries (CEC, 2006).

The three Parties (Mexico, Canada and the United States) of the North American Commission for Environmental Cooperation (CEC)[10] have recently signed a North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane Isomers, under the Sound Management of Chemicals project. The goal of the NARAP is to reduce the risks associated with exposure of humans and the environment to these substances.

Lindane is also listed under the European Water Framework Directive 200/60/EC. This Directive is a piece of water legislation from the European Community. It requires all inland and coastal water bodies to reach at least "good ecological status" and "good chemical status" by 2015. Lindane is one of the listed priority hazardous substances for which quality standards and emission controls will be set at EU level to end all emissions within 20 years. [11]

Lindane is listed under the European Union Regulation 850/2004/EC, that specifies Member States may allow until September 2006 professional remedial and industrial treatment of lumber, timber and logs, as well as indoor industrial and residential applications; and until December 31, 2007 the use of technical HCH as an intermediate in chemical manufacturing and the restriction of products containing at least 99% of the HCH gamma isomer for use as public health and veterinary topical insecticide (Annex F information provided by Germany, 2007).

HCH is listed in Annexes IB (banned substances) and Annex IV (waste regulation) of European Council Directive 850/2004/EEC. Regulation 850/2004/EC was lately amended by regulation 1195/2006/EC in order to include thresholds for POPs containing waste. Article 7 applies to waste containing >50 mg/kg of the sum of alpha, beta and gamma HCH (Annex F information provided by Germany, 2007).

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6 Convention on Long-range Transboundary Air Pollution http://www.unece.org/env/lrtap/

7 Rotterdam Convention http://www.pic.int.

8 OSPAR Convention for the Protection of the Marine Environment of the Northeast Atlantic. http://www.ospar.org/

9 Great Lakes Binational Toxics Strategy http://www.epa.gov/glnpo/gls/index.html

10 North American Commission for Environmental Cooperation. www.cec.org/Lindane

11 European Union Water Framework Directive http://ec.europa.eu/environment/water/water-framework/index_en.html

2. Summary information relevant to the risk management evaluation

2.1 Identification of possible control measures

Lindane control measures currently implemented in several countries include: Production, use, sale and imports prohibition, use restrictions, registrations and use cancellations, clean-up of contaminated sites and public health advisories and hazard warnings issued for pharmaceutical uses.

Africa and Europe
Lindane is also prohibited for agricultural uses in Mauritius (Annex F information provided by Mauritius, 2007). In the Czech Republic Lindane use was banned in 1995, and the site of former producer (Spolana Neratovice) was successfully cleaned-up (Annex F information provided by the Czech Republic, 2007). In Germany, Lindane has not been used in agriculture and forestry since 1989. In the European Union, Lindane can still be used as public health and veterinary topical insecticide until the end of 2007 (Annex F information provided by Germany, 2007). In Sweden, Lindane has not been used for scabies in humans or animals since the 1980s (Annex F information provided by Sweden, 2007).

Lindane is severely restricted in Switzerland under the Ordinance on Risk Reduction related to Chemical Products. The only legal use is in medicinal products. Until the coming into force of the Ordinance, the only legal use of Lindane other than medicinal products was in seed dressings for agricultural purposes (Annex F information provided by Switzerland, 2007).

North America
Production, sale and use of Lindane are prohibited for all pesticide use in Canada. Stocks that existed at the time that pesticide registration was discontinued or suspended were to be sold, used or disposed of in accordance with an established timetable, after which their sale or use became a violation of the Pest Control Products Act (PCPA) (Annex F information provided by Canada, 2007).

In 1998 the United States Environmental Protection Agency (USEPA) cancelled the livestock uses of Lindane. In 2006, the United States announced the cancellation of the remaining agricultural uses of Lindane, effective July 1, 2007. However, the United States Food and Drug Administration (USFDA) determined that Lindane products have benefits that outweigh the risks for individual patients when used as directed as second-line treatment of scabies and lice when other treatments fail or cannot be tolerated. In 2003, USFDA issued a public health advisory, a medication guide, a boxed warning, and limited package sizes to reduce risks from the use of Lindane. (Annex F information provided by the United States of America, 2007). Morton Grove Pharmaceuticals is the sole supplier of Lindane pharmaceutical products in the United Sates. Lindane shampoo and lotions are sold solely for a single application in formulations of 1% concentration. In 2006 were produced 151,600 units of Lindane lotion using 136.4 kg, and 261,440 units of Lindane shampoo using 136.4 kg. Total Lindane used (272.8kg or 600 pounds) represents 0.4% of the 150,000 pounds reported to have been used for seed treatment in the United States in 2006 (Morton Grove Pharmaceuticals, 2007).

South America
In Brazil, Lindane use and imports are prohibited. Imports and formulation of Lindane were allowed until 2006. Commercialization of products with Lindane and use of products legally commercialized are allowed until 2007 (Annex F information provided by Brazil, 2007).

Asia
In Thailand, the use of Lindane-containing products is restricted. Lindane and Lindane-containing products are regulated by the Hazardous Substances Control Act B.E. 2535 (1992). According to the Act, registration and permission of any activities, including production, import, export or possession, are required. Only the use in household and public health programs is permitted under the supervision of the Hazardous Substances Control Group, Food and Drug Administration (Annex F information provided by Thailand, 2007).

Methods for the clean-up of sites contaminated with Lindane include: a) Hazardous waste incinerators and rotary kilns with Gas Phase Chemical Reduction (GPCR), b) Base-catalyzed decomposition, c) Sodium dispersion (alkali metal reduction), d) Subcritical water oxidation, e) Supercritical water oxidation, f) Mechanochemical method and g) GeoMelt. According to

technical proofs conducted by the Ministry of Agriculture, Forestry and Fisheries of Japan, all the methods have destruction efficiencies greater than 99.999% (Annex F information provided by Japan, 2007).

2.2 Efficacy and efficiency of possible control measures in meeting risk reduction goals

The efficacy and efficiency of implemented control measures is country dependent.

The Czech Republic considers clean-up of contaminated sites feasible by application of *Base-catalyzed decomposition* (*BCD)* technology. The estimated remediation cost of a former Lindane production site is 100 000 000 € (Annex F information provided by the Czech Republic, 2007).

In Mauritius, Lindane is already listed as a prohibited agricultural chemical in the Dangerous Chemicals Control Act 2006. All imports of chemicals are subject to control by the Dangerous Chemicals Control Board (DCCB) under the Dangerous Chemicals Control Act 2004. The law provides that no person shall import, manufacture, use or possess Lindane (Annex F information provided by Mauritius, 2007).

The United States cancelled registrations and eliminated all of the remaining agricultural uses of Lindane. In 2002 Lindane was registered as a seed treatment on wheat, barley, corn, sorghum, oats and rye crops. Until 2006, there were no alternatives for use on oats and rye. However, in 2006, *Imidacloprid* was registered for these two uses, and currently alternatives exist for all six seed treatment uses. The scenario for pharmaceutical uses is quite different in the United States, where at this time it is not technically feasible to withdraw Lindane as a treatment for scabies and lice (Annex F information provided by the United States of America, 2007).

Canada has established post-registration monitoring and compliance programs for the agricultural use of Lindane to ensure compliance with federal and provincial legislation. Federal, provincial and territorial hazardous waste programs address small quantities of retired material in the possession of consumers and have collected and safely disposed of pesticide products that are no longer registered (Annex F information provided by Canada, 2007).

In Japan, the distribution of Lindane was banned by the Minister of Agriculture, Forestry and Fisheries in 1971. Lindane is listed as a deleterious substance under Poisonous and Deleterious Substances Control Law. Manufacturers, importers and sellers are required to register themselves to handle Lindane. There are also regulations for labelling containers and packages, and for handling and disposal of Lindane (Annex F information provided by Japan, 2007).

In Thailand, banning of medical use of Lindane is still in question because the current substitutes for the treatment of head lice and scabies appeared not to be as effective as Lindane. For medical purpose, Lindane is in the National List of Essential Medicines (2004). It is the second-line drug of choice for head lice or scabies treatment (Annex F information provided by Thailand, 2007).

2.3 Information on alternatives (products and processes)

Description of alternatives

Chemical and non-chemical alternatives for the agricultural, veterinary and pharmaceutical uses of Lindane in the United States, Canada and Mexico have been reviewed in the North American Regional Action Plan on Lindane and Other HCH Isomers developed by the North American Commission for Environmental Cooperation (CEC, 2006).

In the United States, at least one of the following active ingredients is registered for seed treatment for corn, barley, wheat, oat, rye and sorghum: *Clothianidin, Thiamethoxam, Imidacloprid, Permethrin and Tefluthrin*. For uses on livestock, A*mitraz, Carbaryl, Coumaphos, Cyfluthrin, Cypermethrin, Diazinon, Dichlorvos, Fenvalerate, Lambda-cyhalothrin, Malathion, Methoxychlor, Permethrin, Phosmet, Pyrethrin, Tetrachlorvinfos,* and *Trichlorfon* are registered. Veterinary Drugs include: *Eprinomectin, Ivermectin, Doramectin, Moxidectin*, and *Methoprene*. For pharmaceutical uses, approved treatments for head lice include: *Pyrethrum/Piperonyl butoxide, Permethrin,* and *Malathion.* Lice nit combs are also recommended for use in conjunction with these treatments. For scabies, P*ermethrin* and C*rotamiton* (*Eurax*) are approved treatments (Annex F information provided by the United States of America, 2007).

Canadian alternatives for pharmaceutical uses of Lindane include: Permethrin (1% cream), *Bioallethrin* and *piperonyl butoxide*, *Pyrethrin* and *piperonyl butoxide*, *Permethrin* (5% cream), *Precipitatedisulphur 6% in petrolatum* and *Crotamiton* 10% (*Eurax*). Canadian registered alternatives for agricultural uses include: for canola: *Acetamiprid*, *Clothianidin*, *Thiamethoxam* and *Imidacloprid*; for corn: *Clothianidin*, *Imidacloprid* (only for field corn grown for seed) and *Tefluthrin*; and for sorghum: Thiamethoxam and *Imidacloprid.* Alternatives for livestock treatments include: Carbaryl, *Diazinon*, *Dichlorvos*, *Malathion*, *Phosmet*, *Tetrachlorvinphos*, *Trichlorfon*, *Cyfluthrin*, *Cypermethrin*, *Fenvalerate*, *Permethrin*, *Pyrethrin*, *Rotenone*, *Eprinomectin*, *Evermectin*, *Abamectin*, *Doramectin*, *Moxidectin* and *Phosmet* (CEC, 2006).

Alternatives for use on canola cultivation in the Republic of Zambia include: *Gaucho*, *Helix* and *Primer-Z*, and for head lice treatment: *Nix* (Annex F information provided by the Republic of Zambia, 2007).

In Germany, alternatives against *Atomaria linearis* include: *Thiamethoxam*, *Imidacloprid*, *Imidacloprid* / *Tefluthrin*, *Clothianidin*, *Clothianidin* / *Beta-Cyfluthrin*, *Alpha-Cypermethrin* and Deltamethrin; against *Elateridae*: *Clothianidin*, *Imidacloprid* and *Thiamethoxam;* against leaf-cutting insects: *Lambda-Cyhalothrin*, *Acadirachtin*, *Pyrethrin* / *Rapsöl*, *Beta-Cyfluthrin*, *Alpha-Cypermethrin*, *Lambda-Cyhalothrin*, *Acadirachtin*, *Pyrethrin* / *Rapsöl* and *Methamidophos.* Alternatives for use as a wood protection product include: 3-Iodo-2-propynyl butylcarbamate (IPBC), (E)-1-(2-Chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitro guanidine / *Clothianidin*, 1-(4-(2-Chloro-alpha,alpha,alpha-p-trifluorotolyloxy)-2-fluorophenyl)-3-(2,6-difluorobenzolyl)urea / *Flufenoxuron*, Cyclopropanecarboxylic acid, 3-[(1Z)-2-chloro-3,3,3-trifluoro-1-propenyl]-2,2-dimethyl-, (2-methyl[1,1'-biphenyl]-3-ylmethyl ester, (1R,3R)-rel- / *Bifenthrin*, 3-Phenoxybenzyl-2-(4-ethoxyphenyl)-2-methylpropylether / *Etofenprox*, m-Phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclo propanecarboxylate / *Permethrin*, alpha.-cyano-3-phenoxybenzyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclo propanecarboxylate / *Cypermethrin*, *Dazomet*, *Thiamethoxam* and 4-Bromo-2-(4-chlorophenyl)-1-(ethoxymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile / *Chlorfenapyr*. The alternative used for public health and veterinary topical insecticide is: Infectopedicul solution (*Permethrin*) (Annex F information provided by Germany, 2007).

In Thailand, alternatives for the treatment of head lice and scabies include: P*ermethrin*, C*abaryl*, S*temona* root extract and benzyl benzoate. The alternatives for use on pets are: P*ermethrin*, F*lumethrin* and C*ypermethrin*; and for termite control: *Alpha-cypermethrin*, B*ifenthrin*, C*ypermethrin* and D*elta-methrin* (Annex F information provided by Thailand, 2007).

In Sweden, *Malation*, *Permethrin* and *Disulfiram* with bezylbenzoate have been used as alternatives against scabies and lice in humans. In veterinary applications, *Flumethrin*, *Foxim*, *Fipronil*, *Ivermectin* and *Moxidectin* have been used (Annex F information provided by Sweden, 2007).

Alternatives used in Brazil include: *Cypermethrin* for termite control in compacted wood, *Cypermethrin* and 3-iodo-2-propynyl butylcarbamate (IPBC) for control of insects and fungi in dry wood, *Cyfluthrin* for wood used in construction or furniture fabrication, *Deltamethrin* for control of termite and drill, *Endosulfan* for termite control in wood, *Fipronil* for termite control in manufacture of compacted agglomerated wood, and TBP for fungal control in just-sawed wood (Annex F information provided by Brazil, 2007).

Alternatives used in Switzerland for seed treatment are *Fipronil* and *Thiamethoxam* (Additional information provided by Switzerland, 2007)

Besides the chemical alternatives, there are also non-chemical alternatives to agricultural seed treatment uses of Lindane. Among cultural methods currently known to effectively prevent harm to seeds and crops are: Crop rotation (alfalfa, soybeans and clover), where small grains need to be rotated with a non-host species every year to reduce the severity of infestation and maintain low levels of pests; Site selection and monitoring in order to determine if wireworms are present; Fallowing, starving wireworms by allowing the area to fallow for a few years before planting; Re-seeding with resistant crops such as buckwheat or flax; Timing of seeding and planting, trying to plant in warm, dry conditions, usually later in the season for small grains where larvae are deeper in the soil and giving seedlings a greater chance of survival; Shallow cultivation to starve hatchlings, expose eggs for predation and damage larvae; and Soil packing to impede wireworm travel (CEC, 2006).

Biological methods are also considered as non-chemical alternatives to Lindane. Current research at Pacific Agri-Food Research Centre, in Canada is examining the use of *Metarhizium anisopliae*, an insect fungal pathogen to control wireworm. Additional biological control methods employed in Costa Rica include *Trichodama* spp, *Piper aduncum*, *Trichogram* wasps, and *Bacillus thuringiensis* (Annex F information provided by IPEN, 2007).

There are also non-chemical methods for the treatment of head lice and scabies. Some authors argue that the use of these methods exceed the efficacy of pediculicidal treatments. For the treatment of head lice they suggest application of hot air or mechanical removal using a wet combing method. For scabies treatment some authors suggest that essential oils have shown positive effects against mites in vitro and in field studies. Tea tree oil (*Melaleuca alternifolia*) and a paste made from extracts of neem (*Azadirachta indica*) and tumeric (*Curcuma longa*) are considered highly effective. In a clinical trial in Nigeria, bush tea (*Lippia multiflora*) essential oil showed similarly high cure rates. A randomized control study in Brazil showed a commercially available repellent containing coconut oil and jojoba was highly effective (IPEN, 2007).

Technical feasibility

Chemical alternatives for seed and livestock treatments and approved alternatives for pharmaceutical uses in the United States are technically feasible and are currently in use. However there have been reported treatment failures for all the approved pharmaceutical alternatives for treatment of scabies and lice. Some physicians prescribe off-label oral *Ivermectin* for scabies even when it is not approved by USFDA for treatment for scabies. The manufacturer of oral *Ivermectin* does not have an approved application for its use in scabies and does not advocate its use in scabies. USFDA is currently reviewing potential new treatments for lice from a number of companies and is exploring mechanisms to encourage pharmaceutical companies to submit candidate treatments for scabies (Annex F information provided by the United States of America, 2007).

In Canada, alternative pesticide products are also currently being used. Technical feasibility is a requirement of registration by Canada's Pest Management Regulatory Agency (PMRA) (Annex F information provided by Canada, 2007).

In Sweden, alternatives are all technically feasible, available, freely accessible and effective if used as prescribed. There are no reports of major resistance problems (Annex F information provided by Sweden, 2007).

Costs, including environmental and health costs

Only the United States has information available regarding costs associated with alternatives. The information provided includes data from 2002 to 2006.

In 2006, the usage of Lindane in the United States was less than 150,000 lbs of active ingredient applied annually to about 9.7 million acres. In 2002, Lindane was used in the United States as a seed treatment on wheat, barley, oats, rye, corn, and sorghum. Imidacloprid and Thiamethoxam were the primary seed treatment alternatives to Lindane for barely, corn, sorghum and wheat. Moreover, since 2002, additional alternatives have been registered on corn and sorghum. The alternatives are as effective as Lindane but costlier to use. For wheat and barley, the estimated increase in treatment cost would be $0.36 to $1.71 per acre ($5 million for all US acreage). For corn, the estimated increase in treatment cost would be $1.82 per acre ($8.7 million dollars for all US acreage). For sorghum, the estimated increase in treatment cost would be $3.70 to $4.69 per acre (about $386,000 for all US acreage) (USEPA, 2006).

In 2002, there were no registered alternatives for oats and rye. If these two uses had been cancelled at that time, there would have been a major impact on growers of those crops, estimated at a 9% yield loss. The total aggregate increase in treatment costs is $14 million. Total aggregate value of yield loss on oats and rye is $354,000. By 2006, *Imidacloprid* was registered for use on oats and rye (Annex F information provided by the United States of America, 2007).

Regarding health costs associated with pharmaceutical alternatives, scabies can be a serious problem in long-term care facilities, crowded living environments and economically poor conditions in general. Scabies may be complicated by secondary bacterial infections of the lesions, and scabies has been identified as a risk factor for development of post-streptococcal glomerulonephritis. In the United States, children cannot return to school with untreated lice or scabies (Annex F information provided by the United States of America, 2007).

Efficacy, including benefits and limitations of alternatives versus nominated substance and identification of any critical uses for which there is at present no alternative

In the United States, resistance has been reported for all of the approved treatments for head lice. For scabies, treatment failures have been reported with all of the approved treatments, and resistance has been reported for P*ermethrin* and oral

Ivermectin although the latter is not approved for this indication (Annex F information provided by the United States of America, 2007).

In Thailand, current substitutes for the treatment of head lice and scabies appeared not to be as effective as Lindane (Annex F information provided by Thailand, 2007).

Risk, including information on whether the proposed alternative has been tested/evaluated and any information on potential risks associated with untested alternatives over the life-cycle of the alternative

USEPA conducts risk assessments for pesticide products as a routine part of the registration process; therefore, the USEPA has conducted risk assessments for the alternative products and uses of those products (Annex F information provided by the United States of America, 2007).

Alternatives have been reviewed in Canada by the PMRA and their efficacy and the environmental and health risks associated with their uses have been considered acceptable (Annex F information provided by Canada, 2007).

Availability

Alternatives for the agricultural, livestock and pharmaceutical uses of Lindane in the United States are available and currently in use.

The feasibility of using alternatives in the Republic of Zambia remains undetermined. *Imidacloprid* (Gaucho) is readily available and easily accessible on the local market (Annex F information provided by the Republic of Zambia, 2007).

Accessibility

The availability and accessibility of alternatives in Canada is market dependant (Annex F information provided by Canada, 2007).

Alternative products in Thailand are on the market. Particularly the alternatives for use on pets or for termite control are widely used (Annex F information provided by Thailand, 2007).

2.4 Summary of information on impacts on society of implementing possible control measures

Health, including public, environmental and occupational health

Considering that Lindane meets several internationally accepted criteria for persistence, bioaccumulation and toxicity, the implementation of control measures is expected to reduce the risks from exposure of humans and the environment to Lindane.

Lindane can be found in all environmental compartments and levels in air, water, soil sediment, aquatic and terrestrial organisms and food have been measured worldwide (WHO/ Europe 2003). Lindane can bio-accumulate easily in the food chain due to its high lipid solubility and can bio-concentrate rapidly in microorganisms, invertebrates, fish, birds and mammals. HCH isomers, including Lindane, accumulate in colder climates of the world (CEC, 2006). General population exposure to gamma-HCH can result from food intake particularly from animal origin products like milk and meat, as well as water containing the pesticide (ASTDR, 2005). There is potential dietary exposure particularly to people in Alaska and the circumpolar Arctic who depend on traditional subsistence foods such as fish and marine mammals (USEPA, 2006).

At high doses Lindane has been shown to be neurotoxic, hepatotoxic, immunotoxic and to have reproductive effects in laboratory animals. Human acute intoxication data show that Lindane can cause severe neurological effects and chronic data suggest possible haematological effects. Adverse health effects associated with pharmaceutical use of Lindane include seizures, dizziness, headaches, and paresthesia. Seizures and deaths have been reported following Lindane shampoo use with repeat or prolonged application, but also in rare cases following a single application according to directions. (Additional information provided by IPEN, 2007).

Although there is some evidence for toxicity of Lindane when used topically as a pharmaceutical, this has been generally associated with inappropriate use. Most of the side effects of Lindane have been associated with chronic inhalation by seed treatment workers (Annex F information provided by Canada, 2007). The carcinogenicity of Lindane is less clear. The International Agency for Research on Cancer (IARC) has classified Lindane as possibly carcinogenic to humans (ATSDR, 2005). USEPA reclassified Lindane in the category "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential." The US Center for Disease Control's Agency for Toxic Substances and Registry concurs with USEPA's classification. However, the Joint Meeting on Pesticide Residues (JMPR) of the World Health Organization concluded that "…Lindane is not likely to pose a carcinogenic risk to humans" (CEC, 2006).

The implementation of control measures applied to Lindane pharmaceutical uses has a positive impact to the environment since Lindane application as a lice treatment shampoo or topical lotion that must be washed off, end up in waste water (Annex F information provided by the United States of America, 2007). In 2002, the state of California banned the sale of Lindane for lice and scabies treatments in order to reduce the levels in drinking water supplies. In May 2000, the California Toxics Rule (CTR) established a new water quality criterion of 19 parts per trillion (ppt) for Lindane in existing or potential drinking water supplies for protection of public health based on potential cancer risk to humans. As available treatment technologies were unable to remove Lindane to meet the new California state water quality criterion, a preventive strategy to allow compliance was required. A bill was then sponsored in the California assembly, which passed without opposition, to ban the sale of all pharmaceutical Lindane in the state of California beginning in January 2002. Since the ban, Lindane concentrations in waste water have declined to almost non-detectable levels (CEC, 2006).

Since the California Lindane ban, four scabies outbreaks were reported by four counties to the California Department of Health Services (CDHS) Surveillance and Statistics Section. Prior to the ban, CDHS issued guidelines to all physicians to use *Malathion* instead of Lindane to control head lice. For scabies outbreaks CDHS developed and distributed to healthcare facilities a guideline where CDHS recommends the use of *Ivermectin* to treat patients with severe scabies. Although *Ivermectin* has not been approved by the FDA for use for scabies and it is not recommended by CDHS for typical scabies or prophylaxis, *Ivermectin* has been used in outbreaks in California for treatment of symptomatic cases and for mass prophylaxis because of its ease of use and probable greater compliance and efficacy compared to *Permethrin* (CEC, 2006).

On the topic of pharmaceutical uses restriction there is a general concern. In the United States, if Lindane products were not available, approved treatment options for lice and scabies would be very limited. Cases of lice and scabies could remain untreated or harmful home remedies might be used (Annex F information provided by the United States of America, 2007). A similar concern exists in Canada where it is felt that Lindane should be available for use in cases where an alternative therapy is inappropriate (Annex F information provided by Canada, 2007). In the European Union, Lindane can be used as public health and veterinary topical insecticide until end of 2007, and only a limited number of alternative products (based on *Permethrin*) are currently on the market (Annex F information provided by Germany, 2007). In Thailand, current substitutes for the treatment of head lice and scabies appeared not to be as effective as Lindane (Annex F information provided by Thailand, 2007).

Agriculture, including aquaculture and forestry

There are no impacts of implementing possible control measures reported for this sector.

Biota (biodiversity)

Due to the ease of Lindane to accumulate in wildlife, implementation of control measures is expected to have only positive impacts on biota, especially in Arctic wildlife. Several studies in the Arctic have monitored HCH levels in Steller sea lion, beluga whales, bowhead whales, and polar bears (Annex F information provided by IPEN, 2007).

Economic aspects, including costs and benefits for producers and consumers and the distribution of costs and benefits

Information regarding costs of implementing possible control measures and alternatives is provided in this document in sections 2.2 and 2.3.

Social costs (employment, etc.)

Not evaluated

Other impacts

None identified

2.5 Other considerations

Access to information and public education

In Sweden, extensive information on treatment regimes for all available drugs against scabies and lice may be found on the Swedish Medical Products Agency website http://www.lakemedelsverket.se or in the list of pharmaceutical products in Sweden http://www.fass.se (Annex F information provided by Sweden, 2007).

The USEPA Office of Pesticide Program maintains a website with recent regulatory decisions on Lindane. http://www.epa.gov/oppsrrd1/reregistration/Lindane/. The United States government also maintains an electronic docket (www.regulations.gov). The complete docket is accessible by typing in the docket ID box: EPA-HQ-OPP-2002-0202. USFDA has a website for safety alerts for primary care providers, pharmacists and consumers http://www.fda.gov/medwatch/SAFETY/2003/safety03.htm#lindan (Annex F information provided by the United States of America, 2007).

Mexico developed and published in 2004 a National Diagnostic Report on Lindane. The report includes information on production, imports, exports, commercial names, prices, selling patterns, quantities used and possible alternatives. http://www.ine.gob.mx/dgicurg/download/Proyectos-2003/EL_LINDANO_EN_MEXICO.pdf (Annex F information provided by Mexico, 2007).

The Czech Republic has an education and awareness POPs campaign (SC/UN ECE CRLTAP) based on the Czech National Implementation Plan (Annex F information provided by the Czech Republic, 2007).

Status of control and monitoring capacity

In Canada, control and monitoring capacity of pesticide uses is managed by the Pest Management Regulatory Agency (PMRA) through compliance mechanisms in place at border crossings and entry points to prohibit the import of Lindane to Canada. Compliance issues within Canada may be reported by PMRA through PMRA compliance activities, reporting of suspected infractions and/or results reported from other government agencies (Annex F information provided by Canada, 2007).

In the United States, in December 2006 USEPA announced the cancellation of all agricultural pesticide products containing Lindane under the authority of the Federal Insecticide, Fungicide and Rodenticide Act, effective July 1, 2007. USEPA works with its federal, state and tribal regulatory partners to assure compliance with pesticide laws and regulations in order to protect human health and the environment (Annex F information provided by the United States of America, 2007).

Control and monitoring institutions in the Czech Republic include: RECETOX MU for monitoring in ambient air, surface waters, sediments, soils, mosses and needles, Water Research Institute for monitoring of surface and ground waters and sediments, Central Institute for Supervising and Testing in Agriculture (CISTA), Research Institute of Amelioration and Soil Conservation (RIASC), State Veterinary Inspection and Czech Food Inspection for food control, and National Institutes of Public Health for human exposure and dietary studies (Annex F information provided by the Czech Republic, 2007).

The control and monitoring capacity of the Republic of Zambia is addressed through the Environmental Protection and Pollution Control Act which is enforced by the Environmental Council of Zambia (Annex F information provided by the Republic of Zambia, 2007).

The Brazilian Institute for the Environment and Renewable Natural Resources (IBAMA) controls the stockpiles, the adequate destination of obsolete products and the illegal entrance of products (Annex F information provided by Brazil, 2007).

• Waste and disposal implications

Current production of Lindane seems to be declining with only a few producing countries remaining, but former production and the inefficient production process over the years, have left an enormous amount of waste products.

For the United States it would be technically feasible to use agricultural and pharmaceutical existing stocks for a set time period. USEPA will allow the use of Lindane products in agriculture until October 1, 2009. Therefore it is expected that there will be minimal costs associated with disposal of unusable stocks (Annex F information provided by the United States of America, 2007).

In Switzerland, about 3000 contaminated sites would require remediation. Specially two sites, Bonfol (Canton Jura) and Kölliken (Canton Aargau) which served as chemical waste disposal sites contain around 114 000 and 350 000 tons respectively of special waste, probably containing POPs chemicals. The exact amount of POPs chemicals in these disposal sites is still unknown. The current estimate is that the now initiated full remediation (including on-site incineration in a high tech oven) will require about CHF 200 and 500 million for Bonfol and Kölliken, respectively (Annex F information provided by Switzerland, 2007).

In the Czech Republic, waste problems represent old contaminated sites of former producer Spolana Neratovice, old storages, unknown illegal stores and dumps. Spolana Neratovice is now successfully cleaned-up using the BCD technology. Plans for future remediation of other contaminated sites are under development (Annex F information provided by Czech Republic, 2007).

In Canada there is no commercial reason to maintain stockpiles given that any stocks that existed at the time that pesticide registration was discontinued or suspended were to be sold, used or disposed of in accordance with an established timetable. Federal, provincial and territorial hazardous waste programs address small quantities of retired material in the possession of consumers and have collected and safely disposed of pesticide products that are no longer registered (Annex F information provided by Canada, 2007).

Disposal methods for Lindane as well as costs of disposal and management of HCH isomer wastes in different countries have been reviewed in the report: T*he legacy of Lindane HCH Isomer Production* (Vijgen, 2006). The document describes chemical methods for the conversion of HCH isomers to trichlorobenzene, trichlorophenoxyacetic acid, HCl, hexachlorobenzene, sodium pentachlorophenolate and trichlorophenol. The report also includes the description of studies that have monitored biodegradation of HCH isomers and situations where landfills have been used for disposal of soil contaminated with HCH isomers (IPEN, 2007).

3. Synthesis of information

Published risk assessment reports on Lindane indicate that Lindane is persistent, bioaccumulative and toxic. Lindane has been found in environmental samples all over the world as well as in human blood, human breast milk and human adipose tissue in different studied populations, especially in Arctic communities that depend on subsistence foods[2].

At high doses Lindane has been shown to be neurotoxic, hepatotoxic, immunotoxic and to have reproductive effects in laboratory animals. Human acute intoxication data show that Lindane can cause severe neurological effects, and chronic data suggest possible haematological effects. The International Agency for Research on Cancer (IARC) has classified Lindane as possibly carcinogenic to humans (ATSDR, 2005).

Implementation of control measures is expected to reduce the risks from exposure of humans and the environment to Lindane, especially in the Arctic where Lindane accumulates easily in the wildlife, and where communities depend on subsistence foods.

Lindane control measures that have shown to be technically feasible, efficient and accessible include: Production, use, sale and imports prohibition, use restrictions, registrations and use cancellations and clean-up of contaminated sites. Therefore, they may be appropriate for consideration as potential control measures to be implemented by countries. When Lindane registrations are cancelled, allowing the use of stocks for a reasonable time period is a recommended strategy in order to reduce the amount of waste generated and the costs associated with disposal.

Lindane chemical alternatives that have been reviewed in the present document for agricultural, livestock and veterinary uses are considered efficient, technically feasible and accessible. However, some countries have expressed their worries about the availability and efficacy of alternatives for pharmaceutical uses. For this particular case, it has been proposed to give incentives to find more environmental and health friendly alternatives and to consider a date for phase out of this use when listing the chemical. Issuing public health advisories would also be recommended to control Lindane use patterns and reduce risks associated.

4. Concluding statement

Having evaluated the risk profile corresponding to Lindane, and having prepared its risk management evaluation, the POPs Review Committee of the Stockholm Convention concludes that this chemical is likely, as a result of long-range environmental transport, to lead to significant adverse effects on human health and/or the environment, such that global action is warranted.

A thorough review of existing control measures that have already been implemented in several countries, shows that risks from exposure of humans and the environment to Lindane can be reduced significantly. Control measures are also expected to support the goal agreed at the 2002 Johannesburg World Summit on Sustainable Development of ensuring that by the year 2020, chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.

In accordance with paragraph 9 of Article 8 of the Convention, the Committee recommends the Conference of the Parties to the Stockholm Convention to consider listing and specifying the related control measures of Lindane in Annex A. However, it should be considered there is some information provided by parties and observers pointing to an option for pharmaceutical use exemption.

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