Submission of Information on Lindane

Pursuant to Article 8 of the Stockholm Convention as specified in Annex E of the Convention

Introductory information

Name of the submitting Party/Observer

NGO Observers: Alaska Community Action on Toxics (ACAT) and Pesticide Action Network North America (PANNA) on behalf of the International POPs Elimination Network (IPEN)

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Chemical name: Lindane; gamma-hexachlorocyclohexane (HCH); γ-HCH; formerly known as benzene hexachloride (BHC)

CAS registry number: 58-89-9

γ- hexachlorocyclohexane (HCH) is one of eight isomers of HCH. Of the eight isomers, γ-HCH has the most effective insecticidal properties. Technical-grade HCH is a mixture of the HCH isomers and has also been used as an insecticide. Technical-grade HCH typically contains 10-15% γ-HCH, 60-70% alpha-HCH, 5-12% beta-HCH, as well as delta and epsilon forms of HCH.

Trade names and synonyms:
Aalindan; Aficide; Agrocide; Agrocide 2; Agrocide 7; Agrocide 6G; Agrocide III; Agrocide WP; Agronexit; Ameisenmittel merck; Ameisentod; Aparasin; Aphtiria; Aplidal; Arbitex; BBH; Benhexol; Ben-Hex; Bentox 10; Benzene hexachloride; gamma Benzene hexachloride; gamma-Benzohexachloride; Bexol; BHC; gamma-BHC; Celanex; Chloresene; Codechine; Detmol-extrakt; Detox 25; Devoran; Dol Granule; Drilltox-Spezial Aglukon; ENT 7,796; Entomoxan; Fenoform forte; Forst-Nexen; Gallogama; Gamacarbatox; Gamacid; Gamaphex; Gamene; Gamiso; Gammalin; Gammalin 20; Gamma-mean 400; Gammaterr; Geobilan; Geolin G 3; Gexane; HCC; HCCH; HCH; gamma-HCH; Heclotox; HEXA; Hexachloran; gamma-Hexachloran; Hexachlorane; gamma-Hexachlorane; gamma-Hexachlorobenzene; Hexachlorocyclohexane; 1-alpha,2-alpha,3-beta,4-alpha,5-alpha,6-beta-Hexachlorocyclohexane; gamma-Hexachlorocyclohexane; 1,2,3,4,5,6-Hexachlorocyclohexane; gamma-1,2,3,4,5,6-Hexachlorocyclohexane; 1,2,3,4,5,6-Hexachlorocyclohexane, alpha isomer; Hexachlorocyclohexane, gamma-isomer; 1,2,3,4,5,6-Hexachlorocyclohexane, gamma-isomer; Hexaverm; Hexicide; Hexyclan; HGI; Hilbeech; Hortex; Hungaria L7; Inexit; Isotox; Jacutin; Kokotine; Kwell; Lacco HI lin; Lasochron; Lendine; Lentox; Lidenal; Lindafor; Lindagam; Lindagrain; Lindagranox; Lindane; gamma-Lindane; Lindane; Lindapoudre; Lindatox; Lindex; Lindosep; Lintox; Linvur; Lorexane; Mglawik L; Milbol 49; Mszycol; NCI-C00204; Neo-Scabicidol; Nexen FB; Nexit; Nexit-stark; Nexol-E; Nicochloran; Novigam; Omnitox; Ovadziak; Owadziak; Pedraczak; Pflanzol; PLK; Quellada; RCRA waste number U129 (USA Environmental Protection Agency); Sang gamma; Silvanol; Spritzlindane; Spritz-Rapidin; Spruehpflanzol; Streunex; TAP 85; Tri-6; Verindal Ultra; Viton

Date of submission: 27 January 2006

(a) Sources, including as appropriate production data, uses and releases (summary information and relevant references)

(i) Production Data: Quantity and Location

[1] "None of the isomers or technical-grade HCH are currently produced in the United States. The production of γ-HCH exceeded 2.27×10^6 g in 1976; commercial γ-HCH production in the U.S. reportedly ended in that year. However, the Directory of Chemical Producers for 1987 and 1988 lists one producer of γ-HCH, Drexel Chemical Company; subsequent volumes (1989-1991) give no listings of γ-HCH producers…γ-HCH is not produced in the United States. It is imported from France, Germany, Spain, Japan, and

[1] Agency for Toxic Substances and Disease Registry. USA Department of Health and Human Services. Toxicological Profile for Alpha-, Beta-, Gamma-, and Delta-Hexachlorocyclohexane. August 2005.

China. Once in the United States, it can be formulated in various pesticide products and exported."

[2] "Lindane is no longer produced in North America. Lindane was never produced in Canada or Mexico. Lindane was produced in the United States, however, official records are sparse to non-existent, as production occurred 40-50 years ago…China, India, Romania and possibly Russia currently produce lindane for the world market…China is reported to have been the major world producer of technical HCH, accounting for more than 4.5 million tones between 1945 and 1983. In 1983, China banned both the production and usage of technical HCH. Recent information indicates that China has one company that currently produces lindane. There is no historical information on the amounts of HCH and/or lindane produced in India and usage information is limited. India used approximately 519,000 tonnes of HCH between 1979 and 1991. HCH use was banned in India in 1996, but lindane is still permitted for public health and on certain crops such as paddy rice. There is at least one company that currently produces lindane. Because of the drop in demand, this company is only producing 300 kg of lindane per day, six months per year. The company reported no production in 2004. In 2003, the plant built a landfill to cap the estimated 3,000 tonnes of waste isomers that plant managers refer to as "scum." Romania produces the lindane for the agricultural products used in the USA. No information is available on the amounts of lindane produced or used in Romania. Historical technical-HCH production and usage information in the former Soviet Union is also limited. Li et.al. report usage in 1980 and 1985 to be 11,160 tonnes and 16,693 tonnes respectively. The use of technical-HCH was banned in the late 1980s for use on agriculture crops. However, use of existing stockpiles was allowed even after 1991."

[3] "Historical production sites of technical HCH and/or lindane can be found in many European countries including the Czech Republic, Spain, France, Germany, UK, Italy, Romania, Bulgaria, Poland, and Turkey. Production in the UNECE member countries took place mainly from 1950 or earlier and stopped in 1970 to the 1990s. Only rough estimates on years of production and on produced volumes could be made available. If at all, Rhone Poulenc in France and Inquinosa in Spain run the last sites in West Europe to close down production. Outside Europe manufacturers and suppliers of lindane were also located in the U.S. In 1978 the US EPA set an end to the production of technical-HCH, [in 1998] Canada's manufacturer voluntarily discontinued the production of this compound. Worldwide production volumes decreased steadily:

Production worldwide 1986	approximately 38,000 tonnes per year
World production 1988-1993	4,400 tonnes per year
World production 1990-1995	3,222 tonnes per year

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[2] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[3] Hauzenberger, I. 2004. Reports on Substances Scheduled for Re-Assessments under the UNECE POPs Protocol, Technical Review Report on Lindane. Federal Environment Agency, Austria. http://www.unece.org/env/popsxg/docs/2004/Dossier_Lindane.pdf.

Production in Western Europe in the 1990s	approximately 2,055
Production in the EEC (1991)	1,000-5,000

The trend of the historical production of lindane can also be linked with decreasing usage volumes and pattern. The use of technical HCH was the major source of γ-HCH until the late 1970s. Thereafter lindane became the major source of the isomer, though during the production process alpha-HCH is a major by-product. EU-Directive 79/117/EEC caused a ban of technical HCH (<99% of γ-isomer) in 1979 within EU Member States. From data gathered within the "Popcycling-Baltic" project it was suggested that a total of 382,000 tonnes of technical HCH and 81,000 tonnes of lindane were used in Europe from 1970 to 1996. Assuming a technical HCH pattern of 65-70% alpha-HCH, 10% beta-HCH, and 15% γ-HCH a cumulative use of 259,000 tonnes of alpha-HCH, 20,000 tonnes of beta-HCH, and 135,000 tonnes of γ-HCH were estimated for this time period. Other estimates for global usage of lindane report a drop from 11,900 tonnes in 1980 to 8,400 tonnes in 1990. According to the Centre International D Etudes Du Lindane, an association of lindane manufacturers from France, China, India, and Spain which supported the review of lindane under the EU Plant Protection-Product-Directive (91/414/EEC), the average annual lindane consumption in Europe was 2,130 tonnes from 1992 to 1997. France was a major user of lindane in Europe at that time with an annual average consumption rate of 1,600 tonnes/year…Romania still produces lindane. With the scheduled accession of Romania to the EU in 2007 and subjection to the recently adopted EC Regulation on POPs this production site will have to be closed down in the near future."

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[4] Estimates of current production identify Romania, India, and China as the only known lindane-producing countries in the world. Production between 1990 and 1995 was approximately 3,222 tonnes per year. China has a continuous production of approximately 1,000 tonnes per year. In India, one production facility produces 300 kg/day, but has a capacity to produce 3 tonnes/day. Production estimates for Romania are uncertain.

[5] According to a 2004 UNECE reassessment of lindane production and use, "With the scheduled accession of Romania to the EU in 2007 and subjection to the recently adopted EC Regulation on POPs, this [lindane] production site will have to be closed down in the near future. "

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[4] Vijgen, J. 2006. The Legacy of Lindane HCH Isomer Production. Main Report. A Global Overview of Residue Management, Formulation and Disposal. International HCH and Pesticides Association (ISBN 87-991210-1-8) www.ihpa.info/library_access.php

[5] Hauzenberger, I. 2004. Reports on Substances Scheduled for Re-Assessments under the UNECE POPs Protocol, Technical Review Report on Lindane. Federal Environment Agency, Austria. http://www.unece.org/env/popsxg/docs/2004/Dossier_Lindane.pdf

[6] "India has a total installed capacity of lindane (technical) production of 1,300 tonnes per annum, with two companies producing: Kanoria Chemicals and Industries Ltd. with a capacity of 300 tonnes per annum, and India Pesticides Limited with a 300 tonnes per annum capacity. According to data available from Department of Chemicals and Petrochemicals, Ministry of Chemicals and Fertilizers, between 1995 and 2005, India has produced 5,387 tonnes of technical grade lindane."

(ii) Uses

United States: History and Current Status of Lindane Use

[7] "γ-HCH was initially registered by the U.S. Department of Agriculture (USDA) in the 1940s and over the years, was approved for use on a wide variety of fruit and vegetable crops (including seed treatment), tobacco, greenhouse vegetables and ornamentals, forestry (including Christmas tree plantations), farm animal premises, and other uses. In February 1977, the Environmental Protection Agency (EPA) issued a notice of Rebuttal Presumption Against Registration, now called a Special Review, and continued registration of pesticide products containing γ-HCH. EPA took this action in response to indications of γ-HCH's potential carcinogenic effect, possible developmental and reproductive effects, possible blood dyscrasias, and delayed toxic effects, as well as its acute toxic effects seen in aquatic wildlife (IARC 1979). In October of 1983, EPA issued a 'Notice of Intent to Cancel Pesticide Products Containing γ-HCH.' The contentions concerning developmental and reproductive effects were successfully challenged by industry. EPA no longer permits the use of γ-HCH for purposes involving direct aerial application (EPA 1985b). The notice restricted certain applications of γ-HCH on livestock, structures, and domestic pets to certified applicators or persons under their direct supervision (EPA 1985b). In November 1993, EPA issued a 'Notice of Receipt of a Request for Amendments to Delete Uses' for several formulations of γ-HCH powder, 99.5% technical grade HCH, and dust concentrate, which would delete from the pesticide label most uses of γ-HCH for agricultural crops and use on animals and humans (EPA 1993). According to the EPA's most recent Registration Eligibility Decision (RED), the only current food/feed use of γ-HCH that is being supported for re-registration is seed treatment for barley, corn, oats, rye, sorghum, and wheat (EPA 2002b). Since the 1998 and 1999 use deletions, the registrants are no longer interested in supporting the seed treatment use on broccoli, Brussel sprouts, celery, cabbage, cauliflower, collards, kale, kohlrabi, mustard greens, lettuce, radishes, spinach, and Swiss chard (EPA 2002b).

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[6] Fact Sheet. *Lindane's Dirty Secret: Indian Facilities Dump Toxic Waste*. Compiled by Community Action for Pesticide Elimination as a project of the International POPs Elimination Network (IPEN) Pesticide Working Group. May 2005. http://www.panna.org/campaigns/docsLindane/lindaneDirtySecret.pdf

[7] Agency for Toxic Substances and Disease Registry. USA Department of Health and Human Services. Toxicological Profile for Alpha-, Beta-, Gamma-, and Delta-Hexachlorocyclohexane. August 2005.

"γ-HCH is also available, and regulated by the U.S. Food and Drug Administration (FDA), for the pharmaceutical treatment of scabies and head lice (EPA 2002 b). A 1% γ-HCH lotion is available for the treatment of scabies, and a 1% shampoo is available for the treatment of head lice. Both uses have been on the market since 1947, but were labeled as a second line therapy in 1995 after a review by FDA. The FDA is revising the label for the treatment of scabies, which would effectively prohibit its use son infants and children weighing less than 60 kg (EPA 2002b). In the past, γ-HCH was used in veterinary products to control mites and other pests, but recent data suggest that no products are currently registered in the U.S. for this use (Hauzenberger et.al. 2002). Based on EPA estimates from 1996-2001, about 233,000 pounds of γ-HCH are used annually as a seed treatment."

[8] "Based on US EPA and FDA laws and regulations, the United States has assessed the risk of both the pesticidal and pharmaceutical uses of lindane. These scientific reviews are consistent with the Agencies' regulatory processes for pesticides and drugs. Following these reviews, the United States took specific actions to reduce exposure to lindane.

"Agricultural and Veterinary Uses--Lindane was first registered as a pesticide in the United States in the 1940s for use on a wide variety of food crops, ornamentals, livestock and homeowner and other sites. In 1977, EPA initiated a Rebuttable Presumption Against Registration (RPAR) review of lindane, now called a Special Review. As a part of the Special Review, EPA published Position Documents from 1977 through 1983, resulting in the cancellation of certain uses of lindane.

"EPA issued a Registration Standard for Lindane in September 1985 that included a requirement for the submission of additional data to support lindane registration and to address exposure concerns. In 1998 and 1999, lindane registrants voluntarily cancelled all registered uses of lindane except for seed treatment use on 19 agricultural crops and a dog mange treatment. Lindane dog mange use was voluntarily cancelled in December 2001. In 2001 and 2002, the registrants voluntarily cancelled all but the following six lindane seed treatment uses; barley, corn, oats, rye, sorghum, and wheat.

"As of 2002, the only remaining agricultural uses for lindane are the six seed treatment uses listed above. On July 31, 2002, EPA issued its Reregistration Eligibility Decision (RED) document for lindane. The RED states that the six remaining lindane seed treatment uses are eligible for reregistration provided that: registrants make required label changes; registrants provide required data; and the Agency is able to establish all required tolerances for lindane residues on food. The Agency has expedited the receipt and review of revised lindane end-use product labels to make sure that product labeling reflects the risk mitigation measures stipulated in the RED, and the Agency is currently looking into whether it can establish all required tolerances for lindane residues on food.

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[8] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

"Currently, greater than 99% of lindane used in the United States is for agriculture. Of that, the pre-plant seed treatment of corn and wheat comprises 99% of the agricultural use. Four other grain crops (barley, oats, rye, and sorghum) represent the remainder of the agricultural seed treatment uses. Between 65 and 106 tonnes (approx 233,000 pounds) of lindane are used in agriculture each year. All lindane used in the United States is imported; lindane is no longer manufactured in the United States. Canola is currently being petitioned for use by the United States.

[9] According to a 2004 review of lindane use in UNECE countries conducted under the POPs Protocol of the Convention on Long Range Air Pollutants, the U.S. was the only UNECE country that in 2004 "claimed the use for seed treatment as relevant. All other countries are in the stage of prohibition or had already interdicted all authorization and use of lindane containing plant protection products."

[10] "Pharmaceutical Uses--Lindane use is approved by the US FDA for pediculosis, lice and scabies treatment and has been marketed as a pharmaceutical product since 1951. In 2003, as a result of the reassessment of lindane risk factors, FDA took action to increase hazard warnings and to reduce the maximum package size to minimize the possibility of overuse.

"Annual use of lindane as a pharmaceutical to treat lice and scabies in the United States is less than one metric ton (or 1,000 kg). Lindane accounts for fewer than 1 million treatments out of 10 to 20 million annual cases of lice. In addition, FDA has established processes for facilitating development and approving the use of botanicals and other proposed lice and scabies treatments for pharmaceutical purposes, thereby encouraging the use of lindane alternatives."

Canada: History and Current Status of Lindane Use

[11] Pharmaceutical Uses--"Lindane has never been produced in Canada and the only current allowable use of Lindane is for public health purposes, as a lice and scabies treatment. In the Year 2003, this use amounted to approximately 6 kg of lindane per year, and quantities used continue to decline. Lindane has been registered in Canada as a pharmaceutical since the early 1960s. With the introduction of safer agents like permethrin, the use of lindane has declined over the years. It is now mostly used as a possible second line agent for scabies, and in Quebec (a Canadian province), public health authorities recommendations do not mention lindane in their first three

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[9] Hauzenberger, I. 2004. Reports on Substances Scheduled for Re-Assessments under the UNECE POPs Protocol, Technical Review Report on Lindane. Federal Environment Agency, Austria. http://www.unece.org/env/popsxg/docs/2004/Dossier_Lindane.pdf

[10] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[11] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

recommended treatment options for lice. Because of the *Canadian Food and Drug Act* reassessment of lindane safety, and communications with the public in March 2003, Health Canada decided to re-evaluate the safety profile of lindane in Canada. The product has always been available without prescription.

"Nationally, the total amount of lindane in lotions and shampoos containing 1% active lindane ingredient for the year ending March 2003 is approximately 6 kg. This calculation is premised upon information received from the IMS Health Inc. database. Lindane products have been classified as Schedule 2 products by the National Association of Pharmacy Regulatory Authorities (NAPRA), which means that 'professional intervention from the pharmacist at the point of sale and possibly referral to a practitioner' is required. The product is available only from a pharmacist, over-the-counter, and must be retained within an area of the pharmacy where there is no public access and no opportunity for patient self-selection. Provincial pharmacist associations that are not currently members of NAPRA (Quebec and Ontario) follow similar practices and guidelines. "

Agricultural Uses--As of January 1, 2005, lindane is no longer registered for agricultural pest control uses, including veterinary uses, in Canada. Historically, lindane has been registered in Canada for a wide variety of applications. Canada has imported all technical-grade lindane from foreign companies. Publication of Trade Memorandum T-68 on November 5, 1970, signaled an end to the use of lindane on a range of fruit and vegetable crops, in outdoor foggers, and for the treatment of water for control of mosquitoes. By the mid 1990's, most of the above-ground uses of lindane in Canada were discontinued.

In 1999, pest control products containing lindane were subject to a special review under Section 19 of the Pest Control Products Regulations. Canada had negotiated and ratified the UNECE POPs Protocol of the Convention on Long Range Transboundary Air Pollution. The POPs Protocol established obligations including a commitment to restrict expansion of the uses of lindane and conduct a reassessment of all remaining uses. Sales of all products registered for use on livestock (cattle, horse, sheep, goats, swine) and tobacco were discontinued by registrants effective December 2001 and the remaining products were not allowed to be used after December 2004. Sale of lindane products for use on canola voluntarily ceased in 2001, and the use of lindane-treated canola seed ended following the 2002 planting season. The special review update, published in 2002, included the phase out schedule for all remaining agricultural uses of lindane, those being seed treatment for a variety of crops. The decision to end registrations which were not voluntarily discontinued was based on unacceptable occupational risk. It should be noted that an Independent Review Board has been established to conduct a hearing concerning decisions made by the PMRA regarding lindane. Further information is available from http://www.pmra-arla.gc.ca./english/lindane/lindane-e.html

Mexico: History and Current Status of Lindane Use

[12] The Mexican government made a commitment in 2005 to phase out all agricultural, veterinary, and pharmaceutical uses of lindane. "There is no primary production of lindane in Mexico and no reports of historical production exist. Approximately 20 tonnes per year of lindane are imported and subsequently formulated in Mexico. Formulated lindane for seed treatment is imported from the US by Gustafson (recently bought by Bayer). There are no reported exports of lindane from Mexico to other countries and imports of the active ingredient are declining. As of January 2005, pollutant release and transfer register (PRTR) reporting is mandatory for industry in Mexico. Lindane is listed in Mexico's PRTR as a substance for voluntary reporting and is presently being considered for addition to the mandatory reporting list.

Mexico has recently released the *Mexican National Diagnostic on Lindane* to support activities under this NARAP, and is preparing a National Implementation Plan for POPs management under the Stockholm Convention. Lindane is listed in the CICOPLAFEST 1998 official catalog as a restricted pesticide, meaning that a written recommendation issued by a technician authorized by the federal government is required for its non-pharmaceutical use.

Agricultural and Veterinary Uses -- Currently lindane is authorized for use in Mexico for ectoparasite control on livestock for ticks, fleas, common fly larvae, etc. It is also registered for use as a seed treatment for oats, barley, beans, corn, sorghum and wheat, and as a soil treatment for corn and sorghum. Another use of lindane in Mexico is listed as flea treatment for domestic animals. Lindane is registered in Mexico for public health campaigns and was previously used to control scorpions but this use is no longer recommended by the Ministry of Health. Official information on amounts of lindane used for each purpose is not available. Based on information provided by industry, the majority of lindane is used for agriculture and veterinary uses (approximately 19 tonnes yearly), while a small part is for pharmaceutical uses (less than one tonne per year).

Pharmaceutical Uses -- Pharmaceutical uses of lindane in Mexico include formulation of creams and shampoos for scabies and lice treatment. Lindane-containing pharmaceutical products are available in pharmacies and included in the "Cuadro Básico de Salud", the list of pharmaceuticals required to be readily available throughout the national health system. The estimated amount of lindane used for pharmaceutical uses is less than one tonne. Estimation of the number of treatments is not currently available.

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[12] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

(iii) Releases (Discharges, Losses, Emissions)

[13] We incorporate by reference the recent report concerning Lindane and HCH Isomer Production: Global Overview of Residue Management, Formulation, and Disposal for a summary of HCH-isomer wastes generated from lindane and technical-HCH production.

[14] "Information from a former lindane production site in Nevada [USA] illustrates the scale of the waste isomer problem. A company manufactured approximately 12,000 tonnes of lindane, and approximately 50,000 tonnes of waste HCH isomers have been buried at the site since the late 1970s and capped with a clay liner (Croft, 2004)."

[15] "The Environmental Protection Agency (EPA) identifies the most serious hazardous waste sites in the nation. These sites are then placed on the National Priorities List (NPL) and are targeted for long-term federal clean-up activities. α-, β-, γ-, and δ-HCH has been found in at least 146, 159, 189, and 126, respectively of the 1,662 current or former NPL sites. Although the total number of NPL [Superfund] sites evaluated for these substances is not known, the possibility exists that the number of sites at which HCH is found may increase in the future as more sites are evaluated."

[16] "According to the EPA, there are Superfund sites contaminated with lindane in Delaware, Pennsylvania, North Carolina, Georgia, Alabama, Florida, New Jersey, Oregon, Missouri, California, Puerto Rico, Tennessee, Texas, Michigan and Washington."

[17] Information from lindane manufacturing facilities in India confirms that manufacture of 1 ton of lindane produces an average 9 tons of waste - a complex "muck" of alpha, beta and delta HCH. One Indian lindane production facility produces an estimated 6000 metric tons (MT)/year of muck. Industry representatives claim that the plants are now converting the HCH isomer waste into trichlorobenzene (TCB). However, experts say that only α - and γ–HCH can be converted into TCB, and not the other two isomers β- and δ–HCH. (pp:5) A team from Delhi University in India collected and analyzed 45 soil

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[13] Vijgen, J. 2006. The Legacy of Lindane HCH Isomer Production: A Global Overview of Residue Management, Formulation, and Disposal. Main Report and Annexes. (ISBN 87-991210-1-8) www.ihpa.info/library_access.php

[14] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[15] U.S. Agency for Toxic Substances and Disease Registry, Public Health Statement: Hexachlorocyclohexane. http://www.atsdr.cdc.gov/toxprofiles/tp43-c1.pdf.

[16] FitzGerald, Tara. 2005. "A Pesticide's Toxic Legacy" in *TRIO: The Newsletter for the North American Commission for Environmental Cooperation*. http://www.cec.org/trio/stories/index.cfm?ed=16&ID=178&varlan=english

[17] Fact Sheet. *Lindane's Dirty Secret: Indian Facilities Dump Toxic Waste.* Compiled by Community Action for Pesticide Elimination as a project of the International POPs Elimination Network (IPEN) Pesticide Working Group. May 2005. (pp:6) http://www.panna.org/campaigns/docsLindane/lindaneDirtySecret.pdf.

samples of surface and sub-surface soil from several agricultural sites in and around the HCH manufacturing plant of one of the prime producers of lindane in India, and nine samples of different commercial brands of drinking water from markets in Delhi for the presence of HCH residues. Thirty-nine of the 45 soil samples contained residues of β-HCH (2.5μg/kg-463 mg/kg of soil) and the remaining showed the presence of γ–HCH (0.08 μg/kg – 43 mg/kg of soil). All nine samples of drinking water were found to contain residues of HCH, with three brands showing HCH residue levels up to 141 times higher than EEC norms.

(b) Hazard assessment for endpoints of concern, including consideration of toxicological interactions involving multiple chemicals (summary information and relevant references)

Neurotoxicity

[18] A review of the neurological effects of lindane exposure found that lindane can interfere with learning. These conclusions were based on evidence that repeated exposure to lindane increased the number of errors made by mice in a food-reinforced maze. The authors support this claim with evidence that lindane may interfere with the ability to process new information through effects in the hippocampus. Acute exposure to lindane may cause seizures of varying degrees (grand mal, petit mal, myoclonus etc.), memory impairment, hyperactivity, irritability, and aggression.

[19] Additional studies have shown that exposure to low doses of lindane can interfere with an individual's ability to process new information by altering GABA. GABA is an amino acid derivative that inhibits pre-synaptic transmissions in the central nervous system (CNS). Lindane is a powerful convulsant in humans as a result of its impact on the CNS where it increases the release of neurotransmitters.

[20]**"**Evidence suggests that γ-HCH neurotoxicity is primarily related to the blockade of chloride ion flux through the inotropic $GABA_A$ receptors, resulting in depolarization and hyperexcitation of post-synaptic membranes. There is also evidence that γ-HCH can alter calcium homeostatis, elevating free calcium ion levels intracellularly with the release of neurotransmitters. The inhibition of Ca^{2+}, Mg^{2+}-ATPase, located in the terminal ends of neurons in synaptic membranes, results in accumulation of intracellular free calcium ions with the promotion of calcium-induced release of neurotransmitters from storage vesicles

[18] Duffard, A. and R. Duffard. 1996. Behavioral toxicology, risk assessment, and chlorinated hydrocarbons. Environmental Health Perspectives 104 (Suppl.2):353-360.

[19] Narahashi, T. 2002. Nerve membrane ion channels as the target site of insecticides. Mini Reviews in Modern Chemistry 2:419-432.

[20] Klaassen, C.D. ed. 2001. Casarett and Doull's Toxicology. McGraw-Hill, NY. p 773.

and the subsequent depolarization of adjacent neurons and the propagation of stimuli throughout the central nervous system."

[21]"One recent study of two patients, one with a history of chronic exposure to lindane/heptachlor and one with a history of chronic exposure to aldrin, reported death within two years of developing clinical and electrographic signs and symptoms of chronic motor disease and aggravation of dysphagia and weight loss resulting in the mobilization of adipose tissue and stored insecticide to enhance the neuronal toxicity. Even at low doses, these chemicals tend to induce convulsions before less serious signs of illness occur. Although the sequences of signs generally follows the appearance of headaches, nausea, vertigo, and mild clonic jerking, motor excitability and hyperreflexia, some patients have convulsions without warning symptoms. Exposure to lindane produces signs of poisoning that resemble those caused by DDT (e.g. tremors, ataxia, convulsions, stimulated respiration, and prostration). In severe cases of acute poisoning, violent tonic and clinic convulsions occur and degenerative changes in the liver and renal tubules have been noted. Technical-grade HCH used in insecticidal preparations contains a mixture of isomers: the gamma- and alpha- isomers are convulsant poisons; the beta- and sigma-isomers are CNS depressants. The mechanisms of action remain unknown."

[22]"There were significantly higher concentrations of gamma-hexachlorocyclohexane (lindane) in the substantia nigra in PD (Parkinson's disease) (mean ± SD 0.565 ± 0.434 μg lipid) than in AD (Alzheimer's disease (none detected), CLBD (cortical Lewy body dementia) (0.052 ± 0.101 μg lipid), or nondemented, nonparkinsonian control (0.125 ± 0.195 μg lipid) tissues…Both lindane (Martinez and Martinez-Conde, 1995) and dieldrin Sanchez-Ramos et.al. 1998) have been associated with a toxic effect on dopamine neurones. Thus, increased concentrations of these insecticides in substantia nigra may be directly linked to the reduced dopamine concentrations critical for the pathogenesis of PD…These findings are not inconsistent with the hypothesis derived from epidemiological work and animal studies that organochlorine insecticides produce a direct toxic action on the dopaminergic tracts of the substantia nigra and may contribute to the development of PD in those rendered susceptible by virtue of cytochrome P-450 polymorphism, excessive exposure, or other factors."

Health Risks Specific to Pharmaceutical Use

[23] The American Academy of Pediatrics released a statement on the diagnosis and treatment of head lice that was published in the September 2002 issue of *Pediatrics*. The report included the following statement about lindane: "resistance has been reported

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[21] Klaassen, C.D. ed. 2001. Casarett and Doull's Toxicology. McGraw-Hill, NY. p 772

[22] Corrigan, F.M. 2000. Organochlorine insecticides in substantia nigra in Parkinson's Disease. Journal of Toxicology and Environmental Health, Part A, 59:229-234.

[23] Ressel, G.W. 2002. AAP Releases Clinical Report on Head Lice. American Family Physician 67:1391-1392.

worldwide, and it has low ovicidal activity. It is only available by prescription and should be used cautiously because several cases of seizures in children have been reported."

[24] In a recent study comparing the efficacy of lindane, malathion, pyrethrin, and permethrin in treating head lice, lindane was the least effective and slowest working product. The authors reported that after the recommended ten minute application time no lice had been killed and after 3 hours of exposure, only 17% of the lice had died. Decreased efficacy of the lindane products may increase the likelihood of incorrect application of the product, which can have serious health consequences.

[25] The Food and Drug Administration (FDA) evaluated reports of adverse effects from lindane use and determined that most occurred when the chemical was misused or used in excessive amounts. When lindane is applied too frequently or for prolonged periods of time, it can result in seizures, dizziness, headache, and paresthesia. In extreme cases, improper lindane use has resulted in death. The most common reason for the misuse of lindane is reapplication after the first treatment failed— a situation that will increase in frequency as lindane efficacy declines.

[26] FDA has issued an advisory for lindane use and recommended that it only be considered as a second line treatment after initial treatments have failed. The advisory stresses that it should not be reapplied if initial treatment fails. FDA also noted that certain populations are at increased risk for adverse effects from lindane. These populations identified are infants, children, elderly persons, persons with skin conditions that might increase absorption, and persons who weight less than 49.5kg.

[27] A review of pesticide exposures from 1997-2000 among children under age six along the Texas-Mexico border reported 8% of the children who experienced clinical effects from pesticides were exposed to lindane. Five of these 10 children developed moderate to major effects. Of the 49 total lindane exposures covered in the study, 5% resulted in clinical toxicity.

[28] The potential for adverse effects and the failure of lindane as an effective treatment for head lice are sufficient reasons for it to be removed from the pharmaceutical market. There are safer and more effective alternatives that can replace lindane as a

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[24] Meinking, T. et.al. 2002. Comparative in vitro pediculicidal efficacy of treatments in a resistant head lice population in the U.S. Arch. Dermatol. 138(2):220-224.

[25] Burkhart, C.G. 2004. Relationship of treatment-resistant head lice to the safety and efficacy of pediculicides. Mayo Clinic Proc. 79:661-666.

[26] Center for Drug Evaluation and Research. FDA Public Health Advisory: Safety of topical lindane products for treatment of scabies and lice (2003). Available at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm (October 24, 2005).

[27] Belson, M. et.al. 2003. Childhood pesticide exposures on the Texas-Mexico border: clinical manifestations and poison center use. American Journal of Public Health 93:1310-1315.

[28] Pearlman, D.L. 2005. A simple treatment for head lice. Pediatrics 114:275-279.

pediculicide. Effective non-toxic treatments for head lice exist. Alternatives to pesticide treatments include dry-on, suffocation-based pediculicide and mechanical lice removal tools.

Hematological effects

[29] "Lindane, an insecticide used to treat seeds and soil, has been associated with leucopenia. It is cytotoxic for human CFU-GMs [granuolocyte-monocyte-colony-forming white blood cells] at concentrations observed in blood and adipose tissue from exposed human subjects."

Cardiotoxicity

[30] "Lindane peroxidation of the heart [in rats], as measured by thiobarbituric acid reactive substances was increased, with a decrease in [myocardial] GSH level. An increase in [myocardial] SOD and catalase activities was observed in the 7-mg/kg/day dose of lindane. Interstitial edema in the myocardium was observed in both doses. Ultrastructural changes consisted of loss of integrity of the myofibrils, Z-band disruption, and mitochondrial damage. This is the first study to report lindane-induced oxidative stress in the heart. Our observations have significant clinical relevance, as oxidative stress plays a key role in the pathogenesis and progression of major cardiovascular disorders."

Reproductive Effects/Endocrine Disruption

[31] A summary of observed lindane toxicity in rats found that exposure to the chemical led to impairment of testosterone metabolism and could lead to an alteration of male reproductive systems during prenatal development.

[32] Other animal studies show that high doses of lindane can alter oocyte maturation in mice and marine invertebrates.

[33] A recent study indicated that prenatal administration of lindane may induce long lasting effects of spermatogenesis in mice. Researchers found experimental lindane

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[29] Parent-Massin, D. et.al. 1994. Lindane haemototoxicity confirmed by in-vitro tests on human and rat progenitors. Human Exp. Toxicol. 13:103-106. Summarized in: Klaassen, C.D. ed. 2001. Casarett and Doull's Toxicology. McGraw-Hill, NY.

[30] Ananya, R. et.al. 2005. Oxidative stress and histopathological changes in the heart following oral lindane (gamma hexachlorocyclohexane) administration in rats. Med. Sci. Monit. 11(9):BR325-329.

[31] National Library of Medicine Hazardous Substances Database: Lindane. 2005. Available at http://www.toxnet.nlm.nih.gov/cgi-bin/sis/search/.

[32] Picard, A. et.al. 2003. Effect of organochlorine pesticides on maturation of starfish and mouse oocytes. Toxicological Sciences 73:141-148.

exposure resulted in reduced sperm counts, changes in the pattern of testicular germ cell distribution, and abnormalities in chromatin in the sperm cells of mice.

[34] "Lindane passes to testes and exerts toxic effects at a dose level of 6 mg/kg b.w. For risk assessment total dose should be considered because of the accumulation of lindane in the tissues."

[35] A study examining the effects of lindane exposure on the reproductive systems of mice concluded that developing oocytes exposed to lindane in vivo had an increase of irreversible damage in two-cell embryos. The authors report that the observed effects occurred at lindane concentrations that greatly exceed the concentrations measured in the human population, but they caution that the cumulative effect of lindane stored in the adipose tissue and exposure to other chemicals with similar mechanisms of toxicity might lead to clinically significant effects on reproduction.

[36] [37] Reproductive effects of HCH isomers during fetal development is of particular concern given the recent findings of the U.S. Centers for Disease Control and Prevention that more than half the participants in a national survey of chemicals in blood and urine carried beta-HCH in their blood, with the highest levels found among women of childbearing age.

[38] In the most recent risk assessment for lindane completed in 2002 EPA noted that "Lindane is a potential endocrine disruptor in birds, mammals and possibly fish."

[39] Lindane is ranked as a suspected endocrine disruptor on several target lists of endocrine disrupting chemicals, including the Danish EPA List of Endocrine Disrupting Auxiliaries and the European Union Prioritization List.

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[33] Traina, et.al. 2003. Long-lasting effects of lindane on mouse spermatogenesis induced by *in utero* exposure. Reproductive Toxicology 17:25-35.

[34] Joy RM, Burns, VW 1995. *Effects of Acute Exposure to Lindane on the male reproductive system: I adult rats*; Teratology Jun:51 (6):22A-23 A)

[35] Scascitelli, M. and F. Pacchierotti. 2003. Effects of lindane on oocyte maturation and pre-implantation embryonic development in the mouse. Reproductive Toxicology 17:299-303.

[36] National Center for Environmental Health, U.S. Centers for Disease Control and Prevention, Second National Report on Human Exposures to Environmental Chemicals. January 2003; and Third National Report on Human Exposure to Environmental Chemicals. July 2005. Available at http://www.cdc.gov/exposurereport.

[37] Schafer, K.S. et.al. 2004. Chemical Trespass: Pesticides in Our Bodies and Corporate Accountability. Pesticide Action Network North America. Available at: www.panna.org

[38] U.S. EPA, Environmental Fate and Effects Risk Assessment RED Chapter for Lindane. (p2) (http://www.epa.gov/oppsrrd1/reregistration/lindane/efe_ra_draft.pdf)

[39] As summarized in "Toxicity Information for Lindane" in the PAN pesticides database, http://www.pesticideinfo.org/Detail_Chemical.jsp?Rec_Id=PC32949

[40] Analysis of maternal and umbilical cord blood shows that HCH isomers are some of the chemicals detected in the highest concentrations among residents of the Arctic.

[41] EPA has also noted that lindane is "efficiently transmitted" from mother to child through breastmilk. When women carry HCH isomers in their bodies, infants may be exposed to their damaging reproductive effects both inside and outside the womb.

Carcinogenicity

[42] The International Agency for Research on Cancer (IARC) has determined that there is sufficient evidence demonstrating that lindane and technical HCH are carcinogenic in mice and, based on these observations, IARC has classified lindane and the other HCH isomers as possibly carcinogenic to humans.

[43] EPA has classified lindane as "suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential" based on an increased incidence of benign lung tumors in female mice. The Agency for Toxic Substances and Disease Registry (ATSDR) and the World Health Organization consider lindane a liver carcinogen, as is noted in the North American Regional Action Plan on Lindane.

[44] A 1998 report from the Austrian government cited "lack of adequate data" on lindane's carcinogenicity as the basis for a recommendation to suspend use of the pesticide across the European Union. In response to this report, most lindane uses were banned throughout Europe by 2000.

[45] Testicular cancer is the most common malignancy of young men in industrialized countries and has risen dramatically in Europe and North America. Chronic exposure to environmental chemicals has been suspected, because widely used pesticides are able to promote carcinogenic effects in rodents and are known to concentrate in the testis. "The prevailing model is that these chemicals mimic or interfere with the action of sexual steroid hormones and by inference they are referred to as endocrine disrupters." This study explores the mechanisms by which these chemicals might lead to testicular

[40] Walker, et.al. 2003. Organochlorine levels maternal and umbilical cord blood plasma in Arctic Canada. The Science of the Total Environment 302:27-52.

[41] EPA Memorandum: Lindane—Report of the FQPA Safety Factor Committee. August 2000: p 3.

[42] IARC Monographs. Hexachlorocyclohexane: Summary of Data Reported and Evaluation (1998). Available at http://www-cie.iarc.fr/htdocs/monographs/vol20/hexachlorocyclohexanes.html (24 October 2005).

[43] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[44] Federal Ministry of Agriculture and Forestry, Austria. Lindane: Report and Proposed Decision. Monograph prepared in the context of inclusion of following active substance in Annex I of the Council Directive 91/414/EEC. 1998.

[45] Mograbi, B. et. al. 2003. Aberrant Connexin 43 endocytosis by the carcinogen lindane involves activation of the ERK/mitogen-activated protein kinase pathway. Carcinogenesis 24 (8):1415-1423.

neoplasia by testing the effects of lindane in the cells of mice. The researchers exposed cellular materials to lindane, stained them, and took pictures with a 63x magnification lens using a confocal laser-scanning Leica microscope fitted with a 488 or 543 mm krypton/argon laser allowing simultaneous analysis of the stained cells. They stated that "Altogether, these findings provide the first evidence that Lindane-altered Cx43 endocytosis requires ERK activation [extracelluar signal-regulated kinases]." The researchers point out that their findings demonstrate that lindane inappropriately activates a specified mitogenic pathway (MAPK) while also inactivating a specified tumor suppressor (Connexin 43). They further conclude that lindane may participate in the promotion of neoplastic cell growth in testes and in other similar tissues.

[46] In a 2004 study, researchers state that "environmental contaminants possessing hormonal activity have long been suspected of playing a role in cancer causation." They make reference to studies that support this statement: "Whilst lindane poisoning may result in tremors, ataxia, convulsions, stimulated respiration, prostration and, in especially severe cases, degenerative hepatic and renal tubule changes, there has been speculation that such agents may also play a role in the aetiology of cancer. The primary route of exposure in the general population is through dietary intake, particularly via meat and dairy products. Lifetime feeding studies in mice revealed that technical grade HCH and some of its isomers, including lindane, increased the incidence of hepatocellular tumours. In such animal models lindane-induced damage may result from the generation of superoxide anion radicals and/or DNA single-strand breaks (SSBs) or via epigenetic mechanisms. Surprisingly little is knwn regarding the mutagenic and/or carcionogenic potential of lindane, although it has been shown to induce chromosomal aberrations in human peripheral lymphocytes *in vitro* and micronucleus (MN) formation in bone marrow *in vivo*."

"Incidence rates for cancers of both breast and prostate, which are hormone-responsive tissues, are higher in more developed countries than in less-developed regions. Factors that influence hormonal exposures may modulate risk associated with these cancers. Lindane interferes with reproductive activity in animals, an effect that may be mediated through a direct inhibition of adrenal and gonadal steriodogenesis. This chemical also interferes with gap junction intercellular communication and induces cytochrome P450 metabolic enzymes, factors that may each play a significant role in tumour-producing activity. As a lipophilic agent, lindane becomes concentrated in the ovary and testis, which could be relevant to the increasing incidence of testicular cancer."

The researchers looked at the mechanism by which environmental contaminants possessing hormonal activity could cause cancer. They used lindane on breast and prostate human cells to analyze chromosomal damage, cell viability, and cell cycle kinetics. They concluded that in their own study "the effects produced in cells treated with low doses of lindane... may be important in the context of considering the effects of environmentally relevant concentrations." "These results suggest that environmental

[46] Kalantzi, O.I. et.al. 2004. Low dose induction of micronuclei by lindane. Carcinogenesis 25(4):613-22.

concentrations of lindane can induce a number of subtle alterations in normal breast and prostate cells in the absence of cytotoxicity."

[47] In this 2004 article, researchers conducted a comprehensive literature review to assess the role of environmental agents in breast cancer. They identify a study that assessed the relationship between serum levels of five DDT metabolites, 13 other organochlorine pesticides, and 27 PCBs and the development of breast cancer and report that "women with serum levels in the upper quartile of HCH concentrations were at twice the risk for breast cancer as those with lower-quartile concentration of the chemical." Miltra et al. were referring to a 1999 article by Joanne F. Dorgan and co-authors entitled Serum Organochlorine pesticides and PCBs and breast cancer risk: results from a prospective analysis (USA)– published in Cancer Causes and Control. Vol.10, No. 1. pp. 1-11. These researchers used the Columbia, Missouri Breast Cancer Serum Bank to conduct a case-control study of 105 women diagnosed with breast cancer. For each case, two controls matched on age and date of blood collection were selected. Although they showed that women in the upper three quartiles of hexachlorobenzene were at twice the risk of breast cancer compared to those in the lowest quartile, they concluded that the results of the study "do not support a role for organochlorine pesticides... in breast cancer etiology." There was no evidence for a dose-response relationship, and the association was limited to women whose blood was collected close to the time of diagnosis.

[48] Researchers interviewed 987 farmers in the U.S. Midwest who had been diagnosed with non-Hodgkin's lymphoma and compared them to 2,895 population-based controls. Logistic regression demonstrated that reported use of lindane significantly increased the risk of non-Hodgkin's lymphoma by 50%. The researchers point out that these results could be by chance, because the farmers were exposed to other pesticides as well, and logistic regression analyses could not demonstrate that lindane alone is a major etiologic factor in the development of non-Hodgkin's lymphoma. They claim that a "small role" for lindane in causing this disease "could not be ruled out."

[49] "In oncogenicity studies on rats and mice dosed with lindane - possible adverse effects were observed. These include neoplastic nodules in rat livers, pituitary and thyroid adenomas and carcinomas. Liver toxicity patterns were observed in dosed mice including hepatocarcinogenicity. For gamma-HCH elevated frequencies of tumors in livers of mice, significant at the $p<0.01$ level. Liver tumors observed in male mice fed alpha-HCH and gamma HCH in 3 other studies as well."

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[47] Miltra, A.K. et al. 2004. Breast Cancer and Environmental Risks: Where is the Link? Journal of Environmental Health. Vol. 66, No.7: pp 24-31.

[48] Blair, A., et. al. 1998. Non-Hodgkin's lymphoma and agricultural use of the insecticide lindane. American Journal of Industrial Medicine 33 (1):82-87.

[49] As summarized in the California Environmental Protection Agency Department of Pesticide Regulation Medical Toxicology Branch, Summary of Lindane health effect studies. http://www.cdpr.ca.gov/docs/toxsums/pdfs/359.pdf.

Renal Toxicity

[50] "Lindane causes alpha-2u-globulin nephropathy or hyaline droplet nephropathy. This nephropathy occurs in male rats, is characterized by the accumulation of protein droplets in the S2 segment of the proximal tubule, and results in single-cell necrosis, the formation of granular casts and the junction of the proximal tubule and the thin loop of Henle, and cellular regeneration. Chronic exposure to [lindane and similar compounds] results in progression of these lesions and ultimately in chronic nephropathy."

(c) Environmental fate (summary information and relevant references)

Chemical/physical properties

Persistence

[51] Lindane is persistent and mobile. It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions. Once released into the environment, lindane can partition into all environmental media. Lindane is stable in freshwater as well as in sea water. Degradation takes place much faster under anaerobic conditions than in the presence of oxygen. A limited degradability has been demonstrated in cold areas. Like lindane, the alpha- and beta-HCH isomers are found in air, seawater, seabirds, fish, and mammals in the Arctic food web.

[52] "Lindane is persistent and moderately mobile. It has an estimated soil half-life of 2.6 years and a mean Koc of 1368 mL/g. It is resistant to photolysis and hydrolysis (except at high pH), and degrades very slowly by microbial actions."

[53] [54] "Brubaker and Hites (1998) measured the reaction rate constants of alpha- and gamma-HCHs with OH radicals. Calculations based on these rate constants and a tropospheric average OH radical concentration gave estimated lifetimes in air of 120 d for alpha-HCH and 96 d for gamma-HCH."

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[50] Klaassen, C.D. ed. 2001. Casarett and Doull's Toxicology. McGraw-Hill, NY. p 60.

[51] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[52] U.S. EPA, RED for Lindane, September 2002. (pp:33) (http://www.epa.gov/oppsrrd1/REDs/lindane_red.pdf).

[53] Referenced in Bidleman, T. 2004. Letter and review to the North American Task Force on Lindane. April, 2004.

[54] Brubaker, W.W., Hites, R.A. 1998. OH reaction kinetics of gas-phase alpha- and gamma-hexachlorocyclohexane and hexachlorobenzene**.** Environ. Sci. Technol. *32*, 766 - 769.

[55] [56] "Several measurements have been made of gamma-HCH hydrolysis and fewer of alpha-HCH hydrolysis. These studies were reviewed by Ngabe et al. (1993), who also determined the basic hydrolysis rates of alpha- and gamma-HCH as functions of temperature and pH. Temperature has a very strong influence on the hydrolysis rates because the reaction of HCHs with OH^- ions and the dissociation of water (which produces OH^- ions) are both temperature dependent. Based on the rate constants of Ngabe et al. (1993), calculated half lives in seawater at pH 8 are 0.8 y for alpha-HCH and 1.2 y for gamma-HCH at 20°C. The reaction rates are much lower and the half lives correspondingly longer at 0°C: 80 y for alpha-HCH and 135 y for gamma-HCH. These calculations indicate that, while the HCHs will dissipate relatively quickly from the oceans at tropical latitudes, they will be far more persistent in the Arctic. Similar calculations indicated half lives of 26 y for alpha-HCH and 42 y for gamma-HCH in Lake Huron at pH 8 (the pH of the lake is 7.6-7.8) and 5°C (Ngabe et al., 1993)."

[57] [58] "Microbial degradation proceeds faster than hydrolysis, especially in cold environments. Harner et al. (1999, 2000) estimated half lives in eastern Arctic Ocean water of 6 and 23 y for the (+) and (–) enantiomers of alpha-HCH and 19 y for gamma-HCH. The half lives of (+) and (–) alpha-HCH in a small arctic lake were estimated to be 0.6 and 1.4 y (Helm et al., 2002). These are much shorter than hydrolytic half lives. Harner et al. (2000) estimated that microbial degradation could account for about one-third of the annual loss of alpha- and gamma-HCHs from the Arctic Ocean."

[59] "Dissolved organic matter (DOM) is a ubiquitous component of all surface waters in the Arctic and plays an important role in the fate of persistent organic pollutants, mainly via photochemical degradation. POPs are transported to the Arctic by long-range processes, as well as from locally contaminated areas by sea ice melt and runoff. We have examined the DOM-mediated photolysis of two persistent organic pollutants, lindane and hexachlorobenzene. Lindane was found to display very little photochemical activity (thus possibly explaining its long life time and subsequent high concentrations in Arctic ecosystems. HCB was found to decay rapidly when in the presence of DOM. Our results show that sunlight in the presence of DOM can photolyze certain POPs, while others remain relatively recalcitrant."

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[55] Referenced in Bidleman, T. 2004. Letter and review to the North American Task Force on Lindane. April, 2004.

[56] Ngabe, B., Bidleman, T.F., Falconer, R.L. 1993. Base hydrolysis of alpha- and gamma-HCHs. Environ. Sci. Technol. 27, 1930-1933.

[57] Referenced in Bidleman, T. 2004. Letter and review to the North American Task Force on Lindane. April, 2004.

[58] Harner, T., Jantunen, L., Bidleman, T., Barrie, L., Kylin, H., Strachan, W., Macdonald, R. 2000. Microbial degradation is a key elimination pathway of hexachlorocyclohexanes from the Arctic Ocean. Geophys. Res. Lett. 27, 1155-1158.

[59] Grannas, A. et.al. 2003. Indirect photolysis of persistent organic pollutants by Arctic dissolved organic matter. Symposia Papers Presented Before the Division of Environmental Chemistry American Chemical Society. New York. September 7-11, 2003.

How are chemical/physical properties and persistence linked to environmental transport, transfer within and between environmental compartments, degradation and transformation to other chemicals?

[60] Lindane and other HCH isomers travel long distances via atmospheric currents. Recent studies demonstrate that alpha-HCH has a travel distance of 18,000-22,000 km and gamma-HCH (lindane) a travel distance of 2,400-12,600 km.

[61] During deliberations of the North American Task Force on Lindane and in the preparation of the North American Regional Action Plan (NARAP) on Lindane, task force members considered that for every ton of lindane that is produced, there are 6 – 10 metric tons of other HCH isomers that must be disposed of or otherwise managed. This consideration led to the decision that the NARAP for lindane must also include actions to address the other HCH isomers—of particular concern, in addition to the gamma-isomer, are the alpha- and beta-isomers of HCH.

The Objective of Article 1 of the Stockholm Convention states: "Mindful of the precautionary approach as set forth in Principle 15 of the Rio Declaration on Environment and Development, the objective of this Convention is to protect human health and the environment from persistent organic pollutants." It is important to include consideration of all HCH isomers in the risk profile because of the inherent generation of massive quantities of HCH wastes when lindane is manufactured. These wastes contaminate the local environment and communities surrounding the production site, but also contribute to the global transport and subsequent accumulation of HCH isomers in the Arctic. The risk profile must also consider the possibility of isomerization from gamma-HCH to other isomers, particularly beta-HCH, the most persistent and prevalent of the HCH isomers.

[62] "The behavior of HCH isomers in the environment is complex, because they are multimedia chemicals, existing and exchanging among different compartments of the environment such as the atmosphere, surface water, soil and sediment. The most common isomers found in the environment are lindane (gamma-), alpha-, and beta-HCHs. The physical and chemical properties of these HCH isomers are quite different from one another, which likely reflect some of the differences seen in HCH isomer persistence and variability in bio-magnification, -concentration and –accumulation in the various biological compartments. Differences in accumulation are also likely due to different modes of uptake, metabolism and sources of contamination."

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[60] Shen, L. et.al. 2005. Atmospheric distribution and long-range transport behavior of organochlorine pesticides in North America. Environ. Sci. Tech. 39(2):409-420.

[61] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[62] U.S. EPA, RED for Lindane, September 2002. (pp:40) The RED report can be found at http://www.epa.gov/oppsrrd1/REDs/lindane_red.pdf.

[63] Alpha-HCH concentrations have been documented in the air and water in various geographic regions, including Canada, River Rhine, River Elbe, select rivers in the UK, and the North Frisian Wadden Sea sediments. "Even in Antarctica levels ranging from 0.2-1.15 ug/kg have been found."

[64] Widespread distribution of 2,4-D, 2,4,5-T, Gamma- BHC and alpha-BHC were noted in Western Canadian surface waters between 1971-77. "Wide distribution of lindane and alpha- BHC was attributed to atmospheric transportation and deposition."

[65] "Numerous studies of ambient air (Harner et al., 2001 and Waite et al., 1999), precipitation (Barrie et al., 1992 and Norstrom and Muir, 1994), and surface water (Harner, 1997 and Norstrom and Muir, 1994) have reported HCH residues, particularly α and γ isomers, throughout North America. One concern is whether the current use of lindane in the United States has the potential of atmospheric burdens that arise from secondary emissions owing to agricultural practices like seed treatment and consequently their potential for long-range transport and effects on the ecosystem."

[66] A 1973 research paper documented the isomerization of gamma-HCH to alpha-HCH in the environment. The authors state that "the significance of this work is that we have demonstrated for the first time that microorganisms in pure culture can isomerizes gamma-HCH." While subsequent studies of isomerization are inconclusive, the possibility remains that isomerization of the gamma-HCH isomer to alpha and/or beta-HCH may be an important source of the more persistent HCH isomers in the environment, wildlife, and people.

Many studies in the scientific literature provide evidence supporting isomerization of the gamma-HCH isomer to alpha and/or beta-HCH as an important source of the more persistent HCH isomers. For example:

> [67] Researchers in China reached the following conclusion: "It was found, beta- HCH was most persistent in the environment, that is due to the isomerization of alpha-HCH in large amount to beta- HCH, besides its chemical stability."

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[63] WHO working group; *Alpha- hexacholorocyclohexane*; Environmental Health Criteria Vol: 123(1992) pp 1-66.

[64] Gummer WD, 1980. *Pesticide monitoring in the prairies of Western Canada*, Environ. Sc. Res. 16:345-72:1980.

[65] U.S. EPA, Revised EFED RED Chapter for Lindane, Dec 2001. (pp 8). http://www.epa.gov/oppsrrd1/reregistration/lindane/efed_ra_revised.pdf

[66] Benezet, H. and F. Matsumura. 1973. Isomerization of gamma-HCH to alpha-HCH in the environment. Nature 243:480-48.

[67] Wu Wz, Xu Y, Schramm K-W, Kettrup A. 1997. *Study of sorption, biodegradation and isomerization of HCH in stimulated sediment/ water system*; State Key Lab. Freshwater Ecology Biotechnol., Inst, Hydybiol. Wuhan 430072, China.

[68] In this paper, the causes for persistence of alpha- BHC in atmospheric environment were explored. "Under identical conditions, photochemical studies carried out with alpha-, beta-, delta- BHC isomers unequivocally established that the alpha-isomer was the most stable conformer photochemically although the beta-isomer was the most prevalent metabolic product in mammalian species. Transformation of the BHC isomers to the stable alpha-form may have been responsible for the presence of higher levels of the alpha-isomer than the gamma-form in the rain waters previously observed."

[69] "The high relative concentration of alpha-HCH in the Arctic suggest that gamma-HCH may be transformed to other isomers in the environment. Laboratory studies show the significant photoisomerization of gamma-HCH to alpha-HCH is possible."

[70] A study dealing with the microbial isomerization of Gamma-HCH showed that: "The isomers alpha-, beta-, and delta- HCH, and the compounds tetrachlorobenzene 2,3,4,5,6-pentacholoro cyclohexane and some unidentified metabolites were found. The HCH isomers present after 3 days were dependent on the initial concentration of gamma-HCH; at 10mug/l, the alpha- and beta-isomers were predominant and 50 mug/l delta-HCH was the major isomer present."

[71] "The effect of broad spectrum UV light on gamma-BHC in aqueous solutions with or without Cl was investigated. Gamma- BHC (Lindane) was degraded mainly to hexane-insoluble products more easily in the presence of Cl than in its absence. The gamma- BHC isomer isomerised to the alpha-conformer whether Cl was present or not. When an aqueous solution of lindane was irradiated with UV for 105 h in the absence of Cl, 4-45% of the residual sample contained the alpha-isomer."

[72] Lindane isomerization observed to alpha- HCH, delta HCH, pentachlorobenzene and pentacholorocyclohexene in a lab experiment testing for U.V. irradiation impact on lindane isomerization.

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[68] Malaiyandi M, Shah SM. 1984. *Evidence of photoisomerization of BHC isomers in the ecosphere*, J Environ Sci Health Part A Environ Sci Eng; 19(8).

[69] Walker K, Vallero DA, Lewsi RG. 1999. *Factors influencing the distribution of Lindane and other hexachlorocyclohexanes in the environment;* Environmental Science and Technology; 33 (24). 4373-78.

[70] Engst, R, Fritsche W, Knoll R, Kujawa, M, Macholz, RM, Strabue, G. 1979. *Interim results of studies of microbial isomerization studies of gamma hexacholorocyclohexane;* Bull. Environ. Contam. Toxicol. 22(4-5):699-707

[71] Malaiyandi M, Muzika K, Benoit FM. 1982. *Isomerization of gamma- Hexacholorocyclohexane to its alpha-Isomer by Ultra-Violet Light Irradiation*; J. of Environmental Science and Health, Part A, Environmental Science and Enginerrring, Vol A 17, no.3, pp 299-311.

[72] Steinwandter H. 1976. *Transformation of BHC isomers by UV. I. Isomerization of Lindane to alpha-BHC*, Chemosphere 5(4):245-8.

[73] Isomerization of lindane to alpha-BHC suggested to account for some of the occurrence of alpha- BHC in Canadian prairie pesticide monitoring. Beta-HCH may isomerise in aquatic environments and therefore may be a potential source of more biologically active isomers in the environment.

[74] Study reports that long-term tests with radioactively labeled lindane have revealed distinct transformation of gamma- HCH to alpha- HCH.

[75] In a study of isomerization of gamma isomers in rats it was observed that the beta isomer accumulated in the rat body when alpha-, gamma-, and delta- isomers were administered. Isomers were isomerised to beta isomer in the tissue.

[76] A 2002 paper provides insight to pathways by which HCH isomers reach the Canada Basin of the Arctic Ocean. Alpha-HCH and beta-HCH, are compared with respect to their transport to and distribution within arctic waters. The two isomers differ in the ability of the airborne chemical to dissolve in seawater, with beta-HCH being about 20 times more soluble. This property is thought to account for the observed differences between alpha-HCH and beta-HCH distributions in air and ocean surface water. Being more soluble than alpha-HCH, beta-HCH is preferentially deposited into the North Pacific by rain and exchange with ocean surface water before reaching the high Arctic, and ocean currents then finish the job of delivering it to the Canada Basin. Evidence for removal of beta-HCH en route is also given by its depletion in high arctic air relative to alpha-HCH. Because of this difference, delivery of beta-HCH to the Canada Basin has lagged alpha-HCH by perhaps a decade or longer and the highest concentrations during the late 1980s and mid-1990s were observed in marginal seas rather than in the high Arctic. Beta-HCH is highly persistent in seawater and its deposition into the North Pacific does not ultimately protect the Arctic Ocean but only delays the input and alters its spatial distribution.

[77] The atmospheric transport of lindane is a serious concern for residents of Arctic regions and for residents of areas in close proximity to agricultural lindane applications. A recent study measured the volatilization and transport of lindane from the Canadian prairies where lindane was commonly used as a seed treatment on canola fields. This

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[73] Deo PG, Hasan SB, Majumdar SK. 1980. *Isomerization of Beta-HCH in aqueous solution*, J. Environ. Sci. Health B15(2):147-164.

[74] Heeschen W, Nijhuis H, Bleuthgen A. 1980. *Investigations on the significance of the transformation and degradation of benzene hexachloride (BHC) in the lactating cow and in the surroundings for the BHC-contamination of milk,* Milschwisssenschaft 35(4):221-224. [Article in German]

[75] Kamada T. 1971. *Hygienic studies on pesticide residues: I. Accumulation of BHC (alpha-, bta-, gamma- and delta-) isomers in rat bodies and excretion into urine following oral administration*, Jap J Hyg: 26(4).

[76] Li, Y.F. et.al. 2002. The Transport of beta-hexachlorocyclohexane to the western Arctic Ocean: a contrast to alpha-HCH. Sci. Total. Environ, 291/1-3. :229-246. http://www.msc-smc.ec.gc.ca/data/gloperd/ArcticRes_e.cfm#TransBetaHCH

[77] Waite, D.T. et.al. 2005. Atmospheric transport of lindane (gamma-HCH) from the Canadian Great Lakes, Arctic, and Rocky Mountains. Atmospheric Environment 39:275-282.

study is particularly relevant considering the U.S. decision to continue to permit use of lindane for seed treatments. Waite et al. determined that 12-30% of the lindane applied as a canola seed treatment volatilized and was released to the atmosphere. Volatilized lindane may enter aquatic or non-target terrestrial ecosystems through precipitation or dry deposition where it can have adverse effects on the ecosystem. It is particularly important to consider the impact of such deposition on species that are highly susceptible to lindane toxicity, including fish and aquatic invertebrate species and bees.

[78] As noted in the North American Regional Action Plan on Lindane and Other HCH Isomers, HCH is one of the most abundant contaminants measured in the Arctic atmosphere and in Arctic ocean surface water, where it accumulates in the fatty tissue of marine mammals and fish.

[79] "Like other persistent organic pollutants, lindane and other isomers of HCH can be transported over long distances by air currents. All HCH isomers vaporize and condense, touching down on oceans and freshwater bodies, where they may begin the cycle again. As a result of these characteristics, lindane and other HCH isomers tend to accumulate in colder climates, where they are trapped by low evaporation rates. Certain HCH isomers are some of the most abundant and pervasive organochlorine contaminants found in the environment, especially in the Arctic."

[80] A study of pesticide occurrence in air and precipitation in Quebec, Canada showed that lindane was also one of the major organochlorine pesticides dominating the air and precipitation there. The authors of this study concluded that the high levels of technical HCH, used in large quantities in the region prior to its ban in 1978, were evidence of active long-range distance transport or volatilization of previously used chemicals from soil or water. Ongoing lindane use for seed treatment has the same potential to result in long-range transport, volatilization, and persistence.

Bio-concentration or bio-accumulation factor, based on measured values
(unless monitoring data are judged to meet this need)

[81] "Lindane and other HCH isomers 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, however, bio-transformation and elimination are relatively rapid when exposure is discontinued. Lindane and other HCH isomers occur in different

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[78] Bidleman, T.F. et.al. 1995. Decline of hexachlorcyclohexane in the arctic atmosphere and reversal of air-sea gas exchange. Geophysical Research Letters 22:219-222.

[79] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[80] Auglagnier, F. and L. Poissant. 2005. Some pesticides occurrence in air and precipitation in Quebec, Canada. Environmental Science and Technology 39:2960-2967.

[81] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

compartments and trophic levels of the Arctic ecosystem and are accumulated by species at low trophic levels, while the biomagnification potential is low at the upper end of the food web. The beta isomer of HCH is the most persistent and bioaccumulative form and accounts for almost 90% of the HCH detected in human tissues and breast milk. Experts support the need for additional research to determine why the beta isomer is the most prevalent form of HCH detected in human samples when it only makes up a small percentage of the technical mixture and technical HCH is banned in many countries. Lindane, with a log BAF of 4.1, has a bioaccumulation factor that exceeds the level of concern (log BAF>3.7) determined by the CEC's Substance Selection Task Force. Lindane is metabolized fairly rapidly in standard test species (e.g., rainbow trout, rat) under laboratory conditions. In humans, the half-life of lindane after topical application for treatment of scabies is approximately 1 day."

[82] "Alpha-HCH is regularly detected in fish and aquatic invertebrates, ducks, herons, barn-owls. Average of 70-80 ug/kg of Alpha- HCH was found in the subcutaneous fat of reindeer and Idaho mouse living in areas of negligible pesticide use. "

[83] Oral administration of alpha- and gamma-BHC to rats study: "After 8 wk of administration, tissue retention of alpha-BHC was 10-20 fold greater than that of gamma-BHC. Gamma-BHC was eliminated to a greater extent than alpha- BHC from tissues and in particular from fatty tissue. Alpha- BHC accumulated in fat and brain, while gamma-BHC showed low affinity for lipid."

[84] The study by Li, Y. F. et. al. (2002) shows that of the two HCH isomers, beta-HCH bioaccumulates more strongly and is more resistant to metabolism and microbial degradation. Beta-HCH is the most prominent isomer in human fat.

(d) Monitoring data (summary information and relevant references)

HCH in Human blood

[85] The Center for Disease Control and Prevention (CDC) is engaged in an ongoing assessment of the U.S. population's exposure to environmental chemicals using bio-

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[82] WHO working group; *Alpha- hexacholorocyclohexane*; Environmental Health Criteria Vol: 123(1992) pp 1-66.

[83] Eichler D, Heupt W, Paul W. 1983. *Comparative study of the distribution of alpha-BHC and gamma-BHC in the rat with particular reference to the problem of isomerization*, Xenobiotica; 13(11).

[84] Li, Y.F. et.al. 2002. The Transport of beta-hexachlorocyclohexane to the western Arctic Ocean: a contrast to alpha-HCH. Sci. Total. Environ, 291/1-3. :229-246.
http://www.msc-smc.ec.gc.ca/data/gloperd/ArcticRes_e.cfm#TransBetaHCH

[85]Third CDC National Report on Human Exposure to Environmental Chemicals, 2005
http://www.cdc.gov/exposurereport, and
http://www.cdc.gov/exposurereport/3rd/pdf/thirdreport_summary.pdf)

monitoring as a tool. Bio-monitoring involves assessment of human exposure to chemicals by measuring the chemicals or their metabolites in human specimens such as blood or urine. The results of these assessments have been published by the CDC in three National Reports on Human Exposure to Environmental Chemicals. The overall range of beta-HCH detected among US populations tested between 1999 and 2002 (across the CDC studies two and three) ranged from 49%-62%.

The third National Report on Human Exposure to Environmental Chemicals Report, 2005, presents exposure information for the U.S. population for 148 chemicals. The data for this report was collected between 2001 and 2002. The Report also includes the data from the Second Report, which contained data for 1999-2000. In the third CDC study 3097 individuals were tested for pesticides in their urine and 2517 individuals were tested for pesticides in their blood. The report shows that 46.2 ng/g lipid of beta- HCH was found in blood of adults over 20 tested in the US. Of these, women had 54.5 ng/g lipid of beta-HCH in their bodies. Mexican Americans had the highest levels of beta- HCH present in their blood at 84.4 ng/g lipid, as compared to 45.9 ng/g lipid for Non-Hispanic Blacks and 33.5 ng/g lipid for Non-Hispanic Whites (pp. 10).

[86] In the second National Report on Human Exposure to Environmental Chemicals Report, 2003, (data from 1999- 2000), 9282 people were tested for the presence of 116 chemicals including 34 pesticides in their bodies. In the second CDC study the figures for mean pesticide measured in blood were 25.85 ng/g lipid for Mexican Americans (632 cases), 13.15 ng/g lipid Non Hispanic Blacks (403 cases), 14.36 ng/g lipid Non-Hispanic Whites (702 cases). In women 20 years and older the mean pesticide measured in blood was 19.63 ng/g lipid (599 cases). Men 20 years and older had 13.95 ng/g lipid (524 cases) and boys (316 cases) and girls (298 cases) between 12-19 years had 7.76 ng/g lipid and 6.71 ng/g lipid respectively (pp 48). The second report showed that 62% of all persons tested had beta-HCH in their blood. (ibid: 21).

HCH in Human Breastmilk

[87] "Studies looking at HCH contamination of breastmilk have been conducted around the world, including reported results in the following countries: Austria, Belgium, Brazil, Canada, China, Czech Republic, Denmark, Egypt, Finland, France, Germany, Greece, Hungary, India, Ireland, Israel, Italy, Japan, Kenya, Luxembourg, Mexico, Netherlands, Nigeria, Norway, Poland, Russia, Rwanda, Saudi Arabia, Spain, Sweden, Switzerland, Thailand, Turkey, Uganda, Ukraine, United Kingdom, United States, Vietnam, Yugoslavia and Zimbabwe."

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[86]Schafer, K. et.al. 2004. Chemical Trespass. Pesticide Action Network North America, San Francisco, based on the Second CDC National Report on Human Exposure to Environmental Chemicals, 2003

[87] Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[88] Technical grade hexachlorocyclohexane and its isomers have been found in breastmilk throughout the world. That said, HCH levels vary widely across the globe, with the highest values found in areas of extensive use.

[89] [90] Several additional factors may affect the levels of HCH found in breastmilk. Like DDT, HCH breaks down more quickly in tropical climate zones than in temperate zones. Thus, levels of HCH in the environment, and perhaps in breastmilk, are likely to be relatively lower in warm climates if all other factors are equal. Also, as with other persistent organic compounds that bioaccumulate through the food chain, the concentration of HCH in breastmilk is strongly related to diet. A German study found that women who followed a low-fat diet had lower beta-HCH levels in their breastmilk than women whose diet included large quantities of meat.

[91] [92] In general, countries that have monitored breastmilk for HCH residues over time have witnessed a steady decrease as lindane restrictions and bans take effect. For example breastmilk monitoring data shows a clear downward trend over time in residues among women in the North Rhine Westphalia region of Germany, and a similar downward trend of average lindane and beta-HCH levels in Swedish breastmilk.

HCH in Food

[93] A sampling study of free-range chicken eggs conducted by the International POPs Elimination Network found that of 30 egg samples taken from 17 different geographic locations, lindane was measured above the detection limit (0.1 or 0.2 ng/g fat) in all 30

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[88] Jensen, A.A. and S.A. Slorach. 1991. *Chemical Contaminants in Human Milk*, Boca Raton Ann Arbor Boston: CRC Press, Inc., as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[89] Nair, A., *et al* 1996.." DDT and HCH Load in Mothers and Their Infants in Delhi, India," *Bulletin of Environmental Contamination and Toxicology* 56: pp. 58-64 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[90] Schade, G. and B. Heinzow. 1998. "Organochlorine Pesticides and Polychlorinated Biphenyls in Human Milk of Mothers Living in Northern Germany: Current Extent of Contamination, Time Trend from 1986 to 1997 and Factors that Influence the Levels of Contamination," *The Science of the Total Environment* 215: pp. 31-39 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[91] Furst, P., C. Furst, and K. Wilmers. 1994. "Human Milk as a Bioindicator for Body Burden of PCDDs, PCDFs, Organochlorine Pesticides, and PCBs," *Environmental Health Perspectives* 102: pp. 187-93 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[92] Noren, K. and D. Meironyte. 2000. "Certain Organochlorine and Organobromine Contaminants in Swedish Human Milk in Perspective of Past 20-30 Years," *Chemosphere* ; 40: pp. 1111-1123 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2.

[93] Blake A. 2005. *The Next Generation of POPs: PBDEs and Lindane*, Working Group of the International POPs Elimination Network (IPEN). http://www.oztoxics.org/ipepweb/egg/New%20POPs.html (pp:11)

samples, while beta- HCH was detected in all samples. Levels were particularly high in samples taken in Senegal and India. "…many samples with intermediate lindane concentrations had high concentration of beta-HCH reflecting the relative half lives of the two chemicals."

[94] The U.S. Food and Drug Administration found lindane and other HCH isomers in food residues of 100 food items in the agency's most recent Total Diet Study. The Total Diet Study (TDS), sometimes called the Market Basket Study, is an ongoing program that determines levels of various contaminants and nutrients in foods. The foods collected in the TDS (TDS food list) represent the major components of the diet in the US population. The food list is based on results of national food consumption surveys and is updated from time to time to reflect changes in food consumption patterns. The food list was most recently updated in 2003, based on data from USDA's 1994-96, 1998 Continuing Survey of Food Intakes by Individuals (1994-96, 1998 CSFII) (USDA 2000), and will be reflected in the TDS analytical results beginning with MB 03-1. Gamma-HCH was identified in 49 food items, alpha-HCH in 35 items, beta-HCH in 12 items, and delta-HCH in 4 items.

[95] The Centre for Science and Environment (CSE) in India reported on August 5, 2003 that pesticides had been found in twelve brands of Indian soft drinks. CSE's Pollution Monitoring Laboratory (PML) analyzed samples of bottled soft drinks for 16 organochlorine pesticides, 12 organophosphorus pesticides and 4 synthetic pyrethroides, all of which are used extensively in India. The soft drink brands tested were Blue Pepsi, Coca-Cola, Diet Pepsi, Fanta, Limca, Mirinda Orange, Mirinda Lemon, Mountain Dew, Pepsi, Sprite, Thums Up and 7-Up. Lindane was found in every brand of soft drink tested. Highest concentrations of lindane found by PML were 0.0042 mg/L, or 42 times the European Economic Commission (EEC) standard for drinking water. For all twelve brands, lindane concentrations averaged 21 times the EEC standard.

(e) Exposure in local areas (summary information and relevant references)

General

[96] Regarding exposure to wildlife due to seed treatment uses, EPA includes the following assessment: "There is a possibility of acute and chronic risk to avian and mammalian species consuming a majority of their body weight in treated seed per day. Based on a

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[94] Food and Drug Administration Total Diet Study: Summary of Residues Found Ordered by Pesticide, Market Baskets 91-3, 01-4. June 2003.http://www.cfsan.fda.gov/~acrobat/tds1byps.pdf

[95] Colanisation's Dirty Dozen, Bottled Water Norms Notified, Down to Earth, Science and Environment on-line, http://www.downtoearth.org.in, Hindu Business Line, August 5, 2003, Pepsi, Coke soft drinks contain pesticides: CSE, Pepsi to be Tested for Toxins in India, Reuters, August 12, 2003, CSE Press Release, August 13, 2003.

[96] U.S. EPA, Environmental Fate and Effects Risk Assessment RED Chapter for Lindane. (pp:2) (http://www.epa.gov/oppsrrd1/reregistration/lindane/efe_ra_draft.pdf)

Tier I screening assessment (using GENEEC), the aquatic assessment resulted in risks to aquatic organisms. For estuarine/marine invertebrates, possible high acute risk (RQ = 8.7) may occur even at the low application rates for seed-treatment uses. Restricted use LOC's were exceeded for estuarine/marine invertebrates and freshwater fish. Endangered species LOC's are exceeded for freshwater fish and invertebrates. Chronic risk to estuarine/marine organisms could not be assessed due to a lack of data. Modeling studies showed that lindane concentrations in both surface and ground water may reach environmentally significant levels (>MCL), even when lindane is restricted to seed-treatment uses only."

[97] Community and worker exposures to lindane and the other HCH isomers have been documented in both lindane producing factories in India. One factory, KCIL, discharged its effluents into an adjacent rainwater drain, flowing into a nearby river with villages and forests within 500 meters of the factory. Lindane was reported at 4 of 6 ground water monitoring locations (hand pumps/ wells) near one factory, with the highest concentration recorded being 277 ng/l. Investigations revealed that the 6000 MT/year of HCH waste produced by KCIL was dumped adjacent to the plant and periodically deposited in low-lying areas around the factory or mixed with water and flushed into adjacent water bodies and streams. Prior to 2000, the other lindane factory in India, IPL, dumped its waste in a deep pit in a village situated near the factory. Due to villagers' complaints (including unexplained deaths of cattle in the area), IPL began dumping the muck in nearby low-lying areas. The vegetation around the current dumping area has almost disappeared and the area has HCH muck approximately 6 ft. deep. There are homes located very close to the dumpsite, and wheat, rice, capsicum and other crops have suffered extensive damage due to the dry muck blown by winds and carried to fields through rainwater.

[98] A report published in 2002 by the Indian Ministry of Labor documents high levels of airborne lindane within a lindane manufacturing plant. The report also highlights several safety and health violations such as lack of display of labels or emergency information, workers in direct contact with benzene while filling the tanks, no precaution against fire hazards, lack of alarm systems, workers manually handling muck, crude lindane and wet lindane without protective gear.

[99] In its recent risk assessment of lindane, EPA identified occupational exposures at levels "of concern" to the agency, particularly exposure during on-farm mixing/loading/

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[97] Fact Sheet. Lindane's Dirty Secret: Indian Facilities Dump Toxic Waste. Compiled by Community Action for Pesticide Elimination as a project of the International POPs Elimination Network (IPEN) Pesticide Working Group. May 2005. http://www.panna.org/campaigns/docsLindane/lindaneDirtySecret.pdf

[98] Directorate General Factory Advice Survice and Labour Institutes. Ministry of Labour, Government of India, Mumbai. *Survey of Process Safety, Health and Work Environment in Pesticide Industries in India*. 2002.

[99] U.S. Environmental Protection Agency, Lindane: Preliminary and Early Revised Risk Assessment Documents. http://www.epa.gov/pesticides/reregistration/lindane/

application of formulation to seed, and commercial mixing/loading application of liquid formulation to seed at large commercial facilities.

[100] [101] Production of technical HCH was widespread around the world for many years. In the U.S. alone, EPA has found α-, β-, γ-, and δ-HCH "in at least 146, 159, 189, and 126, respectively of the 1,662 current or former NPL [Superfund hazardous waste] sites." EPA also reports that there are Superfund sites contaminated with lindane in at least 15 states in the U.S. Communities located near these sites risk exposure to lindane and/or its isomers from these waste sites.

Information regarding bio-availability

[102] [103] Especially high levels of HCH in breast milk have been associated with areas of high use. In China and Japan, HCH was commonly used as an insecticide in rice fields, and levels as high as 6,500 ppb of HCH in milk fat have been measured in these countries. Since Japan banned HCH in the 1970s, however, levels of the pesticide in breast milk have decreased. Average levels of HCH in breast milk in Osaka, Japan, dropped significantly between 1972 and 1998.

[104] Beta-HCH levels measured in India were nearly two orders of magnitude higher than that found in many other nations. The study reporting this data was conducted in Delhi, but similarly high beta-HCH levels have been detected elsewhere in India as well. Though gamma-HCH (lindane) has been banned for indoor use in India, it is still permitted to be used on field crops for pest control, and lindane continues to be produced in India.

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[100] U.S. Agency for Toxic Substances and Disease Registry, Public Health Statement: Hexachlorocyclohexane. http://www.atsdr.cdc.gov/toxprofiles/tp43-c1.pdf.

[101] FitzGerald, Tara. 2005. "A Pesticide's Toxic Legacy" in TRIO: The Newsletter for the North American Commission for Environmental Cooperation http://www.cec.org/trio/stories/index.cfm?ed=16&ID=178&varlan=english

[102] Jensen, A.A. and S.A. Slorach. 1991. *Chemical Contaminants in Human Milk*, Boca Raton Ann Arbor Boston: CRC Press, Inc. as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[103] Konishi, Y., K. Kuwabara, S. Hori. 2001. "Continuous Surveillance of Organochlorine Compounds in Human Breast Milk from 1972 to 1998 in Osaka, Japan," *Archives of Environmental Contamination and Toxicology* vol. 40: no. 4: pp. 571-578 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

[104] Banerjee, B.D., S.S. Zaidi, S.T. Pasha, D.S. Rawat, B.C. Koner, Q.Z. Hussain. 1997. "Levels of HCH Residues in Human Milk Samples from Delhi, India," *Bulletin of Environmental Contamination and Toxicology* 59: no. 3: pp. 403-406; Sanghi, R., M.K. Pillai, T.R. Jayalekshmi, A. Nair, "Organochlorine and Organophosphorous Pesticide Residues in Breast Milk from Bhopal, Madhya Pradesh, India" *Human and Experimental Toxicology* 22: no. 2 (2003): pp. 73-76 as cited in Natural Resources Defense Council on-line resource, *Healthy Milk, Healthy Baby. Chemicals: Hexachlorocyclohexane*. http://www.nrdc.org/breastmilk/hch.asp#note2

As a result of long-range environmental transport

[105] "HCH isomers are the most abundant organochlorines in the Arctic Ocean. The highest concentrations of HCH isomers are in the Beaufort Sea and Canadian Archipelago. The elevated residues of HCH isomers in marine mammals of the Archipelago are likely from the high concentrations of HCH isomers in the water. There is an important relationship between meat and fish consumption and concentrations of HCH isomers in human milk and body fat. Various mammals, fish and birds that the indigenous people of the North depend on for subsistence have measurable quantities of the persistent, toxic and bioaccumulative HCH isomers. The indigenous people of the circumpolar Arctic region are concerned that their subsistence diets may increase their exposure to HCH isomers. One reason is that exposure through subsistence diets to HCH isomers that are found in the Arctic food chain result from production and use of HCH isomers in countries outside of North America. Further study is needed to better assess the short and long term effects associated with this exposure pathway."

(f) National and international risk evaluations, assessments or profiles and labeling information and hazard classifications, as available (summary information and relevant references)

National & International risk evaluations, assessments or profiles

[106] The Austrian Federal Ministry of Agriculture and Forestry conducted a review for the Standing Committee on Plant Health in 1998 regarding inclusion of lindane as an approved (Annex I) active substance in the European Union. The Ministry reached the following conclusion, which led to the eventual decision in the year 2000 to disallow lindane agricultural use in the European Union: "For the time being an inclusion of the active ingredient in Annex I of Directive 91/414/EEC cannot be approved. The mentioned concerns regarding environmental fate and behaviour as well as ecotoxicology and effects with relevance to human health arising from exposure to lindane, together with a substantial lack of toxicity/metabolism and residue data lead to the conclusion that lindane should be suspended from the market until a final assessment of the required data is possible and performed. "

The Report and Proposed Decision goes on to cite "a number of deficiencies in the lindane data package, preventing a reliable assessment. . . The data already available suggest :

[105] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[106] Federal Ministry of Agriculture and Forestry, Austria. Lindane: Report and Proposed Decision. Monograph prepared in the context of inclusion of following active substance in Annex I of the Council Directive 91/414/EEC. 1998.

- a potential of accumulation in soil
- high stability in air
- a high tendency to volatilise and possibility of long-range transport
- a particular risk potential for birds
- a particular risk potential for mammals
- a particular risk potential for aquatic organisms
- a potential of accumulation in the food chain
- a particular risk potential for arthropods
- a broad health concern regarding the use of lindane in plant protection products.

"Continued approval in the absence of data to allay these concerns is not considered to be a suitable option. Therefore, the most appropriate decision would be to suspend lindane temporarily from the market until the identified further studies have been submitted and allow a complete assessment of whether the conditions of Article 5 (1) and (2) a) and b) of Council Directive 91/414/EEC are satisfied."

[107] "Under the POPs Protocol to the Convention on Long Range Transboundary Air Pollutants the parties agreed in 1998 to reassess the production and use of lindane (see article 10 of the Protocol and the reassessment clause in annex II). This technical review serves this purpose and is a compilation of two surveys performed in 2001 and 2004 in the UNECE region. From the 49 Parties or Signatories to the Convention, 31 parties provided information via a questionnaire concerning the production and use of lindane, including information of alternatives and control actions.

"Because of its toxic, suspected carcinogenic, persistent, bioaccumulative and suspected endocrine disrupting properties, lindane became a substance of scrutiny and was flagged for regulatory intervention in the recent decades. Thenceforth production as well as marketed volumes steadily decreased. Any production seems to have been discontinued sometime in the mid nineties at the latest.

"It can be concluded that the status of lindane among other pesticidal active ingredients becomes less important and it appears that alternatives and technologies can fully substitute the usage of lindane concerning the restricted uses…Lindane will be subject of other national and international activities e.g. OSPAR, NAFTA and further knowledge on adverse effects, restrictions and regulations can be expected."

[108] Lindane is highlighted at a problem chemical in several of the 12 regional reports produced through the UNEP/GEF Regionally Based Assessment of Persistent Toxic

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[107] Hauzenberger, I. 2004. Reports on Substances Scheduled for Re-Assessments under the UNECE POPs Protocol, Technical Review Report on Lindane. Federal Environment Agency, Austria. http://www.unece.org/env/popsxg/docs/2004/Dossier_Lindane.pdf

[108] GEF/UNEP Chemicals, Reports on the Regionally Based Assessment of Persistent Toxic Substances (12 regional, one global). December 2002. http://www.chem.unep.ch/pts/Default.htm

Substances, with particular emphasis found in the reports for the Arctic and North America regions.

[109] The Decision Guidance Document for lindane developed under the Rotterdam Convention provides a profile of lindane, including identification information, summary of regulatory controls, chemical and physical properties, toxicological and environmental characteristics, routes of exposure, packaging and labeling requirements, and waste disposal methods.

[110] A “Substance Profile” for lindane is included in the 11th edition of the U.S. National Toxicology Program's Report on Carcinogens. The 2005 profile includes information on lindane's carcinogenicity, chemical properties, use, production, exposure and U.S. regulation.

[111] The Agency for Toxic Substances and Disease Registry profiles HCH (all isomers) in a ToxFAQs fact sheet, updated August 2005. The fact sheet includes information on chemical identity, environmental fate, exposure and potential health effects, and particular risks to children.

[112] The U.S. Environmental Protection Agency conducted a risk assessment of lindane in the course of the reregistration process, completed in 2002. The risk assessment identified occupational exposures at levels "of concern" to the agency, particularly exposure during on-farm mixing/loading/application of formulation to seed, and commercial mixing/loading application of liquid formulation to seed at large commercial facilities. The U.S. registration of lindane for seed treatment uses was conditioned on improved worker safety measures and the submission of additional data to address outstanding concerns regarding these exposures.

[113] “The California Safe Drinking Water Act of 1996 requires the Office of Environmental Health Hazard Assessment (OEHHA) to perform risk assessments and adopt PHGs [Public Health Goals] for contaminants in drinking water based exclusively on public health considerations.” The OEHHA assessment considered chemical profile, environmental occurrence and human exposure, metabolism and pharmacokinetics,

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[109] Joint FAO/UNEP Programme for the Operation of Prior Informed Consent, Decision Guidance Documents: Lindane. 1996. http://www.pic.int/en/DGDs/LindaneEN.doc

[110] Report on Carcinogens, Eleventh Edition; U.S. Department of Health and Human Services, Public Health Service, National Toxicology Program. January 2005. http://ntp.niehs.nih.gov/ntp/roc/eleventh/profiles/s102lind.pdf

[111] Agency for Toxic Substances and Disease Registry, ToxFAQs for Hexachlorocyclohexane, August 2005. http://www.atsdr.cdc.gov/tfacts43.html

[112] U.S. Environmental Protection Agency, Lindane: Preliminary and Early Revised Risk Assessment Documents. http://www.epa.gov/pesticides/reregistration/lindane/

[113] Fan, Anna M. and George V. Alexeeff. 1999. Office of Environmental Health Hazard Assessment, California Environmental Protection Agency. Public Health Goal for Lindane in Drinking Water. http://www.oehha.ca.gov/water/phg/pdf/lindan_f.pdf

toxicology, dose-response assessment, risk characterization and calculation of the public health goal (0.032 ppb in drinking water). This public health goal, more protective than the federal drinking water standards (0.2 ppb) contributed to the 2002 phase out of pharmaceutical uses of lindane in California.

[114] Lindane is banned in 52 countries including: Argentina, Armenia, Bangladesh, Barbados, Belgium, Bulgaria, Burundi, Costa Rica, Croatia, Cyrus, Czech Republic, Denmark, Dominican Republic, Equador, Egypt, El Salvador, Finland, Gambia, Georgia, Guatamala, Honduras, Hong Kong, Hungary, Jamaica, Japan, Kazakhstan, Korea (Democratic Republic), Korea (Republic), Latvia, Liechtenstein, Lithuania, Mozambique, Netherlands, New Zealand, Norway, Paraguay, Peru, Poland, (Russia), Singapore, Slovakia, South Africa, St. Lucia, Sweden, Taiwan, Thailand, Tonga, Turkey, Uruguay, Vietnam, Yemen.

Lindane is restricted or severely restricted in: Algeria, Australia, Austria, Belize, Brazil, Canada, China, Columbia, Cuba, European Community, Fiji, France, Germany, Iceland, Ireland, Israel, Italy, Madagascar, Moldova, Morocco, Nigeria, Philippines, Samoa, Senegal, Spain, Sri Lanka, Sudan, Switzerland, Trinidad/Tobago, United Kingdom, United States of America, Venezuela, Yugoslavia.

Lindane is not registered in: Estonia, Guinea-Bissau, Indonesia, Monaco, Mongolia, Niger, Rwanda, Slovenia, Uganda, Vanuatu.

Lindane is registered in: Bolivia, Burkina Faso, Cameroon, Cape Verde, Chad, India, Kenya, Malaysia, Mali, Mauritania, Mexico, Papua New Guinea, Portugal, Syria, Tanzania, Togo, Zimbabwe.

[115] “The state of California has taken regulatory action on lindane. In May 2000, the California Toxics Rule (CTR) established a new water quality criterion of 19 ppt lindane in existing or potential drinking water supplies for protection of public health based on potential cancer risk to humans. Studies conducted of water exiting the Los Angeles County Sanitation Districts' treatment facilities found both peak and mean levels in many cases to be higher than the new (state) effluent standards. As available treatment technology was unable to adequately remove lindane from the water, a preventative strategy to allow compliance was required.

“The Los Angeles County Sanitation Districts calculated that a single treatment for head lice, when rinsed down the drain, contributed enough lindane to the water entering treatment facilities to bring 6 million gallons of water over the CTR standard. Based on a review of California pesticide applicator records and physician surveys conducted by these same districts, there were no significant agricultural sources in the region,

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[114] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[115] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005. (pp:21)

indicating that nearly the entire load was the result of pharmaceutical use. Initially, an education campaign with pharmaceutical lindane providers was started to discourage use. While this appeared to decrease the inflow levels of contamination, it was inadequate to comply with the new standards. 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 Jan 2002.

"Although no systematic evaluation of the consequences of the California ban on lindane in head lice and scabies treatments has been conducted to date, an anecdotal survey of medical and public health authorities conducted by the Los Angeles County Sanitation Districts noted no difficulties or concerns that have been raised by the ban after over two years in a population of over 30 million. Lindane concentrations in wastewater exiting these Districts' treatment plants have declined from non-attainment of the 19 ppt goal to negligible following the 2002 institution of the ban on pharmaceutical sales."

Labeling Information and Hazard Classification

[116] The International Chemical Safety Card on lindane, produced through collaboration of the Commission of the European Communities and the US National Institute for Occupational Safety and Health, provides information on acute hazard symptoms, protective measures and first aid, spillage disposal, storage and packaging/labeling. Physical and chemical properties, occupational safety standards and health effects, and environmental data are also summarized.

[117] The National Institute for Occupational Safety and Health provides labeling and hazard classification information in its 2005 "Pocket Guide to Chemical Hazards: Lindane". The document includes a description of physical and chemical properties of lindane, U.S. exposure limits, personal protection and sanitation, first aid, respirator recommendations, exposure routes, symptoms and target organs.

[118] The U.S. Environmental Protection Agency's Technology Transfer Network produced a Hazard Summary document for lindane, most recently revised in 2000. The summary includes information on use, sources and potential exposures, health hazard information including health data from inhalation exposure, and physical properties.

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[116] National Institute for Occupational Safety and Health/IPCS/CEC, International Chemical Safety Card: Lindane (ISCS 0053). 1994. http://www.cdc.gov/niosh/ipcsneng/neng0053.html

[117] Centers for Disease Control/National Institute for Occupational Safety and Health, Pocket Guide to Chemical Hazards: Lindane, NIOSH Publication No.2005-151. September, 2005. http://www.cdc.gov/niosh/npg/npgd0370.html

[118] U.S. Environmental Protection Agency, Technology Transfer Network/Air Toxics Website, Lindane Hazard Summary, Revised January 2000. http://www.epa.gov/ttn/atw/hlthef/lindane.html

[119] In 2003 the U.S. Food and Drug Administration changed the labeling requirements for lindane in pharmaceutical products to highlight the particular risk of lindane to children.

(g) Status of the chemical under international conventions

[120] "In 2004, the European Parliament adopted Regulation (EC) 850/2004 on POPs that bans the production and use of 13 intentionally produced POP substances. For HCH/lindane, the regulation allows member states a phase out period until December 2007. Member states may request to use lindane for professional lumber treatment and for indoor industrial and residential applications until September 1, 2006. They may request to use lindane for public health and as a chemical intermediate until December 31, 2007." For more information, see: http://europa.eu.int/comm/environment/pops/index_en.htm.

The Great Lakes Binational Toxics Strategy is a voluntary strategy signed in 1997 between the United States and Canada for the virtual elimination of persistent toxic substances in the Great Lakes. HCH, (including lindane) is listed as a Level II substance. This means that only one country has grounds to indicate its persistence in the environment, potential for bioaccumulation and toxicity. The governments of Canada and the United States encourage pollution prevention activities for Level II substances, to reduce their levels in the environment and to conform to the laws and policies of each country. (In contrast, Level I substances such as PCBs are targeted for virtual elimination through collaborative bilateral efforts.) For additional information, see: www.epa.gov/glnpo/bns/.

[121] "In 1998 lindane was on the list of chemicals for priority action under OSPAR (Convention for the protection of the marine environment of the north-east Atlantic) and thus a background document was prepared under the lead of Germany in 2002. As a follow up, relevant actions included cooperation with international bodies, promotion of severe restrictions, suggestions of lindane as a candidate for the Stockholm POP Convention, and a proposal of a monitoring strategy."

LRTAP's Aarhus Protocol - Lindane is included under the 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs), one of the eight protocols under the Convention on Long-Range Transboundary Air Pollution (LRTAP), negotiated under the auspices of the United Nations Economic Commission for Europe (UNECE). The Aarhus POPs Protocol entered into force in October 2003. The UNECE region includes the Russian Federation,

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[119] See U.S. Food and Drug Administration public health advisory and revised label at: http://www.fda.gov/cder/drug/infopage/lindane/lindanePHA.htm and http://www.fda.gov/cder/foi/label/2003/006309shampoolbl.pdf

[120] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

[121] Hauzenberger, I. 2004. Reports on Substances Scheduled for Re-Assessments under the UNECE POPs Protocol, Technical Review Report on Lindane. Federal Environment Agency, Austria. http://www.unece.org/env/popsxg/docs/2004/Dossier_Lindane.pdf. (p. 9)

Central Asia, Europe, Canada and the United States. HCH/Lindane is one of the 16 POPs substances listed in this legally-binding Protocol. The Protocol restricts lindane to six specific uses. As of December 9, 2004, there are 36 Signatories and 22 Parties to Protocol. Canada is a Party and the United States has signed, but not ratified the LRTAP POPs Protocol. For additional information on the LRTAP POPs Protocol, see: www.unece.org/env/lrtap/pops_h1.htm.

In August 2004, The Federal Environment Agency of Austria prepared a technical report on lindane, as part of a scheduled reassessment under the Aarhus Protocol of all restricted uses of lindane. For this report, see: www.unece.org/env/popsxg/mtg_tf_pops.htm.

Rotterdam Convention - Lindane is also included in the Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, which entered into force in February 2004. The "PIC treaty" is legally binding for Parties, with 73 Signatories and 84 Parties as of February 2005. Lindane's inclusion on the PIC list reflects that lindane has been banned or severely restricted by one or more countries in two or more different regions of the world. Under the PIC treaty, when an importing country indicates that no consent for import is provided, exporting countries are obligated to prevent export of that chemical to that country. The scope of PIC does not apply to pharmaceuticals, including human and veterinary drugs. Canada is a Party and the United States has signed, but not ratified the Rotterdam Convention. Mexico deposited its ratification instrument on May 5, 2005 and [became] a party 90 days after this date. To view the list of countries that do not allow the import of lindane, see: http://www.pic.int."