Annex F Submission for Lindane

Chemical name: Gamma-hexachlorocyclohexane (gamma -HCH)

CAS registry number: 58-89-9

Lindane; gamma-hexachlorocyclohexane (HCH); gamma -HCH; formerly known as benzene hexachloride (BHC)

gamma - hexachlorocyclohexane (HCH) is one of eight isomers of HCH. Of the eight isomers, gamma -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% gamma -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

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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Date of submission: 9 February 2007

Additional Annex E information

(i) Production data, including quantity and location

Only India and Romania[1] currently produce lindane for the world market. China stopped manufacturing lindane in 2003.[2]

[3] "None of the isomers or technical-grade HCH are currently produced in the United States. The production of gamma -HCH exceeded 2.27×10^6 g in 1976; commercial gamma -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 gamma -HCH, Drexel Chemical Company; subsequent volumes (1989-1991) give no listings of gamma -HCH producers…gamma -HCH is not produced in the United States. It is imported from

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[1] According to the 2004 Technical Review Report on Lindane prepared by Austria for the LRTAP POPs Protocol, Romania is scheduled for accession to the European Union in 2007. At that time, Romania becomes subject to the European Community regulations on POPs and the "Romanian production site will have to be closed down in the near future".

[2] North American Regional Action Plan on Lindane and Other HCH Isomers (North American Commission for Environmental Cooperation, May 2, 2006)

[3] 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.

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

[4]"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 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."

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

[4] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.
[5] Reports on Substances Scheduled for Re-assessments Under the UNECE POPs Protocol, Technical Review Report on Lindane. Prepared by I. Hauzenberger, Federal Environment Agency, Austria. August 2004.

The trend of the historical production of lindane can also be interlinked with decreasing usage volumes and pattern. The use of technical HCH was the major source of gamma -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 gamma -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% gamma -HCH a cumulative use of 259,000 tonnes of alpha-HCH, 20,000 tonnes of beta-HCH, and 135,000 tonnes of gamma -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."

[6]Estimates of current production include:
Romania and India are the only known lindane-producing countries in the world. Production between 1990 and 1995 was approximately 3,222 tonnes per year. China had 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.

[7] "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."

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. Information from a former lindane production site in Nevada illustrates the scale of the waste isomer

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[6] 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

[7] 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.

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.[8]

(ii) Uses

[9]"Gamma -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 gamma -HCH. EPA took this action in response to indications of gamma -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 gamma -HCH.' The contentions concerning developmental and reproductive effects were successfully challenged by industry. EPA no longer permits the use of gamma -HCH for purposes involving direct aerial application (EPA 1985b). The notice restricted certain applications of gamma -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 gamma -HCH powder, 99.5% technical grade HCH, and dust concentrate, which would delete from the pesticide label most uses of gamma -HCH for agricultural crops and use on animals and humans (EPA 1993). According to the EPA 2002 Registration Eligibility Decision (RED), the only current food/feed use of gamma -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). On August 6, 2006, the U.S. EPA withdrew registration for use of the pesticide lindane in agriculture.

Gamma -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% gamma -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, gamma -HCH was used in veterinary products to control mites and other pests, but recent data

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[8] State of Nevada, 2004 Personal Communication between Todd Croft, State of Nevada Division of Environmental Protection, Las Vegas office, and Janice Jensen, USEPA Office of Pesticide Programs, November 17, 2004.

[9] 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.

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 gamma - HCH are used annually as a seed treatment."

[10]"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.

On August 6, 2006, the U.S. EPA withdrew registration for use of the pesticide lindane in agriculture.

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."

[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 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.17 This calculation is premised upon information received from the IMS Health Inc. database.

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[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.

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

[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

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

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.

(iii) Releases, such as discharges, losses and emissions

[13]We incorporate by reference (see footnote) the recent report: *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)."

A. Efficacy and efficiency of possible control measures in meeting risk reduction goals:

[13] Vijgen, J. 2006. The Legacy of Lindane HCH Isomer Production: A Global Overview of Residue Management, Formulation, and Disposal. Main Report and Annexes. January 2006.
[14] Commission for Environmental Cooperation. The North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. October 2005.

(i) Describe possible control measures

For every ton of lindane that is produced, there are 6 – 10 metric tonnes of other HCH isomers that must be disposed of or otherwise managed. Ceasing the production of lindane would prevent additional environmental, social, health and economic costs of lindane and the other HCH isomers—of particular concern, in addition to the gamma-isomer, are the alpha- and beta-isomers of HCH.

(ii) Technical feasibility

The International HCH and Pesticide Forum, collaborative effort of non-governmental organizations, governmental agencies, and industry, is a working group of experts with the goal of addressing the environmental problems caused by HCH/Lindane production and the clean-up of former HCH/Lindane production sites. Further information on this Forum can be found at www.hchforum.com/forumInfo.php.

(iii) Costs, including environmental and health costs

As evidence that the environmental, social, and health costs of continued lindane production outweigh benefits, at least 52 countries have banned this persistent, toxic, and bioaccumulative pesticide.

B. Alternatives (products and processes):

Describe alternatives (including technical feasibility, environmental and health costs, efficacy, risk, availability, and accessibility)

Chemical and non-chemical alternatives for the primary uses of lindane, including agricultural, veterinary, and pharmaceutical have been reviewed in the North American Regional Action Plan on Lindane and Other HCH Isomers (North American Commission for Environmental Cooperation, May 2, 2006) and in a workshop, Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005). As non-governmental organizations of the International POPs Elimination Network, we support viable and economical non-chemical alternatives to the uses of lindane.

Lindane is banned for use in at least 52 countries, demonstrating that the environmental, social, and economic costs of continuing use of lindane have been deemed too high. For example, the agricultural uses of lindane were discontinued in Canada by December 21, 2004 based on unacceptable risk to workers. In 1999, Costa Rica banned all uses of lindane based on “evidence of teratogenicity, mutagenicity, carcinogenicity, and potential to cause human sterility, produce skin irritation, nervous system toxicity, and leukemia. Costa Rica also found lindane to have a high persistence in soil, bioaccumulation in fatty tissues, and high toxicity in fish, bees, and birds.”[15]

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[15] Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).

Alternatives to the Use of Lindane in Agriculture

Chemical alternatives used to replace agricultural use of lindane include those in the neonicotinoid class (imidicloprid, thiamethoxam). Although these chemical alternatives are considered less environmentally harmful than lindane, integrated pest management and organic methods preclude the need for chemical insecticidal treatments. A variety of cultural methods are currently known to effectively prevent harm to seeds and crops, and current research focuses on promising biological controls.

Integrated cultural methods for agriculture include: crop rotation (such as alfalfa, soybeans, and clover), re-seeding with resistant crops (such as buckwheat or flax), zero or reduced tillage regimes, careful seed selection, increasing seeding rates, shallow seeding and good seed to soil contact, balanced soil fertility to ensure that plants are not predisposed to disease, avoidance of excessively wet seed beds, and use of more competitive crop varieties to limit losses. .[16],[17],[18] A more detailed description of effective cultural methods as alternative to the use of lindane can be found in Annex F of the North American Regional Action Plan on Lindane and Other HCH Isomers.[19] Current research at Pacific Agri-Food Research Centre, in Agassiz, Canada is examining the use of *Metarhizium anisopliae*, an insect fungal pathogen, to control wireworm.[20] The research demonstrates that "microbials can be effective seed treatments" and may be particularly effective when combining *Metarhizium* with neonicotinoid treatments. Additional research with another microbial, *Tricoderma* (T-22), has also demonstrated effective results.[21] In a case study presented at the Workshop on Alternatives to Lindane Use sponsored by the North American Commission for Environmental Cooperation, Dr. Fernando Ramirez-Muñoz of the Regional Institute for Studies in Toxics in Costa Rica, reported that *Metarhizium* and other biological controls are registered alternatives in commercial formulae for use on wireworms and for the treatment of seeds, potatoes and other vegetables, sugar cane, and cantaloupe. This report demonstrates that microbials are technically feasible, efficacious and commercially available as alternatives to the use of lindane. Additional biological control methods employed in Costa Rica include: *Trichodama* spp, *Piper aduncum*, *Trichogram* wasps, and *Bacillus thuringiensis*.[22]

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[16] Dosdall, Lloyd, Ph.D. 2004. Department of Agricultural, Food, and Nutritional Science. University of Alberta, Edmonton, Alberta, Canada. Personal Communication (21 September 2004).

[17] Turkington, K. 2004. Research Scientist in Plant Pathology, Agriculture and Agri-Food Canada, Lacombe, Alberta, Canada (Personal Communication, 22 September 2004).

[18] Glogoza, P. 1998. "Wireworm Management for North Dakota Field Crops." North Dakota State University, Fargo, North Dakota. <http://www. ext.nodak.edu/extpubs/plantsci/pests/e188-1.htm>

[19] North American Regional Action Plan on Lindane and Other HCH Isomers (North American Commission for Environmental Cooperation, May 2, 2006)

[20] Kabaluk, et al. 2001. "Evaluation of *Metarhizium anisopliae* as a Biological Control for Wireworms." Pacific Agri-Food Research Centre. Agassiz, B.C.

[21] Kabaluk, T. 2005. Presentation at the Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).

[22] Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).

Alternatives to the Use of Lindane in Pharmaceuticals (Lice and Scabies Treatment)
A recent report in the journal *Pediatrics* indicates that "the number of cases of head lice is increasing, because lice are evolving resistance to pediculicides."[23] The article describes an effective non-chemical method for the treatment of head lice that resulted in nearly 100% mortality of eggs and 80% mortality of hatched lice. The authors conclude: "Our findings demonstrate that one 30-minute application of hot air has the potential to eradicate head lice infestations. In summary, hot air is an effective, safe treatment and one to which lice are unlikely to evolve resistance. There were no adverse effects of treatment." This article demonstrates that treatment without the use of pediculocides exceeds the efficacy of pediculocidal treatments. A study in the U.K. suggests that a treatment protocol of wet combing was more effective than pesticidal treatment.[24] Dr. Mark Miller, a pediatrician with the American Academy of Pediatrics and University of California, San Francisco, Pediatric Environmental Health Unit, reviewed the Cochrane Data Base of Systematic Reviews in the evaluation of trials of treatments of head lice. "The group did not review any studies looking at lindane as a head lice treatment, as they felt that it did not meet their requirements as a safe and efficacious agent to be reviewed. The Cochrane review found permethrin to be the preferred pediculocidal treatment for both lice and scabies treatment."[25]

In the U.S., the state of California has taken regulatory action on lindane. The following case study provides the imperative and strong evidence that pharmaceutical uses of lindane can be replaced with safer alternatives. The case study is excerpted from the North American Regional Action Plan for Lindane and Other HCH Isomers. "In May 2000, the California Toxics Rule (CTR)[26] established a new water quality criterion of 19 ppt (parts per trillion) 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. These standards were equal to the US national water quality criterion for water bodies that are existing or potential drinking water sources.[27] As available treatment technology was unable to adequately remove lindane from the water, a preventive 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 identified in the region, indicating that nearly the entire load was the result of pharmaceutical use. Initially, an

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[23] Goates, B.M. 2006. An effective non-chemical treatment for head lice. Pediatrics 118(5):1962-70.
[24] Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).
[25] Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).
26 Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Rule. May 16, 2000, Federal Register; 31682. http://www.swrcb.ca.gov/rwqcb2/Agenda/07-21-04/07-21-04-5afinalto.doc
[27] Nationally Recommended Water Quality Criteria; Notice. December 7, 1988. Federal Register; 67548.

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."

"A review 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[28] . Lindane concentrations in wastewater exiting these Districts' treatment plants have declined from non-attainment of the 19 ppt goal to almost non-detectable following the 2002 institution of the ban on pharmaceutical sales. From 2000 - 2004, four scabies outbreaks were reported by four counties to the California Department of Health Services (CDHS) Surveillance and Statistics Section. Statewide the number of scabies outbreaks decreased the first year following the ban with a slight increase the second and third year. A 2005 random survey of California pediatricians (135 responded) indicated that 98.5% of them had not seen any increase in scabies since the ban.[29] Since 1999, CDHS has recommended against the use of lindane for scabies[30] and against its use for head lice since 1987[31]. Prior to the ban, CDHS issued guidelines to all physicians to use malathion instead of lindane."[32]

"Outbreaks of scabies in healthcare facilities, particularly acute care hospitals, are not uncommon in California, and can last for months if not promptly recognized and managed aggressively. To address this problem the CDHS developed and distributed to healthcare facilities a guideline for the management of scabies outbreaks (www.dhs.ca.gov/ps/dcdc/disb/disbindex.htm). In it, CDHS recommends the use of ivermectin to treat patients with severe (e.g. keratotic) scabies that is likely to be refractory to cutaneous medication, and that are the source for outbreaks in healthcare facilities."

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[28] Personal communication Ann Heil, Los Angeles County Sanitation Districts, 2004

[29] Survey conducted by Mark Miller, American Academy of Pediatrics, University of California, San Francisco, Pediatric Environmental Health Unit.

[30] Prevention and Control of Scabies in California Long-Term Care Facilities, California Department of Health Services 1999.

[31] " Head Lice Infestation-Treatment Failures with 1% Lindane" California Morbidity Report, California Department of Health Services, April 17, 1987

[32] S. Husted, "California Program to Prevent and Control Head Lice", Medical Board of California ACTION REPORT, Jan 2000

"Although not recommended by CDHS for typical scabies or prophylaxis, ivermectin has also been used in outbreaks for treatment of symptomatic cases and for mass prophylaxis because of its ease in application and probable greater compliance and efficacy compared to permethrin. It should be noted that ivermectin has not been approved by the FDA for use for scabies. Institution of mass prophylaxis has always been successful in terminating the outbreak. CDHS has received no reports of adverse effects from any of these uses. However, it is not known how adverse effects were monitored for and controlled studies have not been conducted."[33]

Alternatives to the Use of Lindane in Veterinary Applications

A thorough review of alternatives to lindane use for veterinary applications is summarized from the proceedings of an international workshop on Alternatives to Lindane Use held in Mexico City in October 2005.[34]

C. Positive and/or negative impacts on society of implementing possible control measures:

(i) Health, including public, environmental and occupational health

As has been noted, 6-10 tons of waste isomers are produced for every ton of lindane. This massive quantity of persistent and toxic waste poses threats to workers, local communities, and globally through atmospheric transport of the HCH isomers produced. Eliminating the production of lindane is the only way to prevent sources of HCH contamination that cause unnecessary harm to the health of workers, local communities in proximity to production facilities, wildlife and people of the Arctic. Indigenous peoples in the Arctic are particularly vulnerable from dietary exposure to the alpha and beta HCH isomers through subsistence foods, such as caribou, fish, seal and whale.

(ii) Agriculture, including aquaculture and forestry

The U.S. EPA announced in early August 2006 that it has determined that the risks of continued lindane registration outweigh the benefits, and therefore the remaining uses of lindane are not eligible for re-registration. EPA expects the cancellation of these uses to result in no significant loss to U.S. agriculture due to the successful development and registration of safer alternative pesticides in recent years.[35]

(iii) Biota (biodiversity)

Lindane and other HCH isomers accumulate in Arctic wildlife and pose unacceptable threats to the health of wildlife populations, including certain endangered species as Steller sea lions. We have included data below that have not been included in previous submissions to the POPRC.

<u>Steller sea lion</u>

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[33] North American Regional Action Plan on Lindane and Other HCH Isomers (North American Commission for Environmental Cooperation, May 2, 2006)

[34] Workshop on Alternatives to Lindane Use, sponsored by the North American Commission for Environmental Cooperation Lindane Task Force in Mexico City (October 4-6, 2005).

[35] USEPA Pesticides New Story. Remaining Lindane Registrations Cancelled. December 15, 2006.

“Steller sea lion habitats and prey are contaminated with additional chemicals including mirex, endrin, dieldrin, HCH, dioxin compounds, cadmium, and lead…Ikonomou (2002) reported PBDEs had exponentially increased in ringed seals from the Canadian Arctic between 1981 and 2000 and that PBDEs may become the most prevalent POP in arctic ringed seals in the next 50 years. Thus, a significant data gap in our understanding is the potential for unmeasured contaminant exposure in Steller sea lions, many of which may be increasing.”[36] Clearly, marine mammals are burdened with multiple chemical contaminants that may adversely affect the health of the animals and people who consume them—the risk assessment fails to consider additive and synergistic effects of multiple chemical exposures on wildlife and people.

Beluga whales

Data published in the Alaska Traditional Knowledge and Native Foods Database (www.nativeknowledge.org) show a range of HCH levels in beluga whale blubber in ng/g wet wt.:

Sample site	HCH isomer	Sex	Range
Point Hope	alpha-	F (n=4)	162-180.3
	beta-	F (n=2)	99.1-188.2
	gamma	F (n=4)	33.3-95.9
Point Lay	alpha-	F (n=6)	43.9-186.9
	alpha-	M (n=18)	70.8-196.3
	beta-	F (n=3)	22.3-144.1
	beta-	M (n=9)	120-180.8
	gamma	F (n=6)	11.5-49.2
	gamma	M (n=18)	39.6-64.9
	Sum-HCHs	F (n=3)	77.7-364.4
	Sum-HCHs	M (n=8)	265.3-478.3

Bowhead whales

Bowhead whales (n=72) in the vicinity of Barrow, Alaska had concentrations of Sum-HCH of 203 ng/g (geometric mean, wet weight). “The partitioning of HCH isomers between the lower- and higher-latitude marine environments (i.e. the north Pacific versus Arctic Oceans) has been observed in biota. The relative abundance of beta-HCH was significantly greater than the alpha -HCH isomer in pinnipeds from 40-60_N in the western Pacific Ocean. As well, beta-HCH is the most dominant isomer in blubber tissues from minke whales from the north Pacific. However, alpha -HCH is the dominant isomer in ringed seals and low trophic level biota from the high Canadian Arctic. The bowhead whales harvested during the spring migration were recently occupying waters with higher beta-HCH relative to the Beaufort Sea which may explain the PC1 results.”[37]

[36] Barron, M.G. et.al, 2003. Contaminant exposure and effects in pinnipeds: implications for sea lion declines in Alaska. Sci. Total Environment, 311(1-3):111-33.
[37] Hoekstra, P.F, 2002. Bioaccumulation of organochlorine contaminants in bowhead whales (Balaena mysticetus) from Barrow, Alaska. Arch. Environ. Contam. Toxicol. 42(4):497-507

Polar bears

Levels of Sum-HCH in Chukchi and Bering Sea polar bears are among the highest reported in the circumpolar Arctic. Sum-HCH concentrations were highest in Alaska male polar bear fat samples (geometric mean 593, with 95% confidence limits 363-909 ng/g lipid weight). "Sum-HCH concentrations showed the steepest negative west-east gradient across the populations studied. SUM-HCH concentrations were significantly highest in Alaska bears compared to Western Hudson Bay and to populations east of Lancaster Sound/Jones Sound (Tukey's test; $p<0.02$), and lowest in bears from Svalbard (Tukey's test $p<0.001$). There was a six-fold difference in age-adjusted mean SUM-HCH concentrations between bears from Alaska and Svalbard. Muir and Norstrom (2000) and Norstrom et.al. (1988) also reported the highest SUM-HCH concentrations in polar bear fat samples from Alaska (Bering/Chukchi Sea). This may indicate an ongoing contribution of HCHs from China, southeastern Asia, and North America. The west-east geographical trend for SUM-HCH was in general agreement with results of polar bears spanning the regions of Svalbard eastwards to the Chukchi Sea, measurements of HCHs in seawater, and results of ringed seals from the Canadian Arctic eastwards to the Russian Arctic. Furthermore, latitude was negatively correlated with the alpha -HCH: SUM-HCH ratio and was the most pronounced latitudinal gradient measured in this study. No correlation was found between longitude and the alpha -HCH: SUM-HCH ratio. The contribution of the more water-soluble alpha -HCH to SUM-HCH, relative to beta-HCH, was thus highest at the southernmost populations of the distribution range of the polar bear." In Alaska polar bears, the concentrations of SUM-HCH in male bears ranged from 398 up to 1269 ng/g lipid weight and in female bears the concentrations ranged from 332 up to 550 ng/g lipid weight.[38]

In another study, researchers also found that polar bears from the Chukchi Sea had the highest levels of alpha -HCH and beta-HCH. In all the bears, SUM-HCHs was dominated by beta-HCH. Concentrations (ng/g lipid weight) in the blood of adult female polar bears (age >5) in the Chukchi Sea ranged from 108-353 for alpha -HCH and 193-830 for beta-HCH.[39] The SUM-HCH distributions in ringed seals were dominated by alpha -HCH, while beta-HCH was the major isomer in polar bears. Polar bears are eaten (primarily muscle tissue) in the communities along the Bering, Chukchi, and Beaufort Sea coasts and may be an important source of exposure to HCH and other contaminants.

(iv) Economic aspects

(v) Movement towards sustainable development

(vi) Social costs

The continued use of lindane poses unacceptable threats to the social well-being, health and cultural integrity of Arctic Indigenous populations. The recent U.S. EPA decision to

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[38] Verreault, J. et.al, 2005. Chlorinated hydrocarbon contaminants and metabolites in polar bears (Ursus maritimus) from Alaska, Canada, East Greenland, and Svalbard: 1996-2002. Sci. Total Env. 351-352:369-390.

[39] Lie, E. et.al, 2003. Geographical distribution of organochlorine pesticides in polar bears (Ursus maritimus) in the Norwegian and Russian Arctic. Sci. Total Env. 306:159-170.

cancel all remaining agricultural uses of lindane was based in part on the recognition that Arctic Indigenous people were susceptible to adverse health and cultural effects from exposure to alpha- and beta- isomers of HCH through their traditional diets.

EPA's dietary risk assessment "indicates potential risks from dietary exposures to the alpha and beta HCH isomers to communities in Alaska and others in the circumpolar Arctic region who depend on subsistence foods such as caribou, seal, and whale." The information presented in this section of our comments supports this conclusion. Assessments of risk must take into consideration the complexity and diversity of foods that comprise the traditional diets among Indigenous peoples in different regions of Alaska and the circumpolar north.

Almost no information exists in the literature on the contaminant content of subsistence foods as consumed (such as seal oil, dried or smoked fish). Preparation methods may change contaminant content of foods, either by removing, concentrating, or changing the form of contaminants.[40] Adverse cultural effects are caused by contamination of traditional foods and possible health outcomes involving exposures to multiple persistent organic pollutants (not just HCHs), heavy metals, and radio-nuclides.

The Alaska Traditional Diet Project (March 2004) found "substantial regional and seasonal variation in food intake patterns among Alaska Natives" and "substantial reliance on many subsistence foods such as fish, terrestrial mammals, marine mammals, and wild plants." Alaska Native people rely on traditional foods because of cultural importance, availability, preferences in taste and nutrition to store-bought foods. "For Alaska Natives, harvesting and eating subsistence foods is essential to personal, social, and cultural identity."[41]

The Alaska Traditional Diet Project also found that "the most common concerns expressed about subsistence foods were observations of fish and animals with parasites, diseases, or lesions; reduced numbers of fish and [other] animals; and the possible presence of contaminants in fish and [other] animals…there were many comments about unhealthy fish and animals, contamination, or generally reduced quality of subsistence foods. It appears that fears about safety have not yet caused these participants to avoid subsistence foods, but the anxiety they expressed is nevertheless real."[42]

> *"For thousands of years Alaska Natives have remained intimately tied to their environment. The Inupiat, Athabascan, and Yupik of the north; and the Aleut, Supiak, Eyak, Tlingit, Haida, and Tsimshian of the Gulf of Alaska region all developed cultures based on the natural resources of their area. Land and sea animals, plants and birds were all harvested to provide food, medicine, and traditional cultural uses. Each group used a wide range of local resources and was self-sufficient in their territory…"*

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[40] Ballew, C. et.al, 2004. Final Report on the Alaska Traditional Diet Survey. The Alaska Native Health Board Alaska Native Epidemiology Center.
[41] Ibid.
[42] Ibid.

"Information on contaminants and the quality of Alaska's wild foods must be provided in a meaningful manner to Alaska Natives and rural residents. Alaskans are already concerned or aware that many resources may be contaminated. Much of the current information on contaminants is generally large-scale. The information is not specific to the health of a stock or geographic area. Residents become distrustful of wild foods and may avoid foods that are safe to eat, or eat foods or use resources that have been unknowingly contaminated.

In several instances foods have been tested positive for contaminants but rural residents are left in a quandary. They may be advised that the nutritional value of the foods outweighs the risk from contaminants. Or they may be told that scientists are unsure if the level of contamination is a risk with limited human consumption. In western Alaska, Natives may harvest over 500 pounds per person of wild foods, hence, consumption can be significant for foods such as herring in the Bethel area, beluga in the Bristol Bay area, or shellfish in the Gulf of Alaska.

When rural residents stop eating local foods the negative impacts can be considerable. Traditional foods are replaced by store bought foods. Aside from draining limited cash resources, the nutrition and quality of store-bought foods is often inferior to fresh local sources. As local hunting and gathering practices are discontinued, there is a loss of cultural knowledge and a loss of society. This results in a greater dependence on government agencies for food, and for the money to buy these resources. Many Alaska Natives attribute alcoholism, family abuse, and other social horrors to this decrease in self-sufficiency. There has been a groundswell of desire and effort to return to traditional ways and reclaim ties to the land and cultural values. However, this is stymied when Natives are unsure if the traditional foods are still safe. Much of Alaska Native cultural knowledge was lost during the early epidemics, and now precious cultural knowledge is slipping away as Natives avoid collecting and using wild foods."[43]

Murre and other seabird eggs

Murre eggs are harvested by people living in many Alaska coastal communities and comprise an integral part of the Alaska Native diet. Murres (Common, *Uria aalge*, and Thick-billed, *Uria lomvia*) are distributed throughout the Arctic and sub-Arctic, nest in large colonies, and feed at the same trophic level as marine mammals. The average household in the two villages of St. Lawrence Island in the northern Bering Sea consume between 60 and 104 murres and eggs per year.[44] Another report found that Alaska Native people living in villages of the Yukon-Kuskokwim area consumed up to 28 murre eggs per year.[45] In an analysis of persistent organic pollutants (POPs) in Alaskan murre eggs,

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[43] Garza, D, 2001. Alaska Natives assessing the health of their environment. International Journal of Circumpolar Health, 60(4):479-86.

[44] Kucklick, J.R.et.al, 2002. Persistent organic pollutants in murre eggs from the Gulf of Alaska and Bering Sea. 22nd International Symposium on Halogenated Environmental Organic Pollutants and Persistent Organic Pollutants (POPs), Barcelona, Spain, 11-16 August 2002. Organohalogen Compounds, 59:13-16.

[45] Ballew, C, 2004. Final Report on the Alaska Traditional Diet Survey. Alaska Native Epidemiology Center of the Alaska Native Health Board, p 35.

researchers found beta-HCH among the major POPs in concentrations ranging from 59-282 ng/g lipid mass.

Researchers collected and analyzed contaminant levels in murre eggs from several colonies in Alaska. They measured concentrations of various PCB congeners and chlorinated pesticides, including alpha -, beta- and gamma -HCH. Statistical analyses showed variation among colony locations for all compounds except beta-HCH. Researchers found the following concentrations of HCH isomers (data are expressed in ng/g lipid weight),[46 47]

	ALPHA –HCH	BETA-HCH	GAMMA -HCH
East Amatuli	16.1±7.3		4.66±7.1
St. Lazaria	9.51±4.0	143±50	1.97±1.7
Bogoslof Island	22.3±7.2		6.27±1.3
St. George Island	11.0±4.5	161±64	2.63±2.5
Little Diomede	10.0±5.5	183±63	2.62±2.9

While most “legacy” organochlorine contaminants have significantly declined in Canadian Arctic biota from the 1970s to the 1990s, HCH levels have “remained relatively constant in most species and proportions of the toxic beta-HCH isomer have actually increased in seabird eggs and in ringed seal blubber.”[48]

Seal species and seal oil

There are additive effects of contaminant/HCH levels among the various northern seal species, including ringed, spotted, bearded, harbor, ribbon, and northern fur seals. Traditional diets among people in different coastal areas of Alaska vary considerably in the relative importance of the different seal species. Seal oil is an important component of the Alaska Native diet, yet little information exists on the levels of contaminants in this rendered food source. People also consume muscle, liver, heart, kidney, and flipper of seal species, and contaminant levels may be more concentrated in certain tissues. In a dietary survey of 151 people in villages in the Norton Sound region of Alaska, people consumed up to 288 pounds of seal oil per person/year with 80% of the people surveyed eating seal oil.[49] Thus, the estimates for seal consumption provided in the Dietary Profile seriously underestimate the importance of seal and seal oil in the traditional diet.

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[46] Kucklick, J.R. et.al, op.cit.

[47] Vander Pol, S.S. et.al, 2004. Persistent organic pollutants in Alaskan murre (Uria spp.) eggs: geographical, species, and temporal comparisons. Environ. Sci. Tech, 38(5):1305-12.

[48] Muir, D.C, 2005. Contaminants in Canadian Arctic biota and implications for human health: conclusions and knowledge gaps. Sci. Total Env. 351-352:539-46.

[49] Ballew, C. et.al. op cit.

In one study of organochlorine pesticides in the blubber of ringed seals, "wet mass sum HCH (SUM-HCH, sum of alpha -, beta-, and gamma -HCH) values for samples that included beta-HCH measurements, ranged from 146 ng/g wet mass to 561 ng/g wet mass. Muir et.al. (1995) also measured variable SUM-HCH concentrations in ringed seal samples; 246 ± 231 ng/g in females and 274 ± 123 ng/g in males. Schanz et.al. (1996) reported gamma -HCH values in ringed seals from Barrow and Nome, Alaska from 2.1 ± 0.01 ng/g to 633 ± 4 ng/g. For the samples in which all three HCHs were measured, alpha -HCH contributed the most to the SUM-HCHs, ranging from 59% of SUM-HCH in RGSL-047 [sample number] to 68% in RGSL-053."[50]

In a study of northern fur seals, researchers concluded that the "overall toxic equivalency shows levels approaching and exceeding those levels recommended for human consumption at St. George Island and approaching those levels at St. Paul Island." Although the researchers analyzed only for PCB congeners and DDT/metabolites, the study is indicative that contaminant levels may already exceed levels considered safe for consumption without the additional adverse effects that might be caused by HCH and other contaminants. The authors note that fur seals have higher levels of organochlorine contaminants than ringed seals. The researchers also conclude: "Northern fur seal pups, especially first-born, have a substantial exposure to organochlorine contaminants at a critical developmental stage."[51] Concentrations of organochlorine contaminants are likely a key factor in the precipitous declines of northern fur seals and Steller sea lions.

<u>HCH in people of the Arctic</u>

Relative to numerous studies in Canada, there have been few analyses of persistent organic pollutants in people of the Alaskan Arctic and sub-Arctic. One study identified "widespread Alaska Native exposure to organochlorines that originated outside the Arctic, a finding also seen in other studies." The mean level of HCH in blood serum of Alaska Native women by geographical area was reported as follows:[52]

HCH mean (standard deviation) in ng/mL or ppb	
Southcentral (n=47)	0.28 (0.40)
Northwestern (n=28)	0.43 (0.54)
Southwestern (n=50)	0.32 (0.42)
Interior (n=6)	0.20 (0.43)

A later study evaluated maternal plasma concentrations of beta-HCH in women of the Aleutian and Pribilof Islands in Alaska compared with women in other areas of the circumpolar Arctic (1994-1996 geometric means, ppb lipid)[53]:

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[50] Kucklick, J.R. et.al, 2002. Persistent organochlorine pollutants in ringed seals and polar bears collected from northern Alaska. Sci. Total Environ. 287:45-59.

[51] Beckman, K.B. 1999. Factors affecting organochlorine contaminant concentrations in milk and blood of northern fur seal (*<u>Callorhinus ursinus</u>*). Sci. Total Environ. 231:183-200

[52] Rubin, C.H. et.al, 2001. Exposure to persistent organochlorines among Alaska Native women. Int. J. Circumpolar Health, 60 (2):157-69.

[53] Middaugh, J. et.al, 2001. Assessment of exposure to persistent organic pollutants in five Aleutian and Pribilof villages. State of Alaska Epidemiological Bulletin, 5(5):1-19.

Aleutian/ Pribilof Is.	Canada	Greenland	Sweden	Norway	Iceland	Russia
N=40	N=67	N=117	N=40	N-60	N=40	N=51
24.7	9.3	18.5	9.2	8.1	32.1	222.5

In addition to HCH, the study measured other organochlorine pesticides and PCBs. Levels of p,p'-DDE in Aleutian and Pribilof Island women were the highest in the circumpolar Arctic with a geometric mean of 503 ppb lipid (N=40).

Data concerning HCH isomers in the blood serum of Yupik people from St. Lawrence Island[54] revealed the following lipid-adjusted average and maximum concentrations in ppb:

alpha -HCH	4	24
GAMMA -HCH (Lindane)	35	246
Delta-HCH	0	21

beta-HCH was not detected in these analyses. The study also showed elevated levels of oxychlordane and trans-nonachlor compared with levels in people of the lower-48 states.

D. Waste and disposal implications (in particular, obsolete stocks of pesticides and clean-up of contaminated sites) (provide summary information and relevant references):

(i) Technical feasibility

Chemical Disposal methods for Lindane and HCH Isomers:
[55]The following extract is taken from Annex II of the report by John Vijgen on Lindane and HCH isomers, which is submitted by reference (see below). As per Vijgen, these are some of the chemical methods used to dispose lindane and other HCH isomers.

1. Germany
In Germany two manufacturers have been able to eliminate HCH-residuals. In one case a total amount of 40 000 tons of HCH residuals has been completely used within a couple of years for the production of 1,24-trichlorobenzene (TCB) which was then in a thermal destruction converted to 1,2,4,5-tetrachlorobenzene and was chlorinated via trichlorophenol to 2,4,5-trichlorophenoxyacetic acid (2,4,5-T).

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[54] Carpenter, D, 2005. Presentation of unpublished data at the Alaska Conference on Health and Environment, December 2005.
[55] Vijgen, J. January 2006. The Legacy of Lindane HCH Isomer Production- A Global Overview of Residue Management, Formulation and Disposal- Annex II. International HCH and Pesticides Association.

In the other case more than 30 000 tons have been converted to trichlorobenzene.

The method was relative simple, but very cost-intensive due to the high corrosion of the equipments used.

Continuous processes were possible. For the production of 1,2,4,4 tetrachlorobenzene, a trichlorobenzene with 75% 1,2,4 TCB brought an economical advantage. This was possible by means of the application of certain kind of active carbons. The HCl-separation took place on the granulated carbon at high temperature (sublimation). Problems occurred with the sales of the formed HCl, which only could achieve a marketable quality by means of costly adiabetical adsorption and application of active carbon as final polishing step. Therefore HCl was used in most of the manufacturers internally for neutralization purposes. The chlorination to 1,2,4,5-tetrachlorobenzene as pre-product for the 2,4,5-trichlorophenoxyacetic acid (2,4,5-T) brings again a high percentage of undesirable tetrachlorobenzene isomers and high chlorinated side-products (up to penta-and hexachlorobenzene) and these products only seldom could be used!

2. France
The following capacities were mentioned at the beginning of the 90s: 36 000 t/y of HCH, 4 000 t/y of Lindane, 16 400 t/y TCB and 12 000 t/y of HCl. During 1994, the last producer stopped the Lindane production and the production of 1,24-TCB by its cracking. The pure 1,24-TCB was then produced by distillation by another company and sent back to be used as intermediate in the synthesis of a pesticide by the manufacturer in a continuous process in a closed system.

3. Russia
The situation in Russia is described by Treger, (October 2004), at the chemical plant “Khimudobrenij” at the town of Chapaevsk, in 1968 – 1971: “following the isolation of gamma-HCH (for 1 ton of gamma-isomer up to 10-12 tons of "intoxic" isomers were formed), processing of all other isomers was introduced at the industrial scale. The production stopped approximately in 1986-87.

The technological scheme was as follows:
1. Thermal (at 240-250°C), initiated with chlorine, dehydrochlorination of HCH isomers resulting in 1,2,4-trichlorobenzene (TCB) in the liquid phase and isolation of relatively small amount (up to 1 000 t per annum) of purified TCB.
2. High temperature (up to 600°C) chlorination of TCB on the charcoal resulting in the commercial hexachlorobenzene (HCB) – about 1 000 t perannum.
3. Water-alkali hydrolysis of HCB resulting in sodium pentachlorophenolate –annual capacity was 2 400 t.”

This technological scheme was used during more than 15 years, up to end-80s, when all these production facilities, including the ones for HCH, were closed down.

Jones (2005) mentions that China and Russia still manufacture PCP from HCB by caustic soda hydrolysis, which utilises the waste alpha-HCH from Lindane manufacture.

This is believed to be the only current direct use of HCB as a chemical intermediate (Bailey, 2001)

4. Czech Republic

Holoubek et al, (Holoubek, 2004, Matousak, 1994) report that a somewhat different approach, which was applied at the Spolana Factory (presently in the process of remediation). In the year 1965, a complex processing of HCH isomers was introduced according to technology developed by the research department of agrochemical technology in Bratislava. In the first phase, the isomers underwent dechlorination by caustic soda to trichlorobenzene (specifically a mixture of trichlorobenzene isomers), which was isolated from the reaction mixture by steam distillation. Trichlorobenzene was then processed by direct catalytic chlorination to a tetrachloro- and hexachlorobenzene (HCB) compound. Tetrachlorobenzene (hereafter TeCBz) due to the action of caustic soda was converted to sodium trichlorophenolate, which either by acidification was converted to trichlorophenol, or due to the action of chloroacetic acid to the sodium salt of 2,4,5- trichlorophenoxyacetic acid (hereafter just 2,4,5-T). The reaction of sodium salt of 2,4,5-T with butylalcohol produced the butylester of 2,4,5-T acid, which was the main active ingredient of arboricidal preparations ARBORICID E 50 and ARBORICID EC 50.

Sodium pentachlorophenolate was sold dried and in 7-11% water diluted solution forms. Pentachlorophenol was sold dried and as a xylene solution with a minimum 23% PeCP content. PeCP was equally used as one of the active ingredients in the combined insecticidal and fungicidal preparation PENTALIDOL for all types of wood treatment, constructions, bannisters, furniture, flooring and roofing against wood-damaging pests, wood-damaging fungi and various types of moulds.

Due to the action of caustic soda, Tetrachlorobenzene (TCB) was converted to sodium trichlorophenolate, which either by acidification was converted to trichlorophenol, or due to the action of chloroacetic acid to the sodium salt of 2,4,5-trichlorophenoxyacetic acid (hereafter just 2,4,5-T). The reaction of sodium salt of 2,4,5-T with butylalcohol produced the butylester of 2,4,5-T acid, which was the main active ingredient of arboricidal preparations ARBORICID E 50 and ARBORICID EC 50. Non-reacted parent lyes were brought back to previous stages, which on one hand made this technology almost without waste, however on the other hand led to the concentrating of pollutants and reaction side products.

At the time when the technology of processing ballast HCH isomers was being implemented, it wasn’t known that side reactions occur during the abovementioned syntheses with trace amounts of substances harmful to human health, causing liver necrosis and manifested externally by the presence of chloracne. Attention was called to the cause of this problem by the workers of the Chemical- Technical University in Pardubice, who from literature and then during in-person discussion abroad, were able to find out information about similar problems in Germany. There it was discovered, that during dehydrochlorination of HCH and during further processing of chlorinated derivatives of benzene, trace amounts of polychlorodibenzodioxins are created, among them even 2,3,7,8- tetrachlorodibenzo-p-dioxin (TCDD), which has the highest toxicity.

Landfills for disposal of soil contaminated with lindane and HCH:
This is another strategy used for disposal of lindane. The following extract from Vijgen (2006) describes two such cases of landfills in Spain and Netherlands.
[56]"For more than forty years, technical HCH was produced by two companies located in the Basque Country in northern central Spain. Starting in 1953, Lindane was extracted from the technical HCH mixture, leaving behind huge amounts of waste HCH isomers. The authorities in the Basque Country have calculated that 82 000 tons of waste HCH isomers have been dumped at more than thirty sites in their region.

Dumping of waste isomers stopped in 1987, when the Basque authorities banned this practice. Due to the mixing of waste HCH isomers with soils and other wastes, the authorities estimate that there are between 500 000 and 1 Mio tons of contaminated residues in their region. In addition to environmental problems and unacceptable risks to inhabitants this imposes, the contamination has also in the past, hindered important development projects in areas near the sites where the isomers were dumped.

The authorities developed a strategy to manage the contamination. Over a period of 10 years they conducted inventories and constructed two secure hazardous waste landfills for the contaminated soils; one for 176 000 tons and the other for 480 000 tons of waste residues and contaminated soil. In addition, a process called the base catalyzed dechlorination (BCD) process was developed to treat 3 500 tons of HCH waste isomers…

… there was high contamination of soil in the eastern region of Netherlands. At the end of the 1980s, the Dutch government authorized a large project to manage the regional contamination issue. In 1988, a temporary storage site was established on top of a former landfill site. About 200 000 tons of soil excavated from the most contaminated areas of the region, were stored at this site. At the time no adequate technology was available to treat soil contaminated with waste isomers, and the Dutch government invited companies to develop technologies to treat the isomers and investigated their efficiency. By the beginning of 2002, all waste isomers at the temporary storage site had been treated, and the site is now capped, secured, and used by the farming community for summer festivals."

Biodegradation of HCH isomers- a possible solution for HCH contaminated sites:

[57]A 2002 study was conducted to monitor the biodegradation of alpha-, beta-, gamma-, and delta-hexachlorocyclohexane (HCH) isomers in liquid culture by a bacteria of the Pandoraea species; and to determine the influence of pH and temperature on the

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[56] Vijgen, J. January 2006. The Legacy of Lindane HCH Isomer Production- A Global Overview of Residue Management, Formulation and Disposal- Annex II. International HCH and Pesticides Association.

[57] Siddique T. et.al. 2002.Temperature and pH effects on biodegradation of hexachlorocyclohexane isomers in water and a soil slurry. *J Agric Food Chem.* 2002 Aug 28;50(18):5070-6

biodegradation of alpha- and gamma-HCH in liquid as well as in soil slurry cultures. The results of this study suggest that this bacterial strain may effectively be used for remediating polluted sites and water contaminated with different HCH isomers over a range of environmental conditions. The Pandoraea species degraded 79.4% delta-HCH and 34.3% gamma-HCH in liquid culture at 4 weeks of incubation. alpha- and beta-HCH exhibited almost identical rates (41.6 and 42.4%, respectively) of degradation. The highest degradation of alpha- and gamma-HCH (67.1 and 60.2%, respectively) was observed at an initial pH of 8.0 in liquid; 58.4 and 51.7% rates of degradation of alpha- and gamma-HCH, respectively, at an initial pH of 9.0 were found in soil slurry cultures. An incubation temperature of 30 degrees C was optimum for effective degradation of alpha- and gamma-HCH isomers (62.5 and 57.7%, respectively) in liquid culture, and 54.3 and 51.9% rates of degradation of alpha- and gamma-HCH isomers, respectively, were found in a soil slurry. Increasing the soil/water ratio decreased the extent of degradation of both HCH isomers. Degradation of HCH isomers occurred concomitant with bacterial growth. Byproducts of growth from Pandoraea species significantly decreased the pH of the liquid and the soil slurry during the growth on HCH isomers.

[58]In another study examining biodegradation for HCH contaminated sites, researchers isolated a bacterium Pseudomonas aeruginosa ITRC-5 that mediates the degradation of all the four major isomers of HCH under aerobic conditions, both in liquid-culture and contaminated soils. In liquid-culture, the degradation of alpha- and gamma-HCH was found to be rapid and was accompanied with the release of 5.6 micromole chloride ions and 4.1 micromole CO2 micromole(-1) HCH-isomer. The degradation of beta- and delta-isomers was slow, accompanied with the release of 0.9 micromole chloride ions micromole(-1) HCH-isomer, and resulted in a transient metabolite 2,3,4,5,6-pentachlorocyclohexan-1-ol. The strain ITRC-5 also mediated the degradation of alpha-, beta-, gamma-, and delta-isomers in contaminated soils, where degradation of otherwise persistent beta- and delta-HCH was enhanced severalfold in the presence of alpha- or gamma-HCH. The degradation of soil-applied beta- and delta-HCH under aerobic conditions had not been reported earlier. The isolate ITRC-5 thus demonstrated potential for the bioremediation of HCH-wastes and contaminated soils.

(ii) Costs

Spain's and Netherlands's efforts in disposal of soils contaminated with HCH and lindane have been detailed in the previous section. Here the costs of these methods are outlined by Vijgen (2006).

[59] " The Basque Country Region of Spain spent over a decade and an estimated 50 million EUR to build the two secure landfills for wastes and contaminated soils. Of that total amount 8.4 million EUR was spent on the base catalyzed dechlorination process….

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[58] Kumar, M. et.al. 2005 .Enhanced biodegradation of beta- and delta-hexachlorocyclohexane in the presence of alpha- and gamma-isomers in contaminated soils. *Environ Sci Technol.* 2005 Jun 1;39(11):4005-11

[59] Vijgen, J. January 2006. The Legacy of Lindane HCH Isomer Production- A Global Overview of Residue Management, Formulation and Disposal. International HCH and Pesticides Association.

The Dutch government spent approximately 27 million EUR to clean up soil highly contaminated with waste HCH isomers in the eastern region of the Netherlands. Currently there are additionally 200 000 tons of less contaminated soils remaining that may need remediation in the future.

Lessons learned: The revenues generated from the sale of Lindane may be outweighed by costs associated with the clean up of waste isomers. If the waste HCH isomers had been promptly treated once produced, then contamination may have been minimized and the high costs of remediation and damage to the environment may have been avoided."

Regarding costs of disposal and management of HCH isomer wastes from the production of lindane, Vijgen (2006) goes on to say that "Comparing to other POPs and hazardous waste problems, the HCH-residuals differ significantly as the extent of the problem is huge and as an environmentally sound disposal by means of destruction will be necessary. However the enormous financial burden needed to achieve this will be a main barrier. On the other hand, the former practice of simple encapsulation is considered far from sustainable and will leave a huge number of time bombs in the global landscape.

A possible strategy could be to bring together a joint effort of international and financial organizations, as e.g. EU, GEF, World Bank, Industry and others, to set up demonstration projects. This could be accompanied by joint-cooperation of scientists, chemical industry and practitioners aiming at bringing the HCH residuals, consisting largely of chlorine, back into industrial production. This strategy could in fact bring forward economical solutions at the lowest possible price and the guarantee that the residuals will be eliminated permanently."

E. Access to information and public education:

[60] The North America Regional Action Plan on Lindane and Other Hexachlorocyclohexane (HCH) Isomers (NARAP) has laid out the following outreach and education steps for the parties of the North America Agreement on Environmental Cooperation (NAAEC), i.e. Canada, Mexico and United States of America.

Regarding lindane pharmaceutical uses:
"The Parties will strengthen outreach and education efforts to provide information on the possible risks associated with lindane and alternatives for the treatment of lice and scabies. Target groups may include but not be limited to:

- Local communities
- Educators
- Media
- Health care providers
- Medical associations

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[60] Commission for Environmental Cooperation. November 2006. The North America Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. http://www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf

• NGOs and health consortia
• Indigenous and Tribal organizations

This may include exchanging information on cautionary labeling, development of fact sheets, other guidance documents, workshop proceedings etc;
ii) The Parties are committed to sharing information regarding adverse events associated with lindane, new regulatory actions and education strategies in order to improve clinical practice standards in a harmonized way; and
iii) The Parties will ensure that all users including indigenous populations are suitably advised in a culturally acceptable manner on the possible risks associated with the pharmaceutical use of lindane, and inform them about alternatives."

Regarding lindane agricultural uses:

"i) The Parties will explore mechanisms to strengthen outreach and education efforts. This may include exchanging information on cautionary labeling, development of fact sheets, other guidance documents, workshop proceedings etc;
ii) The Parties are committed to sharing information regarding; adverse effects associated with lindane, new regulatory actions, education strategies, and worker safety;
iii) The Parties will ensure that indigenous populations are suitably advised in a culturally acceptable manner on the possible risks associated with the use of lindane, with the presence of lindane and/ or HCH isomers in the environment, with the risk of exposure through traditional foods, and on the use of available alternatives as applicable; and
iv) The Parties will undertake the implementation of "The Globally Harmonized System of Classification and Labeling" (GHS) consistent with the NAFTA Technical Working Group on pesticides initiative in order to provide consistency of labeling information for approved lindane applications as appropriate.

In addition to the outreach and education activities described under the specific uses of lindane, the Secretariat will encourage lindane manufacturers, formulators, and distributors to develop publicly available best practices for lindane use and application and extend these best practices into training and awareness programs for their clients."

F. Status of control and monitoring capacity:

[61]In the United States of America, the Centers for Disease Control and Prevention (CDC) publishes the National Report on Human Exposure to Environmental Chemicals, which provides an ongoing assessment of the exposure of the U.S. population to environmental chemicals using biomonitoring.

The Second National Report on Human Exposure to Environmental Chemicals (Second Report) was released in 2003 and presented biomonitoring exposure data for 116 environmental chemicals for the civilian, non-institutionalized U.S. population over the 2-year period 1999-2000. The Third Report (published in 2005) presented similar

[61] Department of Health and Human Services, Centers for Disease Control and Prevention. July 2005. Third National Report on Human Exposure to Environmental Chemicals. http://www.cdc.gov/exposurereport/3rd/pdf/thirdreport.pdf

exposure data for the U.S. population for 148 environmental chemicals over the period 2001-2002.

In these reports, chemicals or their metabolites were measured in blood and urine samples from a random sample of participants from the National Health and Nutrition Examination Survey (NHANES) conducted by CDC's National Center for Health Statistics. In each of these reports the level of HCH isomers or their metabolites present in the blood and urine a random sample of the U.S. population have been measured.

Thus constant monitoring of the levels of HCH isomers in U.S. populations has been maintained by the CDC.

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%. 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.

[62]Another international program that has been monitoring levels of HCH isomers over time in the Arctic region is the Arctic Monitoring and Assessment Program (AMAP).

The primary function of AMAP is to advise the governments of the eight Arctic countries (Canada, Denmark/Greenland, Finland, Iceland, Norway, Russia, Sweden and the United States) on matters relating to threats to the Arctic region from pollution, and associated issues.

AMAP is responsible for: "measuring the levels, and assessing the effects of anthropogenic pollutants in all compartments of the Arctic environment, including humans; documenting trends of pollution; documenting sources and pathways of pollutants; examining the impact of pollution on Arctic flora and fauna, especially those used by indigenous people; reporting on the state of the Arctic environment; and giving advice to Ministers on priority actions needed to improve the Arctic condition."

AMAP has produced a series of high quality scientifically-based assessments of the pollution status of the Arctic. The AMAP assessments are the result of cooperative efforts involving a large number of scientists, indigenous peoples' representatives, and representatives of the Arctic countries and AMAP observing countries and organizations. These assessments have provided a basis for development of the Arctic Council Action Plan (ACAP).

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[62] Arctic Monitoring and Assessment Program. http://www.amap.no/

Persistent Organic Pollutants (POPs) have been a prime focus of AMAP monitoring and HCH isomers have figured prominently in POPs monitoring by the AMAP.

G. Any national or regional control actions already taken, including information on alternatives, and other relevant risk management information:

As mentioned previously in this document, 52 countries have banned **all uses** of lindane. [63] **National and regional control actions taken on Lindane in North America**:

The **North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers** is a regional undertaking stemming from the North American Agreement on Environmental Cooperation (NAAEC) between the governments of Canada, Mexico and the United States of America. The North American Commission for Environmental Cooperation released the North America Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers in Nov 2006.

The NARAP states that "The three North American countries, Canada, Mexico, and the United States of America, under the auspices of the North American Commission for Environmental Cooperation, (CEC) have recognized that the organochlorine pesticide lindane and other isomers of hexachlorocyclohexane (HCH) may constitute a risk to human health and the environment.

The three Parties of the CEC also recognize that lindane and other isomers of HCH meet several internationally accepted criteria for persistence, bioaccumulation factors and toxicity. While lindane is no longer produced in North America, it continues to be used for varying applications and in different quantities in the three countries. Consequently, the Parties, through the development of this trilateral action plan, will reduce the risks from exposure to the various isomers of HCH, and where warranted, eliminate or ban uses of lindane in particular. This will be accomplished through regulatory and management actions, outreach and education efforts, science and research, capacity building, and collaborative cross-border activities.

On a regional basis, the three Parties will work together to implement the actions described in this plan. A key recommendation is to establish a tri-lateral implementation task force consisting of national representatives with expertise in the fields of health and environmental aspects of lindane and other HCH isomers, to oversee these activities. In addition, based on information gained through the development of this regional action plan, the Parties will participate in other international initiatives to promote emissions reductions from other global sources of lindane.

On a national basis, each Party will address lindane and other isomers of HCH as indicated in the action plan."

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[63] Commission for Environmental Cooperation. November 2006. The North America Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. http://www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf

Regarding alternatives to lindane, the NARAP lists in Annexes C,D, and E the available alternatives to the pharmaceutical and pesticidal uses of lindane in USA, Canada and Mexico. Annex F in the NARAP lists Available Non-Chemical Alternatives to Agricultural Seed Treatment Uses of Lindane

As mentioned in previous sections of this document the three North American governments have taken the following control actions regarding lindane as described in the NARAP,

In Canada: 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.

Lindane 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 recommended treatment options for lice (please see http://www.santepub-mtl.qc.ca/Mi/pediculose/pdf/depliant0304A.pdf).

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.

As of January 1, 2005, Lindane is no longer registered for agricultural pest control uses, including veterinary uses, in Canada.

Lindane is also subject to regulation under the Canadian *Food and Drugs Act.* The *Food and Drugs Act* prohibits the sale of food containing pesticide residues at levels in excess of 0.1 ppm unless specific Maximum Residual Levels (MRLs) are established in Table II of the regulations. The Food and Drugs Act regulations apply equally to imported or domestic commodities.

In Mexico:

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. 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.

Pharmaceutical uses of lindane in Mexico include formulation of creams and shampoos for scabies and lice treatment.

Mexico has agreed to eliminate all agricultural, veterinary, and pharmaceutical uses of lindane through a prioritized, phase-out approach. Reasonable timeframes for a voluntary phase out are currently being negotiated between the Federal Commission for Sanitary Risks Protection, Ministry of Health (COFEPRIS) and industry.

In the United States of America

On August 2, 2006, the U.S. Environmental Protection Agency released an Addendum to the Reregistration Eligibility Decision regarding lindane's agricultural uses. The Agency has found that the costs of continued lindane registration outweigh the benefits of the remaining seed treatment uses. Cancellation of these uses is expected to result in no significant loss to U.S. agriculture due to the successful development and registration in recent years of safer alternatives.

Prior to the 2006 voluntary cancellation requests, greater than 99% of lindane used in the United States was for agriculture.

Lindane use is approved by the US Food and Drug Administration (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.

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.

In Europe:
[64]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.

H. Other relevant information for the risk management evaluation:

I. Other information requested by the POPRC

[64] Commission for Environmental Cooperation. November 2006. The North America Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers. http://www.cec.org/files/PDF/POLLUTANTS/LindaneNARAP-Nov06_en.pdf