The North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers

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Commission for
Environmental Cooperation

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Executive Summary

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. As of January 1, 2005, there are no registered agricultural or veterinary uses of lindane in Canada. Canada has agreed to assess and manage risks from its sole remaining use of lindane as a pharmaceutical drug. Canada will address waste management issues, promote science and research, and strengthen outreach and education.

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. Lindane is currently authorized for use in Mexico on livestock, as a seed treatment on six crops, as a flea treatment on domestic animals, and for public health campaigns. Lindane is also authorized for pharmaceutical use to control scabies and lice.

The United States has received requests for voluntary cancellation from all lindane US registrants for all remaining US registrations of lindane pesticide products and plans to accept the producers' voluntary cancellation requests. The United States has reviewed the six remaining lindane seed treatment uses and determined that the remaining uses are not eligible for reregistration.. The United States will facilitate development of alternatives to lindane to treat lice and scabies, and to strengthen awareness raising initiatives regarding the remaining use of lindane as a pharmaceutical drug for

applications involving children. There are no registered uses of lindane for veterinary purposes in the United States.

The Parties enlisted and received input through a regional task force, from various experts and representatives of indigenous peoples, children's health interests, environmental organizations, and industry in preparing this "*North American Regional Action Plan on Lindane and other HCH Isomers.*" Public meetings were held to solicit additional input and to enlist the aid of experts in toxicology, atmospheric transport, epidemiology, wildlife concerns and indigenous/tribal issues.

Prior to its approval, this plan will have undergone extensive national public and private stakeholder review. This document represents the consensus opinion of the three national governments. It is anticipated that the implementation of this action plan will be conducted in stages with short term, medium term, and long term goals over the next 10 years.

Common Acronyms

CEC	Commission for Environmental Cooperation
HCH	Hexachlorocyclohexane
LRTAP	Long-Range Transboundary Air Pollution
NARAP	North American Regional Action Plan
NAAEC	North American Agreement on Environmental Cooperation
POPs	Persistent Organic Pollutants
SSTF	Substance Selection Task Force
SMOC	Sound Management of Chemicals
US FDA or FDA	United States Food and Drug Administration
US EPA or EPA	United States Environmental Protection Agency

1. Preface

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.

As a parallel side agreement to the *North American Free Trade Agreement* (NAFTA), the NAAEC came into force in January 1994 and established the Commission for Environmental Cooperation (CEC) to "facilitate cooperation on the conservation, protection and enhancement of the environment in their territories." Further information on the NAAEC, the CEC, and the mandate to develop NARAPs is available at: http://www.cec.org/.

NARAPs reflect a regional commitment by the Parties to work cooperatively on chemicals of mutual concern and build upon international environmental agreements and existing policies and laws by:

- bringing a regional perspective to international initiatives that are in place or being negotiated with respect to persistent toxic substances;
- promoting cooperation with Latin American and Caribbean nations and with countries that have territories in the high Arctic;
- encouraging harmonized trade and environment policies that are conducive to the conservation, protection and enhancement of the environment in their territories: and,
- sharing information, risk assessments, and other expertise and experience.

An important dimension of the NARAPs is the formation of close working relationships among the national governmental bodies that address persistent and toxic substances in the three countries. The NARAPs are also intended to help facilitate the meaningful participation of the public, including non-governmental organizations; business and industry; indigenous peoples; provincial, state and municipal governments; academia; and technical and policy experts. At the same time, each NARAP is unique and recognizes the different responsibilities of each of the three partner countries. Council Resolution 95-05 and the Regional Action Plans developed pursuant to it, also take into account each country's respective natural endowments, climate and geographical conditions, and economic, technological and infrastucture capabilities.

NARAPs have been developed for polychlorinated biphenyls (PCBs), dichlorodiphenyltrichloroethane (DDT), chlordane and mercury. At the time of preparation of this NARAP, a NARAP on environmental monitoring and assessment has entered its implementation phase and Phase I of the NARAP for dioxins, furans, and hexachlorobenzene is under implementation while Phase II is under development. In addition, lead has been recommended as a candidate for trilateral action. These NARAPs are on the web at: www.cec.org/programs_projects/pollutants_health/smoc/.

2. Preamble

Recognizing that lindane and other isomers of HCH are persistent, bioaccumulative and toxic organochlorines no longer produced in North America, but lindane continues to be used for varying applications and in different quantities in Canada, Mexico and the United States;

noting that 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;

recognizing lindane and other HCH isomers' potential for long-range atmospheric and oceanic transport regionally and globally;

realizing the important relationship of traditional foods consumption for the subsistence diet of indigenous people and isomers of HCH concentrations in human milk and body fat; and

being aware of Council Resolution 02-07, committing to the development of a North American Regional Action Plan to reduce or eliminate the uses of lindane;

the Parties hereby intend to work cooperatively to build on policies and laws and to improve capacities in order to reduce or eliminate the use of lindane in North America. In addition, the Parties intend to promote similar initiatives on a global basis.

Furthermore based on extensive consultations with the public as well as on the expert advice of the North American Substance Selection Task Force, it was decided that sufficient rationale exists for the development and implementation of a *North American Regional Action Plan on Lindane and other HCH Isomers* in order to reduce the risks associated with exposure to this substance.

3. Introduction

In April 2000, the Substance Selection Task Force (SSTF), working under the direction of the Sound Management of Chemicals (SMOC) Working Group of the CEC, submitted their conclusions that lindane and other HCH isomers "pose risk to humans and wildlife" in North America[1]. The SSTF acknowledged that lindane is of regional concern and that there would be real benefits obtained from collective action in the development and implementation of a *North American Regional Action Plan on Lindane*. It was also recommended that this Action Plan should identify issues related to key implementation measures.

Following these recommendations, in July 2002, the CEC Council of Ministers issued Resolution 02-07[2] directing the SMOC Working Group to develop a NARAP on lindane. Further information is available at: www.cec.org/programs_projects/pollutants_health/smoc/.

This NARAP is a voluntary, non-binding document. It does not constitute an international agreement and does not give rise to rights or obligations under local, national or international law.

What are "Lindane and other HCH Isomers"?

Lindane and other HCH isomers are in a family of manufactured substances known as organochlorine chemicals. In this case, the HCH isomers have one basic chemical structure, 1,2,3,4,5,6-$C_6H_6Cl_6$, but the chlorine atoms are found in varying orientations in the molecule, leading to different properties for the different isomers. Lindane is the only HCH isomer that exhibits insecticidal properties.

HCH or hexachlorocyclohexane was first synthesized in 1825 by reaction of benzene with chlorine in the presence of sunlight (ultraviolet-radiation) to produce what was then called BHC or "benzene hexachloride". This terminology is no longer used. Current nomenclature refers to technical HCH which is a mixture of all the isomers and was used as a pesticide prior to the isolation of the only active isomer, gamma HCH or lindane.The insecticidal properties of technical HCH were first described in the 1940s and the active gamma-isomer was named lindane after Van Linden, discoverer of the alpha and gamma-isomers.

HCH has been commercialized in two predominant products: technical HCH and purified gamma isomer, lindane. Technical HCH contains about 60-70% alpha-HCH, 5-12% beta-HCH and 10-15% gamma-HCH. These are the three most environmentally significant isomers.

The nomenclature of lindane and other HCH isomers has caused confusion in the past. In the context of this NARAP, lindane refers solely to the gamma-isomer of hexachlorocyclohexane.

[1] Decision Document on Lindane, April 2000, page 19.
[2] See Council Resolution 02-07.

3.1. Goals and Objectives

The goals and objectives of the *North American Regional Action Plan on Lindane and other HCH isomers* are to:

- cooperatively take actions within the three member countries towards the reduction of exposure of humans and the environment to lindane and other HCH isomers; by
    - reducing or eliminating uses,
    - providing and promoting outreach and education in North America,
    - encouraging science and research,
    - encouraging the use of safer alternatives,
    - engaging in capacity building through the development of strong and effective partnerships, and
    - strengthening working relationships between regulatory agencies in the three countries.

3.2. Guiding Considerations

This NARAP takes into account, as appropriate, the considerations contained in:

- *Agenda 21: A Global Action Plan for the 21st Century* adopted at the 1992 United Nations Conference on Environment and Development, in particular Chapter 19 on the sound management of chemicals and the precautionary approach as stated in Principle 15 of Agenda 21 and adopted at the Rio Declaration;
- The Persistent Organic Pollutants Protocol to the Convention on Long-Range Transboundary Air Pollution, negotiated under the auspices of the United Nations Economic Commission for Europe;
- The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade;
- The Great Lakes Binational Toxics Strategy: Canada-United States Strategy for the Virtual Elimination of Substances in the Great Lakes; and
- The North American Agreement on Environmental Cooperation (NAAEC).

In addition, this NARAP takes into account, at a regional level:

- the Stockholm Convention on Persistent Organic Pollutants, including the requirement in Article 3.4 of this convention that calls on Parties with regulatory and assessment schemes for pesticides and industrial chemicals to take into consideration within those schemes the Agreement's criteria for persistence, bioaccumulation, toxicity, and long-range transport; as well as,
- the objectives and initiatives outlined in various declarations published by the Arctic Council[3] expressing their concerns regarding persistent organic pollutants, particularly lindane and other isomers of HCH in the Circumpolar region.

[3] The Arctic Council is a high-level intergovernmental forum that provides a mechanism to address the common concerns and challenges faced by the Arctic governments and the people of the Arctic, http://www.arctic-council.org/

3.3. Background and Rationale

3.3.1. Long-range Transport, Exposure, Bioaccumulation, and Toxicity Considerations

Lindane is a persistent, toxic organochlorine that continues to be used for varying applications and in different quantities in Canada, Mexico and the United States. Technical HCH, containing lindane and other isomers, was deregistered in Canada and the USA in 1978; in Mexico since 1987, when official registration of pesticides was started, lindane was registered as a pesticide, whereas technical HCH was never registered for use.

Lindane meets criteria for persistence and bioaccumulation as described in the April 19, 2000 *Decision Document on Lindane* prepared by the Substance Selection Task Force for the Sound Management of Chemicals Working Group of the CEC. The Decision Document can be found at: http://www.cec.org/pubs_docs/documents/index.cfm?varlan=english&ID=1032.

The following information has largely been gathered from the Decision Document as well as references found at: www.cec.org/lindane.

Long-Range Transport

Like other persistent organic pollutants, lindane and other isomers of HCH can be transported over long distances by air currents[4]. 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.

Persistence and Environmental Fate

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.

Bioaccumulation

Lindane and other HCH isomers can bio-accumulate easily in the food chain due to their 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.[5] Lindane and other HCH isomers occur in different 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

[4] Recent information suggests alpha – HCH to have a travel distance of 18,000 to 22,000 kms and lindane a travel distance of 2,400 to 12,600 kms as per Shen, L.; Wania, F.; Lei, Y. D.; Teixeira, C.; Muir, D. C. G.; Bidleman, T. F, Atmospheric Distribution and Long-Range Transport Behavior of Organochlorine Pesticides in North America, *Environ. Sci. Technol.;* (Article); 2005; *39*(2); 409-420

[5] World Health Organization (WHO). 1991. Lindane (Environmental Health Criteria 124). 208 pp.

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.[6] 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.[7]

Lindane has a log bioaccumulation factor (BAF) of 4.1, exceeding the level of concern (log BAF>3.7) determined by the CEC's Substance Selection Task Force.[8]

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.[9]

Exposure

There are two significant pathways for lindane to adversely impact human health. These include intake of food and drinking water containing traces of lindane and its isomers as contaminants, and direct exposure, such as agricultural workers (e.g., seed treaters) or persons to whom lindane has been applied as a treatment for head lice or scabies.

General Exposure

The most wide-spread exposure to lindane for the general public is through food consumption or as a topical treatment for head lice and scabies. Currently lindane is allowed to be used as a pre-plant seed treatment in Mexico. This seed treatment use is being voluntarily canceled in the United States. Crops grown from treated seeds may result in dietary exposure. Adverse affects on children's health are a particular concern in regions where lindane is applied directly to milk and meat producing livestock for pest control. This use has been cancelled in the United States and Canada. On a body weight basis, children consume more milk per unit body weight than adults, and thus may be exposed to significant concentrations of lindane residues. Moreover, children's direct exposure to lindane pharmaceutical products requires careful attention to ensure proper use.

Subsistence Exposure

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.

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[6] Solomon GM and Weiss PM. 2002. Chemical contaminants in breast milk: Time trends and regional variability. Environmental Health Perspectives 110: A339-A347.

[7] Willett KL, Ulrich EM, Hites RA.1998. Differential Toxicity and Environmental Fates of Hexachlorocyclohexane Isomers. Environmental Science & Technology 32: 2197-2207.

[8] Decision Document on Lindane, April 2000, page 4.

[9] Re-registration Eligibility Decision Document for Lindane case 315, USEPA, Office of Prevention, Pesticides and Toxic Substances, September 25, 2002, pg 28.

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.

Human Toxicity

A wide variety of toxicological effects are recorded for lindane and other isomers of HCH, such as reproductive and neurotoxic impairments. Lindane has also demonstrated a potential to adversely affect endocrine systems in animals. Effects from acute exposure at high concentrations to lindane may range from mild skin irritation to dizziness, headaches, diarrhea, nausea, vomiting, and even convulsions and death. Toxicological data indicate that chronic exposure to lindane at high concentrations can adversely affect the liver and nervous system of animals, and may cause cancer and possibly immune system suppression.[10]

Ecotoxicity

The toxicology of alpha, beta- and gamma-HCH isomers has been studied extensively in mammals and to a lesser extent in fish and insects. Lindane is moderately toxic to birds and mammals following acute exposures. Chronic effects to birds and mammals measured by reproduction studies show adverse reproductive effects at low levels, with some effects indicative of endocrine disruption. Acute aquatic toxicity data on lindane indicate that it is very highly toxic to both freshwater and estuarine species. Chronic aquatic toxicity data for freshwater organisms show that reduced growth and reproduction were the most sensitive endpoints to lindane testing. Similar levels of toxicity are expected for estuarine and marine organisms.

Toxicity and Persistence of Other HCH Isomers

As with lindane, all other isomers of HCH cause acute and chronic neurotoxic effects and can produce liver and kidney effects. The alpha isomer also shows some evidence of immunosuppression and blood effects. In past reviews, EPA has classified technical-grade HCH (i.e., predominantly alpha-HCH) as a probable human carcinogen. Beta-HCH has been classified as a possible human carcinogen, while delta-HCH has been designated as not classifiable for human cancer. The International Agency for Research on Cancer (IARC) also has classified technical HCH and alpha HCH as possible human carcinogens. It considers evidence for carcinogenicity in the beta and gamma isomers as limited. Further, EPA has classified HCH as a hazardous waste that must meet certain disposal requirements.

The chronic effects of the beta-HCH isomer are of particular interest because of its predominance among all HCH isomers in mammals, including humans, and its apparent long biological half-life. A half-life of 7.2 years has been estimated for beta-HCH in humans. Beta-HCH has been described as producing estrogen-like effects through nonclassical

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[10] Based on all available data received through 2001, US EPA has classified lindane in the category “Suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential” based on an increased incidence of benign lung tumors in female mice only. The US Center for Disease Control’s (CDC) Agency for Toxic Substances and Disease Registry (ATSDR) concurs with EPA's classification. However the Joint Meeting on Pesticide Residues (JMPR) of the World Health Organization (WHO) concluded that "...lindane is not likely to pose a carcinogenic risk to humans."
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estrogen-dependent mechanisms of action.[11] The bioconcentration factor is higher and the elimination is slower for beta-HCH than for the other HCH isomers.

The reasons for variable compositions of HCH isomers in wildlife tissue are unknown. Possible explanations include "different sources of contamination; different times of exposure; and differences in uptake, metabolism, or storage by various species."[12]

3.3.2. Production of Lindane and other HCH Isomers

Lindane and its precursor technical hexachlorocyclohexane, or technical-HCH, do not occur as natural substances. The manufacture of technical-HCH involves the photochlorination of benzene which yields a mixture of five main isomers. These isomers and their typical yield are listed in Table 1 below:

Table 1: Ratio of Isomers in the Production of Technical HCH

HCH Isomer	Percent in synthesis mixture
Alpha-HCH	60 -70
Beta-HCH	5-12
Gamma-HCH (Lindane)	**10-15**
Delta-HCH	6-10
Epsilon-HCH	3-4

This mixture of technical-HCH isomers is subject to fractional crystallization and concentration to yield 99% pure lindane, produced at a 10-15 percent yield from this mixture. From a waste perspective this means for every tonne of lindane that is produced, there are 6 – 10 tonnes of other isomers that must be disposed of or otherwise managed. As mentioned previously, lindane is the only isomer in the mixture that has insecticidal properties.

Because of the waste isomer problem, the production of HCH/lindane has been a worldwide problem for years. One management option reported by industry is to transform the waste isomers into the solvent trichlorobenzene. The International HCH and Pesticide Forum exists in order to bring together experts to solve the myriad of problems associated with the clean-up of former HCH/Lindane production sites. Further information on this Forum can be found at www.hchforum.com/forumInfo.php.

Two case studies on the legacy of the HCH waste isomer issue can be found in Annex A of this NARAP.

Production Status of HCH/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

[11] Steinmetz, R., P. C. M Young, A.Caperell-Grant, E.A. Gize, B.V. Madhukar, N. Ben-Jonathan, R.M. Bigsby. 1996. Novel estrogenic action of the pesticide residue beta-hexachlorocyclohexane in human breast cancer cells Cancer Res. 56, 5403-5409

[12] Willett KL, Ulrich EM, Hites RA. 1998. Differential Toxicity and Environmental Fates of Hexachlorocyclohexane Isomers. Environmental Science & Technology 32: 2197-2207.

former lindane production site in Nevada 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.[13]

Only India and Romania[14] currently produce lindane for the world market. China stopped manufacturing lindane in 2003. Additional summary information on production from these countries can be found in Annex A.

3.3.3. Overview of Use of Lindane in North America

Over the last several years, countries in North America have been working to limit or phase out uses of lindane. As a result, the use of lindane in North America has declined significantly. At the time that the CEC Council approved the development of this NARAP in 2002, lindane was registered for use in the region in the agricultural sector for the: a) pre-plant treatment of seeds for certain grain and vegetable crops (e.g., barley, corn, wheat, and other small grains); b) protection against insect pests; c) veterinary sector to treat livestock and their bedding; d) public health sector as a treatment for external parasites such as head lice and scabies[15]; e) forestry sector to protect trees and seedlings from various insect pests; and f) home and garden use and the treatment of pets. The public health/pharmaceutical uses of lindane were included in this NARAP based on April 2000 guidance from the SMOC Working Group. The following is a brief overview of the historical and current status of lindane in each of the three countries.

3.3.4. History and Current Status of Lindane in Canada

General Considerations

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. This current use of 6 kg per year of lindane is not a significant source, representing 0.005% to 0.007% of the North American total use.

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 (please see http://www.santepub-

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[13] 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.

[14] 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 would become subject to the European Community regulations on POPs and the "Romanian production site will have to be closed down in the near future".

[15] In the Substance Selection Task Force's "*Decision Document on Lindane Under the Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative*," it was is noted that in each of the three countries, the public health and insecticide and pesticide uses are regulated under separate authorities. Therefore, recognizing this situation, it was also recommended that if a NARAP on lindane was developed, that the Task Force include members from both the public health and pesticide and insecticide regulatory agencies from each country. Although public health/pharmaceutical uses are not as a general matter within the scope of SMOC activities, in the case if lindane it was viewed as being appropriate and that the Lindane Task Force membership should be comprised of subject-matter experts.

mtl.qc.ca/Mi/pediculose/pdf/depliant0304A.pdf). Following the reassessment of lindane safety by the United States Food and Drug Administration (FDA) in March 2003 and subsequent communication to Health Care Professionals and the general public, a joint decision was made by the Therapeutic Products Directorate (TPD) and the Marketed Health Products Directorate (MHPD) of Health Canada to reassess the safety of the human pharmaceutical uses of lindane in Canada. The product has always been available without prescription.

Agricultural and Veterinary 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 use of lindane was phased out on the basis of unacceptable risk to the health of workers exposed to lindane during seed treatment and planting. All registrants of lindane seed treatment products, except Crompton, chose to voluntarily discontinue sales of their products.

As is their right under section 23 of the Pest Control Product Regulations, Crompton Corp. requested a hearing by an independent board to review the PMRA decision with respect to its lindane products. On August 18, 2005, the Board submitted a report of its findings and recommendations to the Canadian Minister of Health. Information on the Board of Review and their report is available at http://www.pmra-arla.gc.ca/english/lindane/lindane-e.html.

As recommended by the Board, the PMRA is initiating a follow up review of the occupational exposure assessment of lindane. To ensure that the risk management decision on the use of lindane products is made with a clear understanding of all the risks, the PMRA is also completing the special review of lindane. This includes completing the human health risk assessment of areas not addressed in the previous evaluation (e.g. carcinogenicity) as well as finalizing the assessment of risk to the environment, in

collaboration with Environment Canada and the United States Environmental Protection Agency. Further information on PMRA's activities is available from the PMRA website at http://www.pmra-arla.gc.ca/english/lindane/lindane-e.html.

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.

Pharmaceutical Uses

Lindane is approved in Canada for lice and scabies treatment as a non prescription drug with 4 commercial products containing 1% lindane in solution, currently marketed by 2 companies.

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.[16] 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.

Labelling requirements for lindane pharmaceutical products are available on-line:

Lindane Lotion:
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/Lindanel_e.html

Lindane Shampoo:
http://www.hc-sc.gc.ca/hpfb-dgpsa/tpd-dpt/Lindanes_e.html

3.3.5. History and Current Status of Lindane in Mexico

General Considerations

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, and it is mandatory to report on lindane industrial releases.

[16] Calculation based on sales data obtained from IMS Health Inc., 2003

Mexico has recently released the *Mexican National Diagnostic on Lindane*[17] (see Section 4.1.2. below) to support activities under this NARAP, and is preparing a National Implementation Plan for POPs management under the Stockholm Convention.

Agricultural, Veterinary and Other 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. 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 per year. Estimation of the number of treatments is not currently available.

3.3.6. History and Current Status of Lindane Use in the United States of America

General Considerations

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, Veterinary, and Other 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

[17] See <http://www.ine.gob.mx/dgicurg/download/Proyectos-2003/EL_LINDANO_EN_MEXICO.pdf>

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 were 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.

In response to the RED, EPA received public comments stating that the other HCH isomers should also be considered in the Agency's decision-making process. Consistent with the RED comments, the Agency has prepared an assessment that considers risks from exposures to the other HCH isomers. On February 8, 2006, the Agency released that assessment to the public for a 60-day public comment period (71 FR 6479) and received comments from the public. The assessment indicates potential risks from dietary exposure to the alpha and beta HCH isomers to communities in Alaska and others in the circumpolar Arctic region who depend on subsistence foods. EPA has carefully considered all comments received on the risk assessment and on the RED.

The United States has received requests for voluntary cancellation from all lindane US registrants for all remaining US registrations of lindane pesticide products. The United States plans to accept the producers' voluntary cancellation requests, following an announcement of these requests in the Federal Register. Once the cancellation process is complete, EPA will propose to revoke the existing tolerances or limits for residues of lindane in animal fat.

In addition, the US has reviewed the six remaining lindane seed treatment uses and has made a determination that the remaining uses are not eligible for reregistration. On August 2, 2006, the Agency released an Addendum to the Reregistration Eligibility Decision that describes this conclusion. The Agency has found that the costs of continued lindane registration outweigh the benefits of the remaining seed treatment uses listed above. 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.

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.

3.3.6.1. Phase-out of Lindane in California

The state of California has taken regulatory action on lindane. In May 2000, the California Toxics Rule (CTR)[18] 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.[19] 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 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[20] . 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.

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[18] 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

[19] Nationally Recommended Water Quality Criteria; Notice. December 7, 1988. Federal Register; 67548.

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

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.[21] Since 1999, CDHS has recommended against the use of lindane for scabies[22] and against its use for head lice since 1987[23]. Prior to the ban, CDHS issued guidelines to all physicians to use malathion instead of lindane.[24]

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.

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.

Status of Lindane Internationally

Lindane and other HCH isomers are also of concern to human health and the environment beyond North America, and are the subject of regulations and international agreements.

International Regulation of Lindane

Based on information collected from a variety of sources, lindane is banned for use in 52 countries, restricted or severely restricted in 33 countries, not registered in 10 countries, and registered in 17 countries. A summary list of these countries is included as Annex B and was derived from information found at http://www.cec.org/lindane.

Several countries in Europe still allow restricted use of lindane. 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

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

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

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

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

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, go to: http://europa.eu.int/comm/environment/pops/index_en.htm.

International Agreements and Treaties

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 had to have 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, go to: www.epa.gov/glnpo/bns/.

The use of lindane has been addressed in at least two international treaties. The first is the 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs). This is 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 POPs Protocol entered into force in October 2003. The UNECE region includes the Russian Federation, 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 April 29th, 2006 there are 36 Signatories and 25 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, go to: www.unece.org/env/lrtap/pops_h1.htm.

In August 2004, Austria prepared a technical report on lindane, as part of a scheduled reassessment under the Protocol of all restricted uses of Lindane. For this report, go to: www.unece.org/env/popsxg/mtg_tf_pops.htm.

The second is 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. It is legally-binding for Parties. As of March 28th, 2006, PIC has 106 Parties. The PIC includes lindane and as of December 2005, 34 countries have banned all import of lindane and 38 have restricted or severely restricted the conditions under which it may be imported. Under the PIC, among other obligations, when an importing country communicates “no consent” to imports of a particular chemical, 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 and Mexico are Parties and the United States has signed, but not ratified the Rotterdam Convention. To view the list of countries that do not allow the import of lindane, go to page 167 of the PIC Circular, which can be found at: http://www.pic.int/en/Circular/CIRC22EN.pdf

Related International Activities

The Stockholm Convention on POPs is a legally-binding treaty that calls for the eventual global elimination of an initial list of 12 POPs with specific criteria and guidelines for adding new POP substances. It entered into force in May 2004 and is legally-binding for Parties. Lindane is not on the initial list of 12 substances. The Stockholm Convention was signed by 151 nations in May 2001 and has been ratified by 124 nations as of May 17th, 2006. There are specific criteria to satisfy for adding additional substances to the Convention, including persistence, bio-accumulation, potential for long-range environmental transport, and adverse effects. Canada and Mexico are Parties and the United States has signed, but not ratified the Stockholm Convention. At the first Conference of Parties to the Stockholm Convention held in May 2005, Mexico indicated that they will be nominating lindane to be added to the Convention. In June 2005, Mexico submitted a proposal to the Stockholm Convention to add lindane to Annex A for elimination In November 2005, the POP Review Committee decided that lindane fulfilled the screening criteria in Annex D of the Convention and that an ad hoc working group be established to prepare a draft risk profile in accordance with Annex E. Mexico is leading that effort. For additional information on the Stockholm Convention, go to: www.pops.int.

4. Actions

COMMITMENT TO ACTION

The CEC Council recognizes that, during the public meetings, many North Americans expressed serious concern regarding the degree to which the recommendations in the plan may be implemented. While it is acknowledged that the regional Action Plans developed under the Sound Management of Chemicals initiative are not legally binding upon any one or all of the Parties to the North American Agreement on Environmental Cooperation, there is a strong resolve by each member country and an equal determination by the Parties as leaders in this important environmental initiative to ensure that this Action Plan results in significant reductions of lindane contamination to the environment.

The CEC Council further directs the Sound Management of Chemicals Working Group to ensure that the actions outlined in this plan are undertaken through the oversight of an Implementation Task Force.

The actions that the countries will take to reduce human and environmental exposure to lindane are national, regional and global in scope. Described below are the specific activities that the Parties and the CEC Secretariat will support to meet the goals and objectives of the NARAP.

4.1. National Actions

The following section describes the actions that the individual countries will take to reduce the risk of exposure to lindane and its isomers in the context of human health and the environment.

4.1.1. Canada

In addition to the primary actions regarding pharmaceutical use of lindane, Canada will undertake supporting actions in waste management; science and research; and outreach and education as well as work cooperatively with Mexico and the United States of America on regional efforts to strictly reduce or eliminate use of lindane and other HCH isomers.

Pharmaceutical

Health Canada will:

- consider developing a fact sheet for health care professionals on therapeutic uses, known risks, and potential environmental impact from the use of the product;
- move towards conducting an environmental impact assessment. In the development of environmental assessment regulations, Health Canada intends to ensure that provisions exist to manage existing substances.

- revisit the labeling of products containing lindane if necessary after completion of the analysis of the safety of the product for pharmaceutical use;
- take any other risk mitigation measures that may be deemed necessary following the safety analysis; and
- continue to monitor for evidence of unsafe and excessive use of lindane by using the Canadian Adverse Drug Reactions Monitoring Program.

Waste Management

Health Canada will:

- assess exposure of surface and ground water to lindane; and
- assess the effectiveness of current waste water treatment facilities to remove lindane from effluents.

Science and Research

Environment Canada will:

- continue to monitor Lindane and other HCH isomers, as warranted, in the biotic and abiotic compartments of various regional ecosystems, including Canada's North, Great Lakes-Gulf of St. Lawrence, and Arctic, Atlantic and Pacific coasts.

Outreach and Education

Health Canada will:

- strengthen outreach and education efforts to the public and medical community to encourage lindane's safe and appropriate clinical use; and
- share information as available under international agreements, with the US and Mexico, regarding adverse events associated with lindane, any new regulatory actions and education strategies in order to raise clinical practice standards in a harmonized way.

4.1.2. Mexico

The Mexican governmental agencies are currently reviewing the exact terms for a national action plan and possible deadlines for the phasing out of lindane**.** The following actions are being incorporated:

Pharmaceutical

- Limited imports of lindane during 2005;
- Companies are being informed of the decision to phase out lindane; and
- Timeframes for phase out to be developed by COFEPRIS (Federal Commission for Sanitary Risks Protection, Ministry of Health) and pharmaceutical companies.

Agriculture and Veterinary

- No imports of lindane for agriculture and veterinary uses have been authorized since January 2005;
- Companies are being informed of the decision to phase out lindane;
- Timeframes for a phase out to be developed by COFEPRIS (Federal Commission for Sanitary Risks Protection, Ministry of Health) and agrochemical companies;

- One company has voluntarily cancelled its registration and is planning to dispose of stocks during 2005; and
- Cancellation of the Secretariats' registration will take place once reasonable timeframes are set.

Science and Research

- Revision of available data on chemical and non-chemical alternatives (effectiveness, relative toxicity, price); and
- Include lindane and other HCH isomers analysis in ongoing or future research projects.

Outreach and Education

- National diffusion, promotion, dissemination and education campaign.

4.1.3. United States of America

To further reduce exposure to lindane and other HCH isomers, and in order to meet the goals and objectives of the NARAP, the United States is also taking the actions listed below.

Pharmaceutical

- The US Food and Drug Administration (FDA) will work proactively with pharmaceutical companies to facilitate the development of alternatives to lindane for the treatment of lice and scabies.
- The US FDA will continue to monitor for evidence of unsafe and excessive use.
- All lice and scabies treatments, including lindane, may show lack of efficacy, and thus it is important to have a number of treatments available. At this time lindane will remain on the market as a second-line treatment. Current alternatives to lindane are products that have been associated with increasing resistance (by lice), as well as unapproved highly toxic household and garden substances, including other pesticides..
- The Indian Health Service will review lindane orders for 2004 and will follow up with the facilities that ordered a substantial amount of lindane, based on the population served and relative to the number of other products used, to determine how lindane products are being used. If needed, education will be provided to the local staff on available alternatives to lindane.
- As soon as possible, the National Pharmacy and Therapeutics Commission will review the treatment of scabies and lice and provide treatment guidelines for the Indian Health Service and tribal health care providers.

Agriculture – Pesticide

- The US EPA has received requests for voluntary cancellation of all remaining lindane pesticide registrations and plans to accept the producers' voluntary cancellation requests.
- The US EPA has reevaluated the continuing registration of seed treatment uses and;

- The US EPA has determined that the remaining pesticidal uses of lindane are ineligible for reregistration and plans to accept the registrants' voluntary cancellation requests;
- Once the cancellation process is complete, the US EPA will propose to revoke the existing tolerances or limits for residues of lindane in animal fat.
- The United States has assessed risks resulting from human and environmental exposures to other HCH isomers.
- The United States has worked towards making sure that alternative pesticides are available to growers for all of the seed treatment uses of lindane in the United States by facilitating a review of the registration of alternative products for treatment of oat and rye seed.

Science and Research

- The United States will continue to monitor for lindane residues in food.
- The United States will continue to monitor for lindane in the Integrated Atmospheric Deposition Network (IADN) program and the Great Lakes Fish Monitoring program.
- The United States will continue to monitor for lindane and its isomers in the National Fish Tissue Study.

Outreach and Education

- The US EPA is implementing projects with China and India that are expected to reduce use and emissions that result in long range transport of lindane and its waste isomers.
- The US FDA is committed to strengthening outreach and education efforts to the public and the medical community to encourage that any clinical use of lindane follow the latest labeling, including that it should not be used unless first-line therapy has failed or is not tolerated.
- The US FDA is committed to share information, as allowed under international agreements, with Canada and Mexico regarding adverse events associated with lindane, new regulatory actions, and education strategies in order to raise clinical practice standards in a harmonized way.

4.2. North American Regional Actions

Recognizing that the allowable uses of Lindane are:

i) in Canada (as of January 1, 2005), only as a pharmaceutical drug to treat lice and scabies;

ii) in Mexico, for agricultural ectoparasite control of livestock, seed treatment for six crops; for veterinary flea treatment of domestic animals; for scorpion control (although not recommended anymore by the Ministry of Health); and as a pharmaceutical drug to treat lice and scabies; and

iii) in the United States, (after the pesticide cancellation process is complete) only as a pharmaceutical drug to treat lice and scabies as a second line treatment;

The following section describes recommended North American regional actions, where appropriate, proposed for reduction of risk with emphasis on:

1. Pharmaceutical uses

2. Agricultural uses for veterinary applications
3. Agricultural uses for seed treatment application
4. Waste management
5. Science and research
6. Outreach, communications and education
7. Trade issues
8. Ensuring compliance and
9. Leveraging resources

Consistent with their individual national laws and legislative authorities the Parties commit to the following:

4.2.1. Pharmaceutical

Recognizing that lindane is approved for use as a pharmaceutical drug to control lice and scabies in all three countries and that it is intended to be phased-out in Mexico, the Parties will commit to actions under the following:

4.2.1.1. Inventory of lindane products used for pharmaceutical purposes.

i) The Parties will make available a current list of suppliers, formulators and wholesalers of lindane containing products; and
ii) The Parties will request sales and purchasing or prescription information in amount of active ingredient, from appropriate sources in order to track trends.

4.2.1.2. Alternatives

i) The Parties will encourage and promote research to investigate the safety and efficacy of alternatives and assess existing information;
ii) The Parties will develop and maintain a list of alternatives (see Annex C); and
iii) The CEC will support a trilateral workshop on alternatives and integrated strategies.[25]

4.2.1.3. Outreach and Education

i) 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

[25] A workshop was hosted by Mexico on October 4th, 5th and 6th, 2005, to investigate available alternatives and integrated strategies for reducing lindane use in Canada, Mexico and the United States. Mexico is to be congratulated in its efforts to move forward regarding actions on lindane even while the NARAP on Lindane and other HCH Isomers was being drafted. The proceedings of this workshop can be found on the website of the Commission for Environmental Cooperation at: www.cec.org\lindane. For more information please contact national Health and Environmental Agencies.

- Educators
- Media
- Health care providers
- Medical associations
- 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.

4.2.2. Agriculture – Veterinary

Recognizing that veterinary uses are no longer registered in Canada and the United States and are intended to be phased out in Mexico, the Parties will commit to the following actions:

4.2.2.1. the Parties will develop capacity through information exchange, outreach and education, and transfer of knowledge for the adoption of safer and cost effective alternatives; and

4.2.2.2. the Parties will develop and maintain a list of alternatives, including those used in other regions (see Annex D).

4.2.3. Agriculture - Pesticide

Recognizing that:

a) agricultural uses are no longer registered in Canada (as of January 1st, 2005);
b) the U.S. has received and plans to accept voluntary cancellation of all remaining pesticide registrations of lindane products and has determined that the agricultural uses of lindane are ineligible for reregistration; and
c) Mexico intends to phase-out its agricultural uses,

the Parties, as appropriate, will commit to actions, under the following:

4.2.3.1. Inventory of lindane products used for agricultural pesticide purposes.

i) The Parties will make available a current list of suppliers, formulators and wholesalers of lindane-containing products.

ii) The Parties will request sales and purchasing information, in amount of active ingredient, from current formulators and suppliers of

lindane for agricultural pesticide purposes.

iii) The Parties will endeavor to collect information on lindane uses.

iv) The Parties will monitor and report on amounts of imports of lindane active ingredients, lindane-containing products and lindane treated-seed through their respective customs and excise agencies.

4.2.3.2. Alternatives

i) The Parties will promote development and use of safer alternatives to lindane for pest management to the extent necessary and feasible;

ii) The Parties will support integrated pest management through the exchange of available and reliable information about natural and organic agricultural control practices such as crop rotation and other cultural and biological methods;

iii) The Parties will develop and maintain a list of alternatives, including those used in other regions (see Annex D and E); and

iv) The CEC will support a trilateral workshop on alternatives, including chemical methods, organic methods and integrated strategies.[26]

4.2.3.3. Outreach and Education

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.

[26] A workshop was hosted by Mexico on October 4th, 5th and 6th, 2005, to investigate available alternatives and integrated strategies for reducing lindane use in Canada, Mexico and the United States. Mexico is to be congratulated in its efforts to move forward regarding actions on lindane even while the NARAP on Lindane and other HCH Isomers was being drafted. The proceedings of this workshop can be found on the website of the Commission for Environmental Cooperation at: www.cec.org\lindane. For more information please contact national Health and Environmental Agencies.

4.2.4. Trade Issues

4.2.4.1. The Secretariat will work with the environment and trade officials of the three countries and other organizations such as the NAFTA Technical Working Group on Pesticides to establish mechanisms to address trade issues that may arise related to the implementation of this NARAP and to ensure equitable and consistent application of its actions.

4.2.5. Waste Management Issues

4.2.5.1. Water contamination

i) The Parties will make determined efforts to assess the exposure of surface and ground water to lindane; and
ii) The Parties will make determined efforts to assess potential options for removing lindane from wastewater.

4.2.5.2. Production residues

i) The Parties will endeavor to determine, through historical records or other mechanisms, the possible locations of lindane and technical HCH production and formulation facilities and waste isomer disposal sites in North America, and
ii) The Parties will endeavor to develop and implement a plan for the management and control of any highly contaminated sites identified in i) above so as to prevent releases to the environment.

4.2.5.3. Existing Stocks

i) Consistent with national laws and regulations, policies or agreements, a Party, upon deregistration of the pesticidal use of lindane, should restrict the use and/or sale of any surplus lindane within a specific timeframe.

4.2.6. Science and Research

In order to add to the knowledge and understanding of lindane and thereby strengthen risk assessment and risk management strategies, the Parties will take the following actions:

4.2.6.1. Environmental Monitoring and Modeling

i) The Parties will promote research and explore ongoing studies to determine to what extent the use of lindane contributes to the atmospheric, terrestrial and aquatic burden of all HCH isomers in North America;
ii) The Parties will review any new information presented to determine to what extent lindane converts to the other HCH isomers and the

environmental pathways involved in any such conversion;
iii) The Parties will promote research and exchange information on environmental effects associated with the use of lindane; and
iv) The Parties will endeavor to support and promote the development of scientific expertise in the field of modeling of pathways in the atmosphere, terrestrial, and aquatic systems, and the applicability of these models to lindane and other HCH isomers.

4.2.6.2. Human Monitoring and Modeling

i) The CEC will support a human tissue or blood monitoring survey in areas where pharmaceutical uses of lindane have been banned to determine the impact of the ban;
ii) The Parties will promote research and exchange information on human dietary exposure and direct exposure to lindane as a result of veterinary use. This research and information will particularly include exposure to children, and dietary exposure as a result of consumption of dairy products; and
iii) To the extent necessary, the CEC will assist in the development of studies to determine the body burden of lindane and other HCH isomers in the North American population and the contribution from traditional foods.

4.2.6.3. Building capacity

i) The Parties will promote use of standardized analytical methods for air, water, soil and human monitoring, including quality assurance and quality control; and
ii) The CEC will catalog data derived from this Action Plan in a universally accessible electronic format.

4.2.7. Outreach and Education

In addition to the outreach and education activities described under the specific uses of lindane,

4.2.7.1. 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.

4.2.8. Ensuring Compliance

4.2.8.1. Enforcement

i) The Parties will monitor and discourage any potential illegal, unauthorized uses or illegal imports and exports of lindane and lindane containing products through cooperative efforts between

individual national pesticide regulatory agencies, national customs agencies and the CEC's Enforcement Working Group;

ii) the Parties will endeavor to share information on national enforcement strategies and commit to enforcing actions through existing legal frameworks.

4.2.8.2. Measuring Success

i) The Parties will request the CEC's Environmental Monitoring & Assessment Task Force to collect baseline data for developing measures of success of this NARAP using available information potentially including body burden information, use information and monitoring data;

ii) in two years, and thereafter, every five years, the Parties will report to the CEC Council on progress made with respect to the NARAP;

iii) the CEC Council will determine the time at which this NARAP has been successfully implemented and should be terminated; and

iv) the Parties will monitor and share information with respect to the number of products, uses and imports of lindane in order to prioritize reduction efforts.

4.2.9. Leveraging Resources

4.2.9.1. Financial Resources

i) In order to build capacity in all three countries, the Parties will work with the Secretariat to seek funding from other sources for projects including the development of national baseline data, human monitoring programs, and education and outreach to the extent feasible.

4.2.9.2. Human Resources

i) The Parties will commit to providing expertise in policy and scientific disciplines for the implementation of the actions contained in this regional action plan. It is suggested that the expertise be provided from agencies within the national governments where applicable.

4.2.10. Integration with International Activities

Recognizing lindane and other HCH isomers' potential for long range atmospheric and oceanic transport regionally and globally:

4.2.10.1. the Parties, independent of the CEC, will endeavor to work through international initiatives and organizations (e.g., UNECE, bilaterals) in their scientific and other efforts to cooperate with other countries to manage and reduce lindane releases to all media with a view to

minimizing adverse affects regionally and globally.

4.2.10.2. The CEC will compile information on the production of lindane. If directed, the CEC will support the Parties in their efforts to promote emission reductions in Lindane producing countries. (Annex A)

4.2.10.3. The Parties, independent of the CEC, will support risk reduction activities in China and India (two of the remaining producers of lindane), building on projects such as those that have been initiated by the US EPA. These include activities to:

i) develop a comprehensive inventory of information regarding lindane production, use sites, and quantities exported;
ii) engage public stakeholders in the inventory process; and
iii) exchange information and experiences on regulatory strategies and implementation of alternatives.

5 Path Forward

Establishing an Implementation Task Force

The development of this "North American Regional Action Plan on Lindane and other Hexachlorocyclohexane Isomers" implies that implementation of certain actions will result in reduced environmental and human exposure to these persistent, bioaccumulative and toxic organochlorine chemicals. The actions described in this NARAP therefore need to be characterized more completely in an implementation strategy which, to the extent possible, should include targets and timeframes. Direction has also been provided previously by the Sound Management of Chemicals Working Group that each NARAP should have a finite lifespan and that the Monitoring and Assessment Steering Committee will oversee the long term assessment of the benefits of implementing these types of plans. It is therefore proposed that upon completion and approval of this developmental phase of the NARAP, the SMOC Working Group authorize the initiation of an implementation task force.

Composition of the Implementation Task Force

It is recommended that the NARAP Implementation Task Force consist primarily of national government representatives of the three Parties. This core group, comprised of federal Health and Environment agency representatives with expertise in toxic chemical, pesticide and pharmaceutical concerns should be authorized to include other representatives as required. It is anticipated that some of the members involved in this developmental phase will also constitute the membership of the implementation task force for purposes of continuity.

Proposed Timelines and Targets for Implementation

Considering that lindane is an actively traded pest control product currently authorized for some uses in all three North American countries, it is proposed that the work of the Implementation Task Force be considered through a program of phased-in initiatives, with initiatives that are considered to be a high priority targeted for completion within 2 years of authorization of the action plan, those of medium priority targeted for completion within 5 years of authorization and those of longer term priority or anticipated to require extended effort, targeted for completion within 5 – 10 years of authorization.

The Development Task Force considers it a priority to establish a Trilateral workshop as soon as possible after authorization of the NARAP, in order to establish priorities and actions deemed to be important by the national bodies and the various stakeholders and other regional authorities in North America.

NARAP Closure

The Lindane NARAP development task force suggests that implementation of this action plan should be targeted for completion within 8 – 10 years of authorization of this NARAP by the CEC Council.

Oversight and Audit

Initiatives involving monitoring and assessment of success and possible realignment of priorities of this NARAP should be based upon the advice of the Environmental Monitoring and Assessment Steering Committee.

The following tables describe a possible course of action involving short, medium and long term initiatives. Table 2 describes Trilateral Actions and Table 3 describes independent national and CEC actions.

Table 2 Trilateral Actions for Proposed Path Forward

Length of Initiative	CEC Secretariat	Parties
Immediate (upon authorization)	Establish Implementation Task Force Call meeting of Implementation task force	Provide Membership Establish NARAP priority action list
Short Term (Targeted for completion in 2 years.)	Compile inventory information provided by Parties on pharmaceutical veterinary and agricultural uses Support a trilateral workshop on pharmaceutical and pesticide alternatives including integrated strategies	Develop list of suppliers, formulators and wholesalers of Lindane containing products Request national sales and prescription (A.I.) details
Medium Term (Targeted for completion in 5 years.)	Assist in cataloging and providing lists of alternatives for pharmaceutical, veterinary and pesticide uses. Coordinate with NAFTA TWG on Pesticides and others to address trade implications of this plan Global actions	Promote research into safety and efficacy of alternatives Maintain and share lists of alternatives Strengthen outreach and education for pharmaceutical and veterinary uses, particularly to indigenous populations
Long Term (Targeted for completion in 5 to 10 years)	Promote reduction and elimination initiatives in anticipation of the closure of the NARAP	Assess exposure of surface and groundwater Assess wastewater treatment as a means of removal of Lindane

Table 3 Independent National and CEC Actions for Proposed Path Forward

Length of Initiative	CEC Secretariat	Canada	Mexico	United States of America
Immediate (upon authorization)	Establish budget and resource requirements	Establish budget and resource requirements	Establish budget and resource requirements	Establish budget and resource requirements
Short Term (Targeted for completion in 2 years.)	1. Provision of resources to conduct implementation meetings. 2. Coordinate science-based programs to build on trilateral reduction opportunities 3. Initiate support for trilateral promotion of alternatives 4. Coordinate information exchange to raise clinical practice standards	1. Develop a pharmaceutical uses fact sheet 2. Continue to Monitor pharmaceutical Uses 3. Continue Lindane monitoring and reporting 4. Revisit labeling 5. Any other risk mitigation measures that may be deemed necessary following the safety analysis	1. Initiate Lindane elimination program 2. Establish timelines for elimination 3. Initiate a program of national information diffusion, promotion of alternatives, dissemination and educational 4. Prepare notifications of deregistration and elimination for UNEP and FAO	1. Monitor foods for residues. 2. Accept voluntary cancellation of lindane pesticidal uses/products and propose to revoke existing tolerances for residues of lindane in animal fat. 3. Continue Lindane monitoring and reporting through IADN 4. Continue monitoring under the National Fish Tissue Study 5. Continue proactive work with sponsors to develop alternatives for lice and scabies treatment 6. Continue monitoring for unsafe and excessive use 7. Continue outreach and education for pharmaceutical uses

Length of Initiative	CEC Secretariat	Canada	Mexico	United States of America
Medium Term, (Targeted for completion in 5 years.)	1. Assist in development of atmospheric modeling capacity 2. Assist in determining global sources and contributions to North America	1. Develop an environmental impact assessment 2. Continue to Monitor pharmaceutical use	1. Improve monitoring capacity 2. Control Lindane in commerce and use 3. Assess and monitor existing reserves of Lindane 4. Update available data on both chemical and non-chemical alternatives, including effectiveness, toxicity relative to Lindane, and comparative costs	1. Promote reductions in India and China
Long Term (Targeted for completion in 5 – 10 years.)	1. Initiate closure of the NARAP 2. Report on Success 3. Provide examples of trilateral successes to global reduction programs 4. Closure and EM&A audit development	Measure success through cooperative actions	1. Measure success through cooperative actions 2. Share lindane phase out experience with other Latin American countries	Measure success through cooperative actions

Annexes

Annex A – Overview of Production, Residue Management, Formulation and Disposal

Part 1 – Case Studies on the Legacy of Lindane/HCH Isomer Production: Overview of Residue Management, Formulation and Disposal in the Netherlands and the Basque country

Case Study #1: The Legacy of "Technical" HCH Production in the Netherlands

Technical HCH was produced at five sites in the Netherlands, primarily between 1947 and 1952. Very little information is available on the amounts of technical HCH produced.

In the early 1950s there was a shift in the market place to the use of lindane rather than technical HCH. Therefore the production facilities started extracting lindane from technical HCH. This shift led to a problem with the accumulation and disposal of waste isomers. For every ton of lindane produced, there were 6-10 tons of unwanted waste HCH isomers that had to be disposed of or otherwise managed. Typically, these waste isomers were stored in piles next to the production site while industry attempted to find a use for these byproducts.

One of these lindane production facilities was located in the eastern part of the Netherlands. Lindane production at this facility resulted in the production of more than 5,500 tons of waste isomers requiring disposal. In 1956, 1,500 tons of HCH isomers were sold by this facility to another producer in the Netherlands for reprocessing. The rest remained stored next to the production site.

In the 1950s and 1960s, a portion of the remaining waste isomers were illegally collected and mixed with soil for construction purposes and dumped at numerous locations. Approximately 290 sites have been identified in a predominantly agricultural area in the eastern region of the Netherlands. In 1974 there was a massive fish kill in a canal next to a site where some of the isomers were stored. At this time there was a public outcry concerning the incident and in 1975 the Dutch regional government put pressure on the new owners of the facility to pay for the complete removal of 4,000 tons of waste isomers, which were consequently shipped to Germany for disposal. See photo 1 below.

At the end of the 1980s, the Dutch government accordingly authorized a large project to deal with this regional contamination issue. In 1988, a temporary storage site was established on top of a former landfill site. Approximately 200,000 tons of soil, excavated from the most contaminated areas of the region, were stored at this site. See photo 2 below. At the time no adequate technology was available to treat waste isomers. The Dutch government invited companies to develop technologies to treat the isomers and investigated their efficacy. By the beginning of 2002, all waste isomers at the temporary storage site had been treated. The site is now capped, secured, and used by the farming community for summer festivals.

Current Status: The Dutch government spent approximately 27 million Euros 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.

Photo 1. This photo was taken during the excavation of the waste HCH isomers in the eastern Netherlands to be shipped for disposal at German salt mines.

Photo 2. This photo from the mid-1990s is of a temporary storage site in the Netherlands for 200,000 tons of soil contaminated with waste HCH isomers.

Sources:

Vijgen, John. 2005. Personal communication between John Vijgen, Director of the International HCH and Pesticides Association and Janice Jensen, Office of Pesticide Programs, USEPA, August 3, 2005.

Cuyten, J. 1999. Cleaning of soil contaminated with HCH, from laboratory tests to commercial practical application, presented at the 5th International HCH and Pesticides Forum, 25-27 June 1998, Bilbao, Basque Country, Spain and included in Forum Book 5, IHOBE, February 1999. (See library at http://www.ihpa.info/index.php)

Grinwis, A. and G. de Jong. 1993. Ten years of soil clean up in the HCH-project in Twente, The Netherlands, HCH and Halogenated Pesticides – State of the Art for Risk Assessment and Technology Development, presented at the 2nd International HCH and Pesticides Forum at IWU – Magdeburg, Germany in 1993, and included in Forum Book 2. (See library at http://www.ihpa.info/index.php)

Grinwis, A. 1993 "Deventer Handelskade" Project, Technical interpretation of the choice of a geohydrological isolation option with supplementary measures to facilitate building development, HCH and Halogenated Pesticides – State of the Art for Risk Assessment and technology Development, presented at the 2nd International HCH and Pesticides Forum at IWU – Magdeburg, Germany in 1993, and included in Forum Book 2. (See library at http://www.ihpa.info/index.php)

Case Study #2: The Legacy of "Technical" HCH Production in the Basque Country of Spain

For more than forty years, technical HCH was produced by two companies located in the Basque Country in north central Spain. Starting in 1953, lindane was extracted from the technical HCH mixture, leaving behind significant amounts of waste HCH isomers. See photo below. 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 million tons of contaminated residues in their region. In addition to environmental problems and unacceptable risks to inhabitants, this contamination has in the past, hindered important development projects in areas near 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 soils. In addition, a process was developed, called the base catalyzed dechlorination (BCD) process to treat 3,500 tons of HCH waste isomers.

Current Status: The Basque Country Region of Spain spent over a decade and an estimated 50 million Euros to build two secure landfill site for wastes and contaminated soils. Of that total amount, 8.4 million Euros were spent on the base catalyzed dechlorination process.

Photo of waste HCH isomers being collected inside a former lindane production facility in Basque Country Region of Spain. (Source: IHOBE, Basque Country)

Sources:

Vijgen, John. 2005. Personal communication between John Vijgen, Director of the International HCH and Pesticides Association and Janice Jensen, Office of Pesticide Programs, USEPA, August 17, 2005.

Azkona, Anton & Quintana Ignacio. 1993. Case studies on HCH Wastes and Contaminated Sites in the Basque Country, presented at the 2nd HCH and Halogenated Pesticides Forum, Magdenburg, (former) East Germany in 1993 and included in Forum Book 2. (See library at http://www.ihpa.info/index.php)

Barquín, M. 1999. Strategy and Present Status of R & D Projects and Infrastructures for Solving the Problem of HCH, presented at the 5th International HCH and Pesticides Forum, 25-27 June 1998, Bilbao, Basque Country, Spain, and included in Forum Book 5. (See library at http://www.ihpa.info/index.php)

Barquín, Marian. 2001. Progress in HCH Infrastructures in the Basque Country, presented at the 6th International HCH and Pesticides Forum, 20-22 March 2001, Poznan, Poland, and included in Forum Book 6. (See library at http://www.ihpa.info/index.php)

Part 2 – Summary of Global Lindane/HCH Production

China is reported to have been the major world producer of technical HCH, accounting for more than 4.5 million tonnes between 1945 and 1983. In 1983, China banned both the production and usage of technical HCH. Recent information indicates that China has stopped manufacturing lindane as of 2003.

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 use 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 producing only 300 kg of lindane per day, six months per year. The company reported no production in 2004. In 2003, the plant built a land fill to cap the estimated 33,256 metric tons of waste isomers that plant managers refer to as "scum". [27]

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, the use of existing stockpiles was allowed even after 1991.

[27] Factsheet on Lindane's Dirty Secret: Indian Facilities Dump Toxic Waste, compiled by the Community Action for Pesticide Elimination, Kerala, India, May 2005.

Annex B – Summary List of International Lindane Registration Status by Country

Banned

Argentina
Armenia
Banladesh
Barbados
Belgium
Bulgaria
Burundi
Costa Rica
Croatia
Cyrus
Czech Republic
Denmark
Dominican Republic
Ecuador
Egypt
El Salvador
Finland
Gambia
Georgia
Guatemala
Honduras
Hong Kong
Hungary
Jamaica
Japan
Kazakhstan
Korea, Dem. Rep
Korea, Rep
Latvia
Liechtenstein
Lithuania
Mozambique
Netherlands
New Zealand
Nicaragua
Norway
Paraguay
Peru
Poland
Russia (?)
Singapore
Slovakia
South Africa
St Lucia
Sweden
Taiwan
Thailand
Tonga
Turkey
Uruguay
Vietnam
Yemen

Restricted/Severely Restricted

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

Not registered

Estonia
Guinea-Bissau
Indonesia
Monaco
Mongolia
Niger
Rwanda
Slovenia
Uganda
Vanuatu

Registered

Bolivia
Burkina Faso
Cameroon
Cape Verde
Chad
India
Kenya
Malaysia
Mali
Mauritania
Mexico
Papua New Guinea
Portugal
Syria
Tanzania
Togo
Zimbabwe

Information for this table was taken from the document "International Registration Status of Lindane by Country" found at: http://www.cec.org/lindane

Annex C – Available Alternatives to the Pharmaceutical Uses of Lindane in Canada, Mexico and the United States

Lindane Pharmaceutical Uses and Alternatives			
Use	**Canadian Alternatives**	**US Alternatives**	**Mexican Alternatives**
Head Lice Treatment	Permethrin (1% cream) Bioallethrin and piperonyl butoxide Pyrethrin and piperonyl butoxide[1]	Pyrethrum/Piperonyl Butoxide Permethrin Malathion	Permethrin Sulfur soap Pyrethrin soap
Scabies Treatment	Permethrin (5% cream) Precipitated sulfur 6% in petrolatum Crotamiton 10% (Eurax)	Permethrin Crotamiton (Eurax)	Permethrin Ivermectin (oral) Benzil benzoate Crotamiton (Eurax)

[March 30, 2006]

Canada also provided information on "natural" alternatives to lindane for the lice treatment, as follows: Wet combing, formic acid preparations, topical vinegar and mineral oil, tea tree oil, acetic acid, citronella oil, camphor, sodium lauryl ether sulfate (SH-206)

Annex D – Available Alternatives to the Pesticidal Uses of Lindane in Canada and the United States

Lindane Alternatives by Use Site			
Use Site	**Pest**	**Canadian Registered Alternatives**	**US Registered Alternatives**
Seed Treatments			
Canola[28]	flea beetle	acetamiprid clothianidin thiamethoxam imidacloprid	clothianidin thiamethoxam imidacloprid
Corn	wireworm	clothianidin imidacloprid (only for field corn grown for seed) tefluthrin	imidacloprid thiamethoxam permethrin tefluthrin clothianidin
Barley	wireworm	No products registered. Seed treatment submission under review	thiamethoxam imidacloprid
Wheat	wireworm		thiamethoxam imidacloprid
Oat	wireworm		imidacloprid
Rye	wireworm		imidacloprid
Sorghum	wireworm	thiamethoxam imidacloprid	thiamethoxam imidacloprid

[March 30, 2006]

[28] Please note that canola was never a U.S. registered use.

Lindane Alternatives by Use Site			
Use Site	**Pest**	**Canadian Registered Alternatives**	**US Registered Alternatives**
Livestock Treatments			
Beef Cattle	hornfly, lice, tick	carbaryl, , diazinon, dichlorvos, malathion, phosmet, tetrachlorvinphos, trichlorfon, cyfluthrin, cypermethrin, fenvalerate, permethrin, pyrethrin, rotenone *Veterinary Drugs :* eprinomectin, ivermectin abamectin, doramectin, moxidectin	carbaryl, coumaphos, cyfluthrin, cypermethrin, diazinon, dichlorvos, fenvalerate, lambda-cyhalothrin, malathion, permethrin, phosmet, pyrethrin, tetrachlorvinfos, trichlorfon *Veterinary Drugs :* eprinomectin, ivermectin doramectin, moxidectin, methoprene
Swine	lice, mange mite, flea	carbaryl, malathion, phosmet, rotenone *Veterinary Drugs:* doramectin, ivermectin	amitraz, coumaphos, malathion, methoxychlor, phosmet permethrin, tetrachlorvinfos *Veterinary Drugs:* doramectin, ivermectin
Ornamental Use			
Ornamental Plants (foliar)	Several	Numerous alternatives are available	Numerous alternatives are available

[March 30, 2006]

Annex E – Available Alternatives to the Pesticidal Uses of Lindane in Mexico

CROP	Pest	Alternatives for the Treatment of Seeds[29]
Canola		Note: Lindane is not registered for use with this crop in Mexico
Maize (corn)	Wireworm (*Gusano de alambre* and *trozador*): *Agrotis spp, Agriotes spp*)	Acephate, bifenthrin, clothianidin diazinon, thiodicarb, tefluthrin
Maize (corn)	Corn rootworm and gallina ciega (larva of the beetle *Melolontha* spp.): *Diabrotica spp* and *Phyllophaga spp.*	Acephate, bifenthrin, clothianidin, diazinon, fipronil, imidacloprid, tefluthrin, thiametoxam, thiodicarb
Sorghum	Wireworm (*Gusano de alambre* and *trozador*): *Agrotis spp, Agriotes spp*)	Bifenthrin, diazinon, imidacloprid, thiodicarb
Sorghum	Corn rootworm and gallina ciega: *Diabrotica spp* and *Phyllophaga spp.*	Bifenthrin, diazinon, fipronil, imidacloprid, thiametoxam
Wheat		No registered alternatives for this seed in Mexico
Barley		No registered alternatives for this seed in Mexico
Oats		No registered alternatives for this seed in Mexico
Rye		Lindane is not registered for use with this crop in Mexico.

[March 30, 2006]

Note: For oats, barley and wheat, agricultural pesticide firms can request expansion of use for the alternatives approved for maize (corn) and sorghum

[29] Shaded blocks indicate that use of lindane is currently still registered for this crop in Mexico.

Annex F – Available Non-Chemical Alternatives to Agricultural Seed Treatment Uses of Lindane

Cultural Methods
Site selection and monitoring Site assessments and an understanding of the ecology leading to infestation are necessary to determine if wireworms are present. Avoidance of areas likely to contain wireworms is an effective way to prevent problems. However, as avoidance is not always practical, proper monitoring will determine whether a field suffers wireworm infestation. Assessment methods include soil sampling, use of bait traps, and adult trapping. Should wireworm infestation be shown to exist, a number of methods are available to reduce and effectively control the population.
Fallowing In areas of previous meadow or pasture, starve wireworms by allowing the area to fallow for a few years before planting. Or, to prevent recurrence, immediately reseed with a resistant crop such as buckwheat or flax.
Crop rotation Small grains need to be rotated with a non-host species every year to reduce the severity of infestation and maintain low levels of pests. Acceptable crops include alfalfa, soybeans, and clover.
Timing of seeding and planting Avoid early planting, especially in cold, wet conditions. Plant in warm, dry conditions whenever possible, usually later in the season for small grains. Larvae are deeper in the soil at this point, giving seedlings a greater chance of survival. Avoid planting too deep (2 to 5 cm is best) and increase seeding rate so stand can fill in if some seedlings or plants are destroyed. Use healthy seed. Encourage root development and early maturity by covering with a thin layer of manure.
Shallow cultivation In early spring, cultivate the upper soil level. This will starve hatchlings, expose eggs for predation and damage larvae. Cultivation of summer fallow in late July can also destroy pupae, although summer fallow is not recommended in the case of wireworm infestation.
Soil packing Firming the soil in the rows will impede wireworm travel. A press drill or packer hitched behind the seeder is recommended to firmly pack the seed row and create difficulties in wireworm movement. Wireworms will look for food in the looser packed soils between rows. Wider row spacing can also assist in decreasing flea beetle infestations. Restrict tillage to the upper 5 to 8 cm of soil to keep a firmly packed layer beneath the tilled layer. This will have the added effect of forcing adults to lay eggs closer to the surface, where they more easily desiccate or are located by predators.
Biological Methods
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. Results are promising so far, but no commercial product currently exists.