

North American Regional Action Plan on Lindane and Other Hexachlorocyclohexane Isomers

Final Evaluation Report

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September 2013



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Please cite as:

CEC 2013. *North American Regional Action Plan on Lindane and other Hexachlorocyclohexane Isomers: Final Evaluation Report*. Montreal, Canada: Commission for Environmental Cooperation, 45 pp.

This report was prepared by Joanne O'Reilly and Mario Yarto for the Secretariat of the Commission for Environmental Cooperation of North America. The information contained herein is the responsibility of the authors and does not necessarily reflect the points of view of the CEC or the governments of Canada, Mexico, or the United States.

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Publication Details

Publication type: Report
Publication date: September 2013
Original language: English
Review and quality assurance procedures:
Final Party review: May 2013
QA12.12

Disponible en español – Disponible en français (Sommaire de rapport)

Legal deposit – *Bibliothèque et Archives nationales du Québec*, 2013

Legal deposit – Library and Archives Canada, 2013

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Acronyms

AMAP	Arctic Monitoring and Assessment Program
AMIFAC	Mexican Association of the Phytosanitary Industry (<i>Asociación Mexicana de la Industria Fitosanitaria, A.C.</i>)
CanMETOP	Canadian Model for Environmental Transport of Organochlorine Pesticides
C-BAS	Community-based Assessment Software
CDHS	California Department of Health Services
CEC	Commission for Environmental Cooperation
Cicoplafest	Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (<i>Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas</i>)
CLRTAP	Convention on Long-Range Transboundary Air Pollution
Cofepris	Federal Commission for Protection against Sanitary Risks (<i>Comisión Federal para la Protección contra Riesgos Sanitarios</i>)
Conasa	National Technical Advisory Council on Animal Health (<i>Consejo Técnico Consultivo Nacional de Sanidad Animal</i>)
COP	Conference of the Parties
CPS	Compendium of Pharmaceuticals and Specialties
CTR	California Toxics Rule
DNAs	Designated National Authorities
DRG	Dietary Record Generator
EU	European Union
FSU	Former Soviet Union
GAPS	Global Atmospheric Passive Sampling
GHS	Globally Harmonized System (of Classification)
HCH	Hexachlorocyclohexane
IADN	Integrated Atmospheric Deposition Network
ICAMA	Institute for Control of Agrichemicals, Ministry of Agriculture
IHS	Indian Health Service
INE	National Institute of Ecology (<i>Instituto Nacional de Ecología</i>)
IPM	Integrated Pest Management
LRTAP	Long-Range Transboundary Air Pollution
MEDIA	Multi-compartment Environmental Diagnosis and Assessment
MRL	Maximum Residue Limit
NAAEC	North American Agreement on Environmental Cooperation
NAFTA	North American Free Trade Agreement
NAPRA	National Association of Pharmacy Regulatory Authorities
NARAP	North American Regional Action Plan

NCP	Northern Contaminants Program
NGO	Nongovernmental Organization
NHANES	National Health and Nutrition Examination Survey (United States)
NIP	National Implementation Plan
OSPAR	Oslo/Paris (Convention for the Protection of the Marine Environment of the Northeast Atlantic)
PBT	Persistent, Bioaccumulative and Toxic
PCBs	Polychlorinated biphenyls
PIC	(The Rotterdam Convention on) Prior Informed Consent
PMRA	Pest Management Regulatory Agency
POPs	Persistent Organic Pollutants
POPRC	Persistent Organic Pollutant Review Committee
ppt	parts per trillion
Proname	National Program for Environmental Monitoring and Assessment of Persistent, Bioaccumulative and Toxic Substances (<i>Programa Nacional de Monitoreo y Evaluación Ambiental de Sustancias Tóxicas, Persistentes y Bioacumulables</i>)
QSP	Quick Start Program
SAICM	Strategic Approach to International Chemicals Management
Sagarpa	Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (<i>Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación</i>)
SCT	Secretariat of Communications and Transportation (<i>Secretaría de Comunicaciones y Transportes</i>)
Semarnat	Secretariat of the Environment and Natural Resources (<i>Secretaría de Medio Ambiente y Recursos Naturales</i>)
SHCP	Secretariat of Finance and Public Credit (<i>Secretaría de Hacienda y Crédito Público</i>)
SIAMI	Tariff Information System Via Internet (<i>Sistema de Información Arancelaria Vía Internet</i>)
SISCO	Computer Information System of Contaminated Sites (<i>Sistema Informático de Sitios Contaminados</i>)
SMOC	Sound Management of Chemicals
SSTF	Substance Selection Task Force
UASLP	Autonomous University of San Luis Potosí (<i>Universidad Autónoma de San Luis Potosí</i>)
UNECE	United Nations Economic Commission for Europe
USA	United States of America
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration

Preface

This final report for the *North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers*^{*} is the concluding task of the Lindane Task Force under the auspices of the Commission for Environmental Cooperation (CEC) as it endeavors to meet its commitments under the NARAP. Representatives from Canada, Mexico and the United States of America (USA) have worked side by side since 1999 to develop and implement a regional plan to reduce the risk of exposure to the North American environment and people to lindane and other HCH isomers.

Lindane has been shown to be persistent, bioaccumulative and toxic (PBT) to biota and humans. It is one of the most abundant and pervasive organochlorine insecticide contaminants in the arctic environment as it can be transported from temperate and tropical zones where it is used, to colder northern environments. At the time of lindane's nomination for consideration for actions under a NARAP, it was still being used for various pharmaceutical, veterinary and agricultural pesticide applications in each country. The three countries worked together to phase out uses and identify alternatives, while building capacity in monitoring and modeling of lindane and other HCH isomers in humans and environmental media.

Moving forward with initiatives under the NARAP encouraged Mexico in its nomination of lindane and its isomers alpha and beta for elimination under Annex A of the Stockholm Convention. In 2009, Mexico's nomination was accepted and lindane production and agricultural use is now banned for Parties who have ratified the Convention, with a time-limited specific exemption that allows it to only be used as a second-line pharmaceutical treatment for lice and scabies.

Many people within the governments of Canada, Mexico and the USA undertook the actions completed under the NARAP, with assistance from scientists and experts in the field as well as other stakeholders including members from industry and nongovernmental environmental groups.

It is the hope of the members of the Lindane Task Force that the lessons learned under this NARAP can be adopted and applied in countries or regions outside of North America, in efforts to continue to contribute to the reduction of risk of exposure to lindane and other HCH isomers on a global scale.

This document is organized in five sections. The first one provides a general view on the regional and global concerns about lindane and alpha- and beta-HCH isomers, which gave rise to this NARAP. Section 2 presents a brief description of the path covered by Canada, Mexico and the USA since lindane registration and begging of use until its current status. The third section outlines national actions implemented in the three

* See <http://www.cec.org/NARAP_lindane-HCH>.

countries as driving and complementary initiatives to the NARAP. Section 4 describes the trinational efforts developed on a regional base to comply with the NARAP. Finally, section 5, as a conclusion of this document; expound the benefits obtained and the lessons learnt from the NARAP, as well as the indication that the SMOC Working Group could decide to continue working on a trilateral basis.

The information gathered to prepare this document was obtained from the review of official records and internal documents prepared by the Lindane Task Force, or by direct consultation to representatives from the government, civil society organizations and industrial associations.

Executive Summary

Canada, Mexico, and the United States of America (USA), under the Commission for Environmental Cooperation (CEC) recognized that the organochlorine pesticide lindane [γ -hexachlorocyclohexane (γ -HCH)], as well as the alpha- and beta- isomers of HCH (α -HCH and β -HCH), constitute a risk to human health and the environment. Lindane and other isomers of HCH meet several internationally accepted criteria for persistence, bioaccumulation factors and toxicity. Consequently, the countries, through the formation of a trilateral implementation task force and the initiatives under a NARAP, acted cooperatively to reduce the risks from exposure to the isomers of HCH.

To develop the action plan, Canada, Mexico and the USA enlisted and received input from various experts and representatives of indigenous peoples, children's health interests, environmental organizations, and industry in preparing the NARAP. 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.

Historically, lindane has been used in Canada for a wide variety of applications: agricultural uses, including crops, seeds, livestock, and water, and pharmaceutical uses to treat scabies and lice. In 2002, Canada's Pest Management Regulatory Agency (PMRA) completed a review of lindane, and agricultural product registrations were phased out by 1 January 2005. Currently, no lindane products are registered under the Pest Control Products Act. Lindane has been authorized for sale in Canada as a pharmaceutical since the early 1960s. With the introduction of safer agents, the use of lindane has declined over the years. As of 2012, lindane remains in use as a second-line therapeutic product under the Food and Drugs Act to control lice and scabies outbreaks in humans, when alternatives have failed. This last Canadian use, as a pharmaceutical agent, is to cease by 2016.

In Mexico, lindane was authorized for seed treatment, for ectoparasite control on livestock and domestic animals, and use against common fly larvae, scabies, lice, fleas, ticks, spiders and scorpions. In 2009 a total of 18 pesticide-use authorizations were in force for lindane-based products, whereas currently 14 pesticide registrations have been canceled, and four continue to remain in effect. At this time (mid-2012) there remain three registrations in effect for lindane-containing products for pharmaceutical uses, but they are in the process of being revoked by the Secretariat of Health.

Lindane was first registered as a pesticide in the United States in the 1940s for use on a wide variety of food crops, ornamentals, and livestock, around the home and at other sites. In 1998 and 1999, lindane registrants voluntarily canceled all registered uses of lindane except for seed treatment use on 19 agricultural crops and as a dog mange treatment. Lindane dog mange use was voluntarily canceled in December 2001. In 2001 and 2002, the registrants voluntarily canceled all but the following six lindane seed treatment uses: barley, corn, oats, rye, sorghum, and wheat. In July of 2006, the United States had received requests for voluntary cancellation from all lindane registrants in

the country for all remaining registrations of lindane pesticide products. October 1, 2009, was the last day on which lindane seed treatment end-use products could be used. Lindane use is approved by the US Food and Drug Administration (FDA) for 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, the FDA took action to increase hazard warnings and to reduce the maximum package size to minimize the possibility of overuse.

While developing the NARAP, the three North American countries worked together to develop and exchange information on safer alternatives to lindane, which they presented at a trilateral workshop of experts and stakeholders, held in Mexico in 2005. The governments have mandated appropriate labeling on products for any remaining uses, such as that of a second-line treatment for scabies and lice in Canada and the United States. Information generated at this workshop as well as other information gathered by the Lindane Task Force contributed to the development of background documents for Mexico's nomination of lindane and other HCH isomers to Annex A of the Stockholm Convention. The incorporation of these chemicals in the Stockholm Convention in 2009 mandates their complete elimination for all countries that have ratified the Convention, unless a Party decides to request a specific exemption according to the rules of the Convention. The exemption period is for five years, with possibility of extension for another five years, permitted under Article 4 of the Convention.

In addition, through the CEC, Canada, Mexico and the United States supported the development of the first North American data set for some environmental contaminants, including lindane, dioxins and metals like lead and mercury, in the blood of women of childbearing age. This trilateral monitoring study promoted capacity building and strengthened Mexico's biomonitoring initiatives.

Both Canada and the US undertook initiatives with China to prepare and improve the use of emissions information on lindane in China, and thus assess the impact of such emissions on the North American environment.

The members of the Lindane Task Force consider the actions specified under the NARAP to have been accomplished to a reasonable degree. In Mexico, some coordinated efforts remain necessary to effectively complement NARAP achievements. The country will continue to work toward cancellation of all remaining lindane registrations and support the use of alternatives; it will continue monitoring and biomonitoring efforts and build capacity in this area, and establish a financial mechanism for assuring Proname's long-term operations. More research is needed there to assess health effects and risks from exposure to HCH isomers in contaminated sites, and identify any remaining sources of release of these isomers to the Mexican environment. Further support or collaborations of the three countries regarding lindane and its isomers, if needed, can be achieved through trilateral meetings or other international fora.

1. History and Introduction

1.1. History of Lindane and Other HCH Isomers

Hexachlorocyclohexane (HCH) 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,” although this terminology is no longer used. Current nomenclature refers to “technical-grade HCH,” which is a mixture of all HCH isomers (see Table 1)¹ and was used as a pesticide prior to the isolation of the only active isomer, gamma- (γ -) HCH or lindane. The insecticidal properties of technical-grade HCH were first described in the 1940s and the active γ -isomer was named “lindane” after Van Linden, discoverer of the alpha- (α -) and γ -isomers.²

Lindane and technical-grade HCH do not occur as natural substances. The manufacture of technical-grade HCH yields a mixture of five main HCH isomers. These isomers and their typical yield are listed in Table 1.

Table 1. Ratio of Isomers in the Production of Technical-grade HCH

HCH Isomer	Percent in synthesis mixture
(Alpha-) α -HCH	60–70
(Beta-) β -HCH	5–12
(Gamma-) γ-HCH (lindane)	10–15
(Delta-) δ -HCH	6–10
(Epsilon-) ϵ -HCH	3–4

This mixture of technical-grade 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 that for every tonne of lindane produced, 6–10 tonnes of other isomers must be disposed of or otherwise managed.

Like other persistent organic pollutants (POPs), lindane and other isomers of HCH can be

¹ Isomer(s, isomerism) is a chemical term for related chemical compounds that have the same chemical formula but whose atomic structure (physical arrangement of the component atoms) differs stereoscopically. Since chemical reactivity can differ significantly according to the actual position of the atoms relative to one another, different stereoisomers of the same compound can exhibit markedly different chemically reactive properties, such as toxicity. Such is the case with the HCH isomers.

² CEC. 2006. North American Regional Action Plan on Lindane and Other HCH Isomers. Montreal: Commission for Environmental Cooperation. <http://www.cec.org/NARAP_lindane-HCH> (consulted July 2012).

transported over long distances by air currents.³ Certain HCH isomers are some of the most abundant and pervasive organochlorine contaminants found in the environment, especially in the Arctic.⁴

Lindane and other HCH isomers bioaccumulate in moderately to highly toxic levels in biota and humans. Indigenous peoples and northern populations, who rely on subsistence foods, are at greater risk for exposure, as evidenced by the high levels of lindane in their diet.

Toxicological data indicate that lindane and other HCH isomers, at high concentration exposures, can adversely affect reproduction, nervous, endocrine, and possibly immune systems, and have the potential to cause cancer in animals after long-term chronic exposure.⁵ Workers who formulate lindane products for sale in North America have the greatest potential for chronic exposure.

Lindane's primary use in North America has been in the agricultural sector, mainly for seed treatment as protection against insect pests. The other principal use of lindane was in the veterinary and public health sectors for the treatment of lice and scabies.

Lindane as a Global Issue

The isomers of HCH vary in their ability to bioaccumulate, persist in the environment and result in toxic effects, but all are of global concern. Because they can be transported by wind and water, lindane and other HCH isomers can and do affect people and wildlife far from where they are produced and released. They persist in the environment and can bioaccumulate, passing from one species to the next through the food chain. Lindane, though previously used locally and regionally, was transported and deposited throughout North America. A project undertaken in 2005 showed significant amounts of lindane were carried to North America through long-range atmospheric transport. Estimated total depositions of lindane from global sources were 30 tonnes in Canada, 12

³ Shen, L., F. Wania, Y.D. Lei, C. Teixeira, D.C.G. Muir, and T.F. Bidleman. 2005. Atmospheric distribution and long-range transport behavior of organochlorine pesticides in North America. *Environ. Sci. Technol.* 39(2): 409–420 and Zhang, L., J. Ma, S. Venkatesh, Y.F. Li, and P. Cheung. 2008. Modeling evidence of episodic intercontinental long-range transport of lindane. *Environ. Sci. Technol.* 42(23): 8791–97.

⁴ Li, Y.F. and R. MacDonald. 2005. Sources and pathways of selected organochlorine pesticides to the Arctic and the effect of pathway divergence on HCH trends in biota: A review. *Sci. Total Environ.* 342: 87–106, and Becker, S., J. Halsall, W. Tych, R. Kallenborn, Y. Su, and H. Hung. 2008. Long-term trends in atmospheric concentrations of α - and γ -HCH in the Arctic provide insight into the effects of legislation and climatic fluctuations on contaminant levels. *Atmospheric Environment* 42(35): 8225–33. <<http://www.sciencedirect.com/science/article/pii/S1352231008006857>>.

⁵ CEC. 2000. Decision Document on Lindane Under the Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative. Montreal: Commission for Environmental Cooperation. See <<http://www.cec.org/Storage.asp?StorageID=2172>> (consulted July 2012).

tonnes in the United States, and 1 tonne in Mexico.⁶

To help address this global concern, on 29 June 2005, Mexico proposed that lindane and the α - and β -isomers of HCH be added to Annex A of the Stockholm Convention as POPs to be eliminated from commercial use.⁷ As a result of Mexico's initiative, a risk profile and a risk management evaluation were drafted and approved by the POPs Review Committee (POPRC). Following discussions, the Committee recommended to the Conference of the Parties (COP) that it consider listing these substances under Annex A of the Convention, and the recommendation was accepted. At the Fourth Meeting of the Conference of the Parties (COP 4), nine POPs were added to Annex A (substances for elimination of use) of the Stockholm Convention. The nine included lindane and α - and β -HCH to, although the inclusion provided an exemption for the pharmaceutical use of lindane on humans as a second-line treatment against lice and scabies. On 26 August 2010, the amendments to the annexes went into effect for all the Parties except those that had presented a notification of non-acceptance. Canada and Mexico are Parties to the Stockholm Convention and the United States has signed but not ratified the Convention.⁸ In the case of Canada, amendments to the annexes enter into force only on deposit of an instrument of ratification. This occurred on 4 January 2011. The amendment listing lindane came into force for Canada 90 days later, on 4 April 2011.

Monitoring Trends in North America

Lindane use has been decreasing significantly in North America over the past decade as evident from usage data in each country. In many areas in North America, and across many media, HCH concentrations have decreased, but levels in the Arctic do not show a consistent pattern.

Lindane has been monitored in air and precipitation through the Integrated Atmospheric Deposition Network (IADN) in the Great Lakes region of Canada and the United States since 1991.⁹ A recent time-trend analysis of α -HCH and lindane in IADN

⁶ Li, Y.F. et al. 2009. Quantifying the concentrations to gamma-HCH deposited to North America and the Great Lakes from major source regions, in: *Great Lakes Binational Toxics Strategy, 2009 Biennial Progress Report*, <<http://www.epa.gov/greatlakes/bns/index.html>>.

⁷ UNEP. 2006. Stockholm Convention on Persistent Organic Pollutants, Report of the Persistent Organic Pollutants Review Committee on the work of its second meeting, Risk Profile on Lindane. UNEP/POPS/POPRC.2/17/Add.4, <<http://chm.pops.int/Convention/POPsReviewCommittee/Reviewedchemicals/tabid/781/Default.aspx>> (consulted July 2012).

⁸ The new POPs under the Stockholm Convention. Nine new POPs. See <<http://chm.pops.int/Convention/ThePOPs/TheNewPOPs/tabid/2511/Default.aspx>>.

⁹ US-Canada IADN Scientific Steering Committee. 2008. Integrated Atmospheric Deposition Network (IADN): Information Resources, in: <<http://www.epa.gov/greatlakes/monitoring/air2/iadn/resources.html>>.

data from 1991 through 2007 show very significant decreases, with concentrations halving every three to five years.¹⁰

The Great Lakes Fish Monitoring and Surveillance Program (GLFMSP) also measures lindane and other HCH isomers in top predator fish of the Great Lakes. Since the late 1990s, concentrations of lindane in whole fish composites of the Great Lakes have substantially decreased.¹¹

The National Oceanic and Atmospheric Administration's National Status and Trends Program has measured lindane in the tissues of bivalves throughout the coastal United States and Great Lakes. A trends assessment using data pooled for the entire country indicates that there has been a statistically significant decline in lindane levels from 1986 through 2003.¹²

In a recent review of studies of temporal trends among legacy POPs in Arctic biota, α -HCH and lindane in a high proportion of time-series studies showed significantly decreasing trends, although β -HCH was an exception. The authors of the review speculated that long-range transport through the ocean rather than the atmosphere may explain several increasing trends that were detected in the Canadian Arctic.¹³ Support for this comes from a recent study of the Hudson Bay region of Canada, where brominated and chlorinated contaminants were analyzed in adipose tissues taken from a subpopulation of polar bears at intervals between 1991 and 2007. Again, levels of α -HCH were found to have decreased (-11%/year) whereas levels of β -HCH actually increased (+8.3%/year).¹⁴ In addition to the beta isomer's known slower rate of metabolism in adipose tissue, it has been speculated that climate change and the loss of Arctic sea ice, leading to the mobilization of some POPs, may also have an impact on these trends.¹⁵

¹⁰ Venier, M., and R.A. Hites. 2010. Time trend analysis of atmospheric POPs concentrations in the Great Lakes region since 1990. *Environmental Science and Technology* 44(21): 8050–5. <<http://www.ncbi.nlm.nih.gov/pubmed/20932001>>.

¹¹ Data from the Great Lakes Fish Monitoring and Surveillance Program (GLFMSP) <<http://www.epa.gov/greatlakes/monitoring/fish/index.html>>, and Salamova, A., Pagano, J.J., Holsen, T.M., and R.A. Hites. 2013. Post-2010 temporal trends of PCBs and organochlorine pesticides in the atmosphere and in fish from the Great Lakes basin are similar. *Manuscript submitted for publication*.

¹² NCCOS. COAST's National Status and Trends Program. NOAA: National Centers for Coastal Ocean Science <<http://ccma.nos.noaa.gov/about/coast/nsandt/default.aspx>>.

¹³ Rigét, F., A. Bignert, B. Braune, J. Stow, and S. Wilson. 2010. Temporal trends of legacy POPs in Arctic biota, an update. *Sci. Total Environ.* 408(15): 2874–84

¹⁴ McKinney, M.A., J. Stirling, N.J. Lunn, E. Peacock, and R.J. Letcher. 2010. The role of diet on long-term concentration and pattern trends of brominated and chlorinated contaminants in western Hudson Bay polar bears, 1991–2007. *Sci. Total Environ.* 408(24): 6210–22.

¹⁵ Gaden, A., S.H. Ferguson, L. Harwood, H. Melling, J. Alikamik, and G.A. Stern. 2012. Western Canadian Arctic ringed seal organic contaminant trends in relation to sea ice break-up. *Environ. Sci. Technol.* 46(8): 4427–33.

Other studies reveal a lag in the decrease of HCH concentrations expected in biota of the Arctic. Trends in α -, β -HCH and lindane concentrations were examined in blubber lipid of ringed seals from the Canadian Arctic between 1978 and 2006. Concentrations of α -HCH and lindane showed no change during this time period, but again β -HCH concentrations increased significantly, about 8- to 10-fold in females and 4- to 5-fold in males. The authors postulate that although global emissions of both α -HCH and β -HCH have declined since the early 1980s, HCH emission changes have not yet resulted in the expected decrease in concentrations in ringed seals. The authors conclude that any such decline may not be detected by analyses for another decade or so, due to the longevity of the seals.¹⁶

In Canada, HCH isomers have been detected in a range of foods, including dairy products, meat, fish, poultry, fruits, vegetables, peanuts, seeds, sugars, oils, and fats.^{17,18} Results from the Canadian Total Diet Study indicate that average HCH residue levels in food are generally below 1 $\mu\text{g}/\text{kg}$, although in some years, residue levels of up to 8 $\mu\text{g}/\text{kg}$ were found in peanuts, peanut butter, and chocolate bars.¹⁹ In foods where a Maximum Residue Limit (MRL) has been established (according to the Canadian Food and Drug Regulations) by Health Canada, detectable levels of HCH isomers were typically less than 1% of the MRL.

Canada also obtains data on lindane in blood through the Canadian Health Measures Survey. The results of the first cycle of the survey, including data on HCH isomers in the Canadian population, were released in August 2010. Lindane itself was not detected.²⁰

Monitoring and biomonitoring studies have been conducted in a number of Mexican states, particularly in those characterized by intensive agricultural activity or where there are established industrial centers that may release POPs into the environment. For example, Mexico's National Institute of Ecology (INE) has, in connection with Proname, conducted studies for determining the presence of POPs, including lindane, in the Valle

¹⁶ Addison, R.F., D.C.G. Muir, M.G. Ikononou, L. Harwood, and T.G. Smith. 2009. Hexachlorocyclohexanes (HCH) in ringed seal (*Phoca hispida*) from Ulukhaktok (Holman), NWT: Trends from 1978 to 2006. *Sci. Total Environ.* 407: 5139–5146.

¹⁷ Gartrell, M.J., J.C. Craun, D.S. Podrebarac, and E.L. Gunderson. 1986. Pesticides, selected elements, and other chemicals in adult total diet samples, October 1980–March 1982. *J. AOAC.* 69: 146–61.

¹⁸ Health Canada. 2009. Canadian Total Diet Study: Concentration of Contaminants and Other Chemicals in Food Composites. <<http://www.hc-sc.gc.ca/fn-an/surveill/total-diet/concentration/index-eng.php>> (consulted February 2012).

¹⁹ *Ibid.*

²⁰ Health Canada. 2010. Report on Human Biomonitoring of Environmental Chemicals in Canada, Results of the Canadian Health Measures Survey Cycle 1 (2007–2009). <<http://es.scribd.com/doc/79051789/Report-on-Human-Biomonitoring-of-Environmental-Chemicals-in-Canada-Results-2007-2009-Health-Canada-2010>> (consulted July 2012).

de Yaquí, Sonora,²¹ and Coatzacoalcos, Veracruz.²² Low levels of lindane were reported in both sites, found in soil and sediment, although considerably spread out.

In 2005 and 2006, the spatial and temporal variation of organochlorine pesticides in air across Mexico was investigated by deploying passive samplers at eleven stations across the country. Integrated samples were taken over three-month periods and the results showed that HCHs were evenly distributed across the country, suggesting that the residues were older and more diffuse throughout the environment.²³

In 2010, a study was conducted to examine the geographical distribution of organochlorines in rural, urban and agricultural soils of Mexico and the net direction of soil–air exchange by coupling soil residue data with air concentrations from co-located samplers. The researchers found α -HCH and lindane above the level of detection only in some urban and agricultural soils. No β -HCH or δ -HCH were detected in any of the samples.²⁴

Although some of these studies failed to detect significant levels of lindane or other isomers of HCH, the concentrations found in other cases would seem to stem from past uses of these substances, primarily in agricultural areas and other rural areas where they have been used in public health campaigns.²⁵

1.2. History of the Lindane NARAP

The NARAP on Lindane and Other HCH Isomers was a regional undertaking stemming from an initiative on sound management of chemicals, under the auspices of the Commission for Environmental Cooperation, which was created by the North American Agreement on Environmental Cooperation (NAAEC) between the governments of Canada, Mexico and the United States of America. A parallel side agreement to the North American Free Trade Agreement (NAFTA), the NAAEC came into force in January 1994 and established the CEC to “facilitate cooperation on the conservation, protection and enhancement of the environment in their territories.”

²¹ INE. 2008. Diagnóstico de contaminantes orgánicos persistentes (COP) en el Valle del Yaquí. Reporte final. Mexico: *Instituto Nacional de Ecología* <<http://www.ine.gob.mx/sqre-estudios>> (consulted July 2012).

²² INE. 2007. Monitoreo ambiental, determinantes de la exposición y efectos de contaminantes críticos en humanos y biota en Coatzacoalcos, Veracruz. Informe final. <<http://www.ine.gob.mx/sqre-estudios>> (consulted July 2012).

²³ Wong, F., H.A. Alegria, T.F. Bidleman, V. Alvarado, F. Angeles, A. Ávila-Galarza, E.R. Bandala, I. de la Cerda-Hinojosa, I. Galindo-Estrada, G. Galindo-Reyes, G. Gold-Bouchot, J.V. Macías-Zamora, J. Murguía-González, and E. Ramirez-Espinoza. 2009. Passive air sampling of organochlorine pesticides in Mexico. *Environ. Sci. Technol.* 43(3): 704–10.

²⁴ Wong, F., H.A. Alegria, and T.F. Bidleman. 2010. Organochlorine pesticides in soils of Mexico and the potential for soil-air exchange. *Environ. Pollut.* 158(3): 749–55.

²⁵ Ramos, J., A. Gavilán, T. Romero, and I. Ize. 2011. Mexican experience in local, regional and global actions for lindane elimination, *Environ. Sci. Pol.* 14(5): 503–509.

The CEC's the Sound Management of Chemicals (SMOC) Working Group strives to prevent pollution and reduce risk to the public through cooperative actions for the sound management of persistent, toxic chemicals of regional concern. To realize this goal, the SMOC Working Group has developed and implemented regional action plans for various substances. Under the CEC Process for Identifying Candidate Substances for Regional Action, a substance is nominated by one or more of the North American governments and subsequently evaluated to determine if it meets criteria for trinational action.²⁶

In January of 1999, the United States submitted a Nomination Dossier for lindane.²⁷ In April 2000, the Substance Selection Task Force (SSTF) of the SMOC Working Group concluded in its evaluation that lindane and other HCH isomers "pose risk to humans and wildlife" in North America and that there would be real benefits obtained from collective action regarding lindane.²⁸ They also noted that in each of the three countries, the public health and insecticide and pesticide uses are regulated by separate authorities and thus that the task force should include members from the relevant regulatory agencies of each country.

Based on information presented and extensive consultations with the public, as well as on expert advice from the SSTF, in July 2002 the CEC Council of Ministers issued Resolution 02-07 directing the SMOC Working Group to develop and implement the Lindane NARAP to reduce the risks associated with exposure to this substance.

1.3. Goals of the Lindane NARAP

The goals and objectives of the NARAP were that the three member countries would take cooperative actions to reduce human and environmental exposure 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

²⁶ CEC. 1997. Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative, Report to the North American Working Group on the Sound Management of Chemicals. <<http://www.cec.org/Storage.asp?StorageID=1750>> (consulted July 2012).

²⁷ CEC. 2003. Foundation for Action Plan on Lindane, Substance Selection, Nomination and Decision Documents. <<http://www.cec.org/Storage.asp?StorageID=1322>> (consulted July 2012).

²⁸ CEC. 2000. Decision Document on Lindane Under the Process for Identifying Candidate Substances for Regional Action under the Sound Management of Chemicals Initiative. <<http://www.cec.org/Storage.asp?StorageID=2172>> (consulted July 2012).

- strengthening working relationships between regulatory agencies in the three countries.

2. Update on Domestic Programs

The following is a brief overview of the historical information and status, as of 2012, of lindane in each of the three countries.

2.1. History and Current Status of Lindane Use and Registration in Canada

Agricultural and Veterinary Uses

The sale and use of pesticides, including lindane, is regulated in Canada by Health Canada's PMRA. In 2002, the PMRA completed a review of lindane and product registrations were phased out by 1 January 2005. No lindane products are registered under the Pest Control Products Act.

Historically, lindane has been registered in Canada for a wide variety of applications, including use on crops, seeds, livestock, and in water. Canada imported all technical-grade lindane from foreign companies, as lindane has never been produced domestically.

Publication of Trade Memorandum T-68, on 5 November 1970, signaled an end to the use of lindane on a range of fruit and vegetable crops, in outdoor foggers, and for spraying on water bodies to control mosquitoes. By the mid 1990s, most of the aboveground uses of lindane in Canada had been 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 United Nations Economic Commission for Europe (UNECE) POPs Protocol of the Convention on Long-Range Transboundary Air Pollution (CLRTAP). The POPs Protocol established obligations that included a commitment to restrict expansion of the uses of lindane and conduct a reassessment of all remaining uses.²⁹

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 prohibited from use after December 2004. Due to the possibility of trade-related issues, use of lindane as a seed treatment ended after the 2002 planting season, although the sale of lindane products for use on canola had voluntarily ceased in 2001. 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.

²⁹ UNECE. 1979. Convention on Long-range Transboundary Air Pollution, United Nations Economic Commission for Europe. <<http://www.unece.org/env/lrtap/>> (consulted July 2012).

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

As is its right under section 23 of the Pest Control Product Regulations, Chemtura (formerly Crompton Corp.) requested a hearing by an independent board to review the PMRA decision concerning its lindane products. On 18 August 2005, the Board submitted a report of its findings and recommendations to the Canadian Minister of Health.³⁰

The Board recommended that PMRA prepare a follow-up review of the occupational exposure assessment of lindane. This Lindane Risk Assessment (REV2009-08)³¹ was duly published for public comment on 29 August 2009, and describes the risks that lindane poses to human health and the environment that cannot be adequately mitigated. It also confirmed the 2002 decision to phase out all registrations of lindane.

Lindane is also subject to regulation under the Canadian Food and Drugs Act³² that prohibits the sale of food containing pesticide residues at levels in excess of 0.1 ppm, unless specific MRL are established in Table II of the regulations. The Food and Drugs Act regulations apply equally to imported or domestic commodities.

Pharmaceutical Uses

Lindane remains in use as a second-line therapeutic product under the Food and Drugs Act to control lice and scabies outbreaks in humans, when alternatives have failed. This last Canadian use, as a pharmaceutical agent, is to cease by 2016.

This use in Canada as a pharmaceutical aid dates from the early 1960s. With the introduction of safer agents, however, its use has declined over the years. Only four commercial products, containing 1% lindane in solution, are currently available in Canada, produced by two companies.

Following the reassessment of lindane safety by the US 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 and the Marketed Health Products Directorate of Health Canada to reassess the safety of the human pharmaceutical uses of lindane in Canada. It was found to be safe under conditions of use. The product has always been available without prescription.

³⁰ For more information about Crompton Co. (Chemtura), see section 4.4.

³¹ Health Canada. 2009. Lindane Risk Assessment, Re-evaluation Note REV2009-08. <http://publications.gc.ca/collections/collection_2010/arla-pmra/H113-5-2009-8-eng.pdf> (consulted July 2012).

³² Department of Justice Canada. 2012. Food and Drugs Act (R.S.C., 1985, c. F-27). <<http://laws-lois.justice.gc.ca/eng/acts/F-27/>> (consulted 2012).

Lindane products have been classified as Schedule 2 products by the National Association of Pharmacy Regulatory Authorities (NAPRA),³³ 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.

2.2. History and Current Status of Lindane Use and Registration in Mexico

There are no reports indicating that lindane has been produced in Mexico, but instead the active ingredient was imported and used to develop formulations for subsequent commercialization.

Up until 2002, there was limited information available at the national level (on uses, imports, risks) for supporting the establishment of regulatory and voluntary actions for gradually eliminating the uses of lindane in Mexico. However, derived from the actions established in the NARAP, within the framework of the CEC, a preliminary diagnostic assessment of lindane in Mexico was conducted in 2003³⁴ with the objective of evaluating its status.

This effort constituted an initial step in the decision-making process, and as a result of this research work and consultation, stakeholders involved considered lindane and its isomers to be a risk to public health and to ecosystems. For this reason the pertinent steps were initiated for cancelling lindane registration in Mexico. Also, during 2005, a risk profile was developed to serve as the basis for global actions aimed at eliminating the uses of lindane at the international level.

Lindane is included in the Catalogue of Pesticides (2004)³⁵ prepared by the Inter-Secretarial Commission for the Control of the Processing and Use of Pesticides, Fertilizers and Toxic Substances (*Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas*—Cicoplafest). The main objective of the Intersecretarial Commission is to coordinate actions within the environment, health, economic, and agriculture ministries in Mexico to implement activities for the regulation and control of pesticides, fertilizers and toxic chemicals. This coordinated effort also provides a regulatory framework for the registration, export and import of chemicals. The purpose of this catalogue is to assist in the sound use and management

³³ NAPRA. National Drug Schedule, National Association of Pharmacy Regulatory Authorities. <<http://napra.ca/pages/Schedules/Search.aspx>> (consulted July 2012).

³⁴ INE. 2004. El Lindano en México. <http://www.ine.gob.mx/descargas/sqre/el_lindano_en_mexico.pdf> (consulted July 2012).

³⁵ Cicoplafest. 2004. Catálogo de Plaguicidas. *Comisión Intersecretarial para el Control del Proceso y Uso de Plaguicidas, Fertilizantes y Sustancias Tóxicas*. <<http://www.salud.gob.mx/unicidades/cofepris/bv/libros.htm>> (consulted July 2012).

of pesticides, and it includes information related to public health and environmental effects of substances listed. The catalogue also provides data on the pesticides that are registered in the country and the applications for which they have been authorized.

Mexico is a signatory to the Stockholm Convention (ratified in February 2003) and the Rotterdam Convention (ratified in May 2005). It should therefore fully comply with the obligations derived from these Conventions, since they acquire the status of national law.

Import and Export

In Mexico there are three tariff classifications for importing lindane: 29035101 for pharmaceutical use; 29035102, corresponding to a combination of the stereoisomers of 1,2,3,4,5,6-HCH—1,2,3,4,5,6-HCH (ISO) (including lindane); and 29035199 which refers to other products—1,2,3,4,5,6-HCH (ISO) (including lindane).

According to information obtained from the NARAP corresponding to the 1999–2001 period, nearly 20 tonnes of lindane were imported annually into Mexico for use. The same report indicates that no records of exports to other countries were found for this time period.

As a result of the recommendations made following the national diagnostic assessment, import licenses for lindane were suspended in May 2005. Consultations carried out through the Tariff Information System Via Internet (*Sistema de Información Arancelaria Vía Internet—SIAVI*)³⁶ indicate no reports of lindane imports between 2005 and 2012.

According to Mexico's Secretariat of Finance and Public Credit (*Secretaría de Hacienda y Crédito Público—SHCP*), there are no reports of lindane being imported since 2007 with the tariff classifications 29035101 and 29035102. Regarding tariff classification 29035199, only two records of lindane imports have been identified for the 2007–2012 period, equivalent to US\$173 and US\$50, and each of an amount less than 1 kilogram, apparently intended as standards for analytical use.

Agricultural and veterinary uses

According to registries of the Secretariat of Agriculture, Livestock, Rural Development, Fisheries and Food (*Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación—Sagarpa*), lindane was authorized in Mexico for seed treatment (oats, barley, beans, corn, sorghum and wheat); for ectoparasite control on livestock (cattle, horses, sheep and goats) and domestic animals (cats and dogs), and was particularly effective against common fly larvae, scabies, lice, fleas, ticks, spiders and scorpions.

³⁶ *Secretaría de Economía (SE)*. 2012. Sistema de Información Arancelaria Vía Internet (SIAVI). <<http://www.economia.gob.mx/comunidad-negocios/204-comunidad-de-negocios/sistemas-de-informacion/7687-sistema-de-informacion-arancelaria-via-internet>> (consulted July 2012).

With respect to progress in the cancellation of registrations, according to the NARAP, and data provided by the Federal Commission for Protection Against Sanitary Risks (*Comisión Federal para la Protección contra Riesgos Sanitarios—Cofepris*) and backed by the Mexican Association of the Phytosanitary Industry (*Asociación Mexicana de la Industria Fitosanitaria A.C.—AMIFAC*), of a total of 18 authorizations existing in 2009 for lindane-based products for pesticide use, 14 registrations have been canceled, with only four remaining in effect.

A segment of the phytosanitary industry sector, through AMIFAC, has confirmed that there are no inventories of products containing lindane formulations, or products with the active ingredient.

Pharmaceutical uses

In Mexico the registration of pesticides for human use, such as pediculicides and scabicides, consider these products to be pharmaceuticals and not hygiene products. Lindane-containing pharmaceuticals were formerly included in the Secretariat of Health's "Cuadro Básico de Salud,"³⁷ which is a very useful tool for public health institutions, providing them with a list of inputs that enables them to bring order to both purchasing and prescription processes for first-level medical services. These products are no longer part of this tool. Currently, there are three registrations in effect for lindane-containing products for pharmaceutical uses, but they are in the process of being revoked by the Secretariat of Health.

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

Based on the US Environmental Protection Agency (US EPA) and US FDA laws and regulations, the USA has assessed the risk of both the pesticide and pharmaceutical uses of lindane. These scientific reviews are consistent with the Agencies' regulatory processes for pesticides and drugs. Following these reviews, the USA 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, the US EPA initiated a Rebuttable Presumption Against Registration review of lindane, which resulted 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

³⁷ *Diario Oficial de la Federación (DOF)*. 2008. Novena Actualización de la Edición 2006 del Cuadro Básico y Catálogo de Medicamentos.
<http://cdvirtual.salud.gob.mx/interiores/diario_oficial/diario_2008/pdfs/febrero/9act180208.pdf> (consulted July 2012).

address exposure concerns. In 1998 and 1999, lindane registrants voluntarily canceled all registered uses of lindane except for seed treatment use on 19 agricultural crops and a dog mange treatment. Subsequently, use of lindane to treat mange on dogs was voluntarily canceled in December 2001 and that same year and in 2002, the registrants voluntarily canceled all lindane seed treatment uses except on barley, corn, oats, rye, sorghum, and wheat.

On 27 July 2006, the United States had received requests for voluntary cancellation from all lindane registrants in the country for all remaining registrations of lindane pesticide products. In addition, EPA had reviewed the six remaining lindane seed treatment uses and determined in the July 2006 Addendum to the 2002 Reregistration Eligibility Document on Lindane³⁸ that the remaining uses were not eligible for reregistration.

The EPA thus accepted the producers' voluntary cancellation requests and published a notice of receipt of these requests in the *Federal Register* of 23 August 2006 (71 FR 49445).³⁹ Following that publication, EPA sent final cancellation orders to the registrants, granting the requested cancellations and published a notice announcing these cancellation orders in the *Federal Register* on 13 December 2006 (71 FR 74905).⁴⁰ The cancellation of manufacturing-use products became effective on 4 October 2006, and that of end-use products on 1 July 2007. The Agency established in the cancellation orders that 1 July 2007, was the last day on which lindane manufacturing-use products could be used and 1 October 2009, was the last day on which lindane end-use products could be used.

In addition, in a *Federal Register* notice dated 13 June 2007 (72 FR 32570),⁴¹ the Agency published a proposed rule to revoke all remaining lindane tolerance, effective 2 October 2009, concurrent with the last date of lindane use. The Agency published a rule finalizing this proposal on 19 September 2007 (72 FR 53449) and all remaining lindane tolerances were revoked effective 2 October 2009.

Prior to the 2006 voluntary cancellation requests, more than 99% of all lindane used in the United States was for agricultural purposes.

³⁸ US EPA. 2004. Reregistration Eligibility Decision: Lindane. United States Environmental Protection Agency. Search "R.E.D. Facts, Lindane" at <<http://nepis.epa.gov/>> (consulted July 2012).

³⁹ *Federal Register* 49445. 2006. Lindane; Notice of Receipt of Requests to Voluntarily Cancel Lindane Pesticide Registrations, United States Environmental Protection Agency [EPA-HQ-OPP-2002-0202; FRL-8089-1]. 71(163). <<http://www.gpo.gov/fdsys/pkg/FR-2006-08-23/pdf/E6-13955.pdf>> (consulted July 2012).

⁴⁰ *Federal Register* 74905. 2006. Lindane; Cancellation Order, United States Environmental Protection Agency [EPA-HQ-OPP-2002-0202; FRL-8103-4], 71(239). <<http://www.gpo.gov/fdsys/pkg/FR-2006-12-13/pdf/E6-21101.pdf>> (consulted July 2012).

⁴¹ *Federal Register* 32570. 2007. Amitraz, Atrazine, Ethephon, Ferbam, Lindane, Propachlor, and Simazine; Proposed Tolerance Actions, United States Environmental Protection Agency, 40 CFR Part 180, [EPA-HQ-OPP-2007-0187; FRL-8133-3] 72(113) <<http://www.gpo.gov/fdsys/pkg/FR-2007-06-13/pdf/E7-11324.pdf>> (consulted July 2012).

Pharmaceutical Uses

Lindane is approved by the FDA for use in 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, the FDA increased hazard warnings and required reductions in 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 in 2005 totaled less than one metric ton (or 1000 kg). Lindane accounted for fewer than 1 million treatments out of 10 to 20 million annual cases of lice. By 2009, annual use of lindane to treat lice and scabies in the United States had dropped to less than 80 kg and was prescribed for fewer than 91,000 out of 10 to 20 million annual cases of lice. In addition, the 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.

Phase-out of Lindane in California

The state of California has taken independent regulatory action on lindane. In May 2000, the California Toxics Rule (CTR)⁴² established a new water quality criterion of 19 ppt (parts per trillion) lindane in existing or potential drinking water supplies for the protection of public health, based on potential cancer risk to humans. Studies conducted on 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, which are equivalent to the US national water quality criterion for water bodies that are existing or potential sources of drinking water.⁴³ 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 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. A review of California pesticide applicator records and physician surveys by the Sanitation Districts revealed no significant agricultural sources 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 yield compliance with the new standards. A bill was then sponsored in the California assembly, which passed

⁴² *Federal Register* 31682. 2000. Water Quality Standards; Establishment of Numeric Criteria for Priority Toxic Pollutants for the State of California; Rule 2000, 40 CFR Part 131, Part III, Environmental Protection Agency. <http://www.waterboards.ca.gov/water_issues/programs/tmdl/records/state_board/2003/ref476.pdf> (consulted July 2012).

⁴³ *Federal Register* 67548. 1998. National Recommended Water Quality Criteria, Environmental Protection Agency, [frl-ow-6186-6a]. 63(234) December. <<http://www.gpo.gov/fdsys/pkg/FR-1998-12-07/pdf/98-30272.pdf>> (consulted July 2012).

without opposition, to ban the sale of all pharmaceutical lindane in the state of California, beginning in January 2002.

Two years later, a review of the ban's effects conducted by medical and public health authorities of the Los Angeles County Sanitation Districts noted that no difficulties or concerns had been raised among a population of over 30 million. And lindane concentrations in wastewater exiting the Districts' treatment plants had declined from non-attainment of the 19 ppt goal to almost non-detectable levels.

A 2005 survey of California pediatricians (135 respondents) indicated that 98.5% of them had not seen any increase in scabies since the ban.⁴⁴ The California Department of Health Services (CDHS) has developed and distributed to healthcare facilities, a Guideline for the management of scabies outbreaks.⁴⁵ In it, CDHS provides information on all options for treatment and prophylaxis with the pros and cons for each, allowing the users to decide on which to use. This information includes the off-label (i.e., not approved by the US FDA) use of ivermectin to treat patients with severe (e.g., keratotic) scabies that is likely to be refractory to cutaneous medication. Because oral ivermectin has not been approved by the FDA for use as a treatment for scabies, the agency cannot recommend it for use.

2.4. International Regulation of Lindane

As well as Mexico's accepted proposal that lindane be added to Annex A of the Stockholm Convention, lindane is regulated in a number of international fora.

The Great Lakes Binational Toxics Strategy⁴⁶ is a voluntary strategy signed in 1997 by 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 or the other has to have grounds to indicate its persistence in the environment, potential for bioaccumulation, and toxicity. (In contrast, Level I substances, such as PCBs, are targeted for virtual elimination through collaborative bilateral efforts.) The governments of Canada and the US 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.

⁴⁴ Miller, M. 2006. Reducing Children's Exposures to Environmental Chemicals. American Academy of Pediatrics, University of California, San Francisco, Pediatric Environmental Health Special Unit. <<http://preventionlane.org/braindevelopment/Materials/MILLER-HBD-Conf08-workshopIII.pdf>> (consulted July 2012).

⁴⁵ California Department of Public Health. 2008. Management of Scabies Outbreaks in California Health Care Facilities. <<http://www.cdph.ca.gov/pubsforms/guidelines/documents/mgmntofscabiesoutbreaks.pdf>> (consulted July 2012).

⁴⁶ EPA. 2012. Binational Toxics Strategy. US Environmental Protection Agency. <<http://www.epa.gov/bns/>> (consulted July 2012).

The use of lindane has been addressed in the 1998 Aarhus Protocol on Persistent Organic Pollutants.⁴⁷ This is one of the eight protocols under the CLRTAP. The POPs Protocol entered into force in October 2003. The Protocol restricts lindane to six specific uses. Canada is a Party and the United States has signed, but not ratified the CLRTAP POPs Protocol.

Lindane is also listed under the European Water Framework Directive 2000/60/EC.⁴⁸ This legislation from the European Community requires all inland and coastal water bodies to reach at least “good ecological status” and “good chemical status” by 2015. Lindane is one of the listed priority hazardous substances for which quality standards and emission controls will be set at EU level to end all emissions within 20 years.

Lindane is also listed under European Union Regulation 850/2004/EC, specifying that Member States are allowed its use, until September 2006, in the professional remedial and industrial treatment of lumber, timber and logs, as well as for indoor industrial and residential applications; and until 31 December 2007, are allowed the use of technical-grade HCH as an intermediate in chemical manufacturing, but that products containing at least 99% lindane are restricted from uses in public health or as veterinary topical insecticide.⁴⁹

HCH is also listed in Annex IV (waste regulation) of European Council Directive 850/2004/EC and its amending regulation 1195/2006/EC,⁵⁰ in order to include thresholds for POPs containing waste. Article 7 applies to waste containing >50 mg/kg of the sum of α - and β -HCH and lindane.

The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade⁵¹ includes lindane. 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 exports of it 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.

⁴⁷ UNECE. Protocol on Persistent Organic Pollutants (POPs), United Nations Economic Commission for Europe <http://www.unece.org/env/lrtap/pops_h1.html> (consulted July 2012).

⁴⁸ *Official Journal of the European Union*. 2000. Directive 2000/60/EC of the European Parliament and of the Council establishing a framework for Community action in the field of water policy. <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2000:327:0001:0072:EN:PDF>> (consulted July 2012).

⁴⁹ *Official Journal of the European Union*. 2004. Regulation (EC) No. 850/2004 of the European Parliament and of the Council on persistent organic pollutants and amending Directive 79/117/EEC. Refer to Annex 1, Part B, in <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:158:0007:0049:EN:PDF>> (consulted July 2012 and January 2013).

⁵⁰ *Official Journal of the European Union*. 2006. Council Regulation (EC) No. 1195/2006 amending Annex IV to Regulation (EC) No. 850/2004 of the European Parliament and of the Council on persistent organic pollutants. <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:217:0001:0003:EN:PDF>> (consulted July 2012).

⁵¹ Rotterdam Convention. 1998. <<http://www.pic.int/>> (consulted July 2012).

3. National Actions

The following section describes actions that the individual countries took to reduce the risk to human health and the environment from exposure to lindane and its isomers.

3.1. Canada

In addition to phasing out pharmaceutical use of lindane, Canada undertook actions in science and research; and outreach and education as well as worked cooperatively with Mexico and the United States on regional efforts to strictly reduce or eliminate use of lindane, as per the commitments outlined in the NARAP.

In 2009, Health Canada completed its Reevaluation of the Lindane Risk Assessment,⁵² which confirmed the earlier decision by the PMRA to withdraw all pest control products containing lindane from use in Canada. Health Canada continues to monitor for evidence of unsafe and excessive use of lindane pharmaceutical products by using the Canada Vigilance Program.⁵³

Science and Research

Environment Canada continues to support monitoring of lindane and other HCH isomers in the biotic and abiotic compartments of various regional ecosystems, including Canada's North, the Great Lakes-Gulf of St. Lawrence, and on the Arctic, Atlantic and Pacific coasts. Health Canada supports the measurement of lindane and other HCH isomers in the blood of Canadians, including vulnerable populations such as children and people in the northern regions of the country.

Outreach and Education

Health Canada has strengthened outreach and education efforts to the public and medical community to encourage the safe and appropriate clinical use of lindane. Canada has shared information with the United States 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.

3.2. Mexico

Mexico has valuable experience in developing coordinated actions at the national and regional levels, including public participation through consultation forums on PBTs and wastes. In Mexico, social participation through consultative fora has increased substantially.

The regulatory actions that have been implemented in Mexico in recent years have been complemented by activities aimed at gradually eliminating lindane uses in the country.

⁵² See note 31, *supra*.

⁵³ Health Canada. 2011. Canada Vigilance Program. <<http://www.hc-sc.gc.ca/dhp-mps/medeff/vigilance-eng.php>> (consulted July 2012).

Alternatives Identified for Various Uses of Lindane

A list of alternatives has been determined that contains a wide variety of products authorized for use in agricultural, veterinary, and pharmaceutical applications. There is no documented information, however, regarding a specific campaign or strategy for disseminating this information to the general public.

For products of agricultural use, a total of 38 technical reports have been written on the biological effectiveness of the 18 products that may be used as substitutes for lindane. There are also seven new registrations for products that can be used as alternatives to lindane. Along these same lines, there are 61 active ingredients registered, corresponding to 166 commercial products used as substitutes for lindane.

Also, the Secretariat of the Environment and Natural Resources (*Secretaría de Medio Ambiente y Recursos Naturales*—Semarnat) conducted a study in 2009 on alternatives and substitutes for chemical substances subject to control measures from international agreements on environmental matters, specifically those included in the Stockholm and Rotterdam Conventions. The report from this work included proposed substitutes for lindane for various pests and farm crops, which is summarized in Tables 3 and 4 in Sections 4.2.1 and 4.3.2.⁵⁴

Pharmaceutical Uses

The process for revoking the registration of pharmaceutical products containing lindane has taken place gradually, since the Secretariat of Health must conduct this type of administrative procedure independently for each company involved. As of 2012, there are only three registrations for pharmaceutical use that are still in effect, and they are in the process of being revoked. The list of alternatives available for pharmaceutical uses of lindane has been updated in the corresponding public health sector and is included in Table 2 in Section 4.1.2.

Environmental Management

In the framework of the Stockholm Convention and in compliance with the actions established in the Action Plans included in Mexico's National Implementation Plan (NIP),⁵⁵ some related activities aimed at the sound management of POPs (including lindane) have been developed. For example, in accordance with Action Plan No. 4 of Mexico's NIP, Semarnat conducted a study in 2008 to update the inventory of obsolete pesticides to enhance the information on remaining stockpiles and wastes addressed in the Stockholm Convention. Also, in the framework of Proname, a project was developed

⁵⁴ Unfortunately, the full report from this study has not been made publicly available as of this writing (December 2012).

⁵⁵ Semarnat. 2007. Plan Nacional de Implementación del Convenio de Estocolmo. *Secretaría de Medio Ambiente y Recursos Naturales*. <http://siscop.ine.gob.mx/novedades/pni_mexico.pdf> (consulted July 2012).

for technical assistance to facilitate the implementation action of the Stockholm Convention in relation to contaminated sites.⁵⁶

Legal foundations have been established for identifying and characterizing POP-contaminated sites with the aim of generating strategies to ensure that the treatment of these sites will be environmentally appropriate and cost-effective. Semarnat has developed and published Guidelines for Requesting an Evaluation of Environmental Risk Studies at Sites with Contaminated Soil (*Guía para la Solicitud de Evaluación de Estudios de Riesgo Ambiental en Sitios con Suelos Contaminados*)⁵⁷ and activities have been carried out to update the inventory of these contaminated sites.

Furthermore, initial activities have been carried out for designing and implementing a Global Harmonized System (GHS) of chemical classification and labeling. In 2011 a Mexican Standard (Norma Mexicana—NMX) (NMX-R-019-SCFI-2011)⁵⁸ was published to establish the criteria for classifying and communicating the hazards associated with chemical products, in accordance with provisions in the United Nation's "Purple Book."⁵⁹ In this context the Secretariat of Health published the Mexican Official Standard (*Norma Oficial Mexicana*) NOM-232-SSA1-2009,⁶⁰ in which the GHS is adopted for the labeling of pesticides for agricultural, forestry, livestock, garden, urban, industrial and household use. For its part, the Secretariat of Communications and Transportation (*Secretaría de Comunicaciones y Transportes—SCT*) has published Mexican Official Standards NOM-003-SCT/2008,⁶¹ NOM-027-SCT2/2009 and NOM-028-SCT2/2010,⁶²

⁵⁶ Cedillo, L.A., 2008. Proyecto de asistencia técnica para facilitar la acción de la implementación del Convenio de Estocolmo en relación a sitios contaminados. <http://siscop.ine.gob.mx/descargas/proyectos/reporte_final_sp_leonor_cedillo.pdf> (consulted July 2012).

⁵⁷ Semarnat. Guía para la Solicitud de Evaluación de Estudios de Riesgo Ambiental en Sitios con Suelos Contaminados, <http://www.semarnat.gob.mx/temas/gestionambiental/Materiales_y_Actividades_Riesgosas/sitioscontaminados/estudioderiesgo/Estudios.pdf> (consulted July 2012).

⁵⁸ *Diario Oficial de la Federación* (DOF). 2011. Sistema Armonizado de Clasificación y Comunicación de Peligros de los Productos Químicos. <<http://200.77.231.100/work/normas/nmx/2010/nmx-r-019-scfi-2011.pdf>> (consulted July 2012).

⁵⁹ UNECE. 2011. Globally Harmonized System of Classification and Labelling of Chemicals. Fourth revised edition. <http://www.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html>.

⁶⁰ *Diario Oficial de la Federación* (DOF). 2009. Norma Oficial Mexicana NOM-232-SSA1-2009, Plaguicidas: que establece los requisitos del envase, embalaje y etiquetado de productos grado técnico y para uso agrícola, forestal, pecuario, jardinería, urbano, industrial y doméstico. <<http://www.dof.gob.mx/normasOficiales/4020/salud/salud.htm>> (consulted July 2012).

⁶¹ *Diario Oficial de la Federación* (DOF). 2008. Norma Oficial Mexicana NOM-003-SCT/2008, Características de las etiquetas de envases y embalajes, destinadas al transporte de sustancias, materiales y residuos peligrosos. <http://dof.gob.mx/nota_detalle.php?codigo=5056785&fecha=15/08/2008> (consulted July 2012).

⁶² *Diario Oficial de la Federación* (DOF). 2010. NORMA Oficial Mexicana NOM-028-SCT2/2010, Disposiciones especiales y generales para el transporte de las sustancias, materiales y residuos peligrosos de la clase 3 líquidos inflamables. <http://dof.gob.mx/nota_detalle_popup.php?codigo=5143461> (consulted July 2012).

which refer to the labeling of hazardous substances, materials and wastes, and in which the GHS system is contemplated.

During 2012 it is anticipated that Mexico will initiate a project for capacity building in implementing the GHS in the country. This project has been approved by the Quick Start Program (QSP) of the Strategic Approach to International Chemicals Management (SAICM).⁶³

Research and Monitoring

In Mexico, assistance has been provided to applied research in the area of chemical substances during recent years. A number of scientific forums on POPs have offered opportunities for exchanging information and establishing research networks among the main academic centers that conduct studies in this field.

One of the most significant achievements in this aspect has been the creation of Proname, whose objective is to serve as a scientific tool for generating data on environmental levels of the country's high-priority chemical substances.

As part of Proname activities, several manuals on POP sampling and chemical analysis were developed during 2009 and 2010, with the aim of standardizing the methods used for evaluating the environmental and biological samples collected at sites addressed in this program, and thus obtain comparable results.

Research and the ongoing monitoring efforts in Mexico will make it possible to obtain reliable, updated data for assessing trends in lindane concentrations over time. As well, generating this type of data will provide pertinent information for meeting the obligations established in the context of the Stockholm Convention.

On the international arena, Mexico has actively participated in groups of experts who evaluate scientific information on POPs, including lindane. These groups have included the POPs Review Committee associated with the Stockholm Convention (2005–2010) and the Chemical Review Committee of the Rotterdam Convention (2007–2012).

Awareness-Raising and Education

The National Technical Advisory Council on Animal Health (*Consejo Técnico Consultivo Nacional de Sanidad Animal—Conasa*) is an advisory body with Sagarpa. It organizes forums for analyzing and issuing opinions on health matters. These forums also include activities for promoting education and awareness-raising on issues associated with the prevention, control and eradication of pests and diseases affecting animal life and health, and promoting actions aimed at good livestock practices in the production of

⁶³ Strategic Approach to International Chemicals Management (SAICM). 2011. Table of projects funded by the Quick Start Programme (QSP) trust fund of the Strategic Approach to international Chemicals Management (SAICM).

<http://www.saicm.org/images/saicm_documents/_menu_items/QSP%20trust%20fund%20approved%20projects%20tables%20Oct%202011.pdf> (consulted July 2012).

goods of animal origin. In addition, there is a National Campaign against Ticks,⁶⁴ which has disseminated materials indicating the risks associated with organochlorine pesticides and emphasizing that lindane should not be used.

In the framework of the Stockholm Convention on POPs, activities were initiated in 2009 to follow up on Action Plan No. 8⁶⁵ on Communication, Awareness-Raising and Citizen Participation within Mexico's NIP. Some of the initial activities included forming an inter-secretarial working group for developing a proposal for a strategy and work plan, with the aim of obtaining and disseminating information on the additional POPs, including lindane and alpha- and beta-isomers of HCH.

Also, the National Institute of Ecology has carried out various activities aimed at disseminating information on the experiences and lessons learned as a result of the efforts that led Mexico to propose that lindane and other isomers of HCH be addressed in the Stockholm Convention. These activities have fomented access to information for interested sectors in other countries, through online seminars (webinars) organized by the Secretariat of the Stockholm Convention, for example.

3.3. United States of America

Pharmaceutical Uses

The US FDA continues to work proactively with pharmaceutical companies to facilitate the development of alternatives to lindane for the treatment of lice and scabies. The FDA also continues to monitor for evidence of unsafe and excessive use. At this time lindane will remain on the market as a second-line treatment.

The Indian Health Service (IHS) reviewed lindane orders for the year 2004 and followed 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 were being employed. Education was provided to the local staff on available alternatives to lindane. The National Pharmacy and Therapeutics Commission reviewed the treatment of scabies and lice and provided treatment guidelines for the IHS and tribal health care providers. As of 2005, most IHS sites had already switched to non-lindane containing products for first-line treatment of scabies and lice and only use lindane products as second-line therapy.⁶⁶

Agriculture

⁶⁴ Conasa. 2007. Situación actual y Perspectivas de la Campaña Nacional Contra la Garrapata. *Consejo Técnico Consultivo Nacional de Sanidad Animal*. <[http://www.conasamexico.org.mx/2007garrapataNOE%20SOBERANES%20\[Modo%20de%20compatibilidad\].pdf](http://www.conasamexico.org.mx/2007garrapataNOE%20SOBERANES%20[Modo%20de%20compatibilidad].pdf)> (consulted July 2012).

⁶⁵ See footnote 55, *supra*.

⁶⁶ Robert Pittman (Principal Pharmacy Consultant, Indian Health Service). 2005. OB/GYN CCC & Pediatrics Corner 3(5): 8, Use lindane products as second-line treatment only. [In: OB/GYN Chief Clinical Consultant's Corner—Maternal and Child Health for American Indians and Alaska Natives] <<http://www.docstoc.com/docs/53582864/OBGYN-Pediatrics-CCC-Corner>> (consulted July 2012).

The United States accepted producers' voluntary cancellation requests for the remaining seed treatment uses for lindane, and published a notice of receipt of these requests. As per commitments, the EPA published a proposed rule to revoke all remaining lindane tolerance, effective 2 October 2009, concurrent with the last date of lindane use.⁶⁷

Science and Research

The United States will continue to monitor for lindane residues in food through surveillance at the state level, USDA's Pesticide Data Program (PDP),⁶⁸ and the FDA's monitoring of imports. The United States will continue to monitor for lindane and other HCH isomers in the environment (air and fish) through the IADN program, the Great Lakes Fish Monitoring and Surveillance Program, and the National Fish Tissue Study. Monitoring levels of lindane and other HCH isomers in the blood of Americans is ongoing through the National Health and Nutrition Examination Survey (NHANES).

Outreach and Education

The US EPA worked with China to reduce use and emissions that result in long-range transport of lindane and its waste isomers. The work was concluded in 2005. China has reported that lindane is no longer registered for use and that there is no current production or export.

The 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 and the FDA is committed to continue to share information, as allowed under international agreements, with Canada and Mexico, through other international fora, regarding adverse events associated with lindane, new regulatory actions, and education strategies in order to raise clinical practice standards in a harmonized way.

4. North American Regional Actions

The following section describes the actions taken regionally by the three countries in their efforts to meet their commitments under the lindane/HCH NARAP.

4.1. Pharmaceutical Uses

4.1.1. Inventory of Lindane Products Used for Pharmaceutical Purposes

The Parties provided lists of current suppliers, formulators and wholesalers of lindane containing products in each country; and provided information on the amount of active

⁶⁷ *Federal Register* 72(113), 13 June 2007 <<http://www.gpo.gov/fdsys/pkg/FR-2007-06-13/html/E7-11324.htm>>.

⁶⁸ USDA. Agricultural Marketing Service. <<http://www.ams.usda.gov/>> Search "Pesticide Data Program."

ingredient used or sold in order to track trends. These data were also included in the NARAP.

There are two market authorization holders marketing lindane in Canada. In Canada, data indicates that sales of lindane have continued to decrease through to 2011. In 2003, sales for public health use amounted to approximately 36 kg of lindane, which declined to 5.6 kg in 2011.⁶⁹

Information indicates that usage also continues to decline year by year in the United States: the amount in 2005 was less than 1000 kg and in 2009 the amount was less than 80 kg.⁷⁰

In Mexico there is no legal instrument to ask suppliers, formulators and medical services to inform the authorities about lindane prescriptions and sales or purchasing records so these data were not obtained. There is some evidence that lindane as a treatment option for lice and scabies is no longer found in the pharmacies from certain localities in Mexico.

4.1.2. Alternatives

The Parties continue to support research into the development of alternatives to pharmaceutical use of lindane in North America and have compiled a list of alternatives in each country.

To support the development of a list of alternatives, a workshop was hosted by Mexico on 4–6 October 2005, to investigate available alternatives and integrated strategies for reducing lindane use in Canada, Mexico and the USA. Representatives from federal government departments, nongovernmental organizations and international experts discussed the potential impacts and suitability of various alternatives to lindane. The outcomes of the workshop regarding the available alternatives for pharmaceutical uses have been integrated and updated in Table 2.

⁶⁹ Information provided to the authors by Xavier Tremblay of Health Canada, April 2012.

⁷⁰ Information provided to the authors by Abigail Jacobs of the US FDA, April 2012.

Table 2. Available Alternatives to the Pharmaceutical Uses of Lindane in Canada, Mexico and the United States of America.

Use	Canada*	Mexico	US
Head Lice Treatment	Permethrin (1% cream) Bioallethrin and piperonyl butoxide Pyrethrin and piperonyl butoxide	Permethrin Sulfur soap Pyrethrin soap	Malathion lotion (5%) Benzoyl alcohol lotion (5%) Spinosad topical suspension (0.9%) Sklice (ivermectin) lotion, (0.5%) Permethrin cream rinse (1%) Pyrethrum/piperonyl butoxide Nit comb: Combing is desirable to accompany all treatments
Scabies Treatment	Permethrin (5% cream) Precipitated sulfur 6% in petrolatum Crothamiton 10% (Eurax)	Permethrin Ivermectin Benzyl benzoate Crothamiton 10% (Eurax)	Permethrin Crothamiton (Eurax)

[May 2012]

* 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).

4.1.3. Outreach and Education

The Parties have strengthened outreach and education efforts to provide information on the possible risks associated with lindane and alternatives for the treatment of lice and scabies. Lindane is listed in the Canadian Compendium of Pharmaceuticals and Specialties (CPS) to ensure that the lindane monograph is readily available to Canadians and prescribers via this widely used reference.

The United States works through the FDA Center for Drug Evaluation and Research and the Office of Communication and Training to prepare articles on lindane targeted to

parents, pediatricians, and general practitioners.⁷¹ The US EPA, US FDA and the Tribal Pesticide Program Council have worked together to address tribal concerns on the availability of lindane as a lice treatment to ensure indigenous populations were suitably advised in a culturally acceptable manner on the possible risks associated with the pharmaceutical use of lindane, and to inform them about alternatives. The United States also monitors and compiles data on adverse effects.

As noted in Section 3.2, Mexico formed an inter-secretarial working group to obtain and disseminate information on the additional POPs added to the Stockholm convention, including lindane and the alpha- and beta-isomers of HCH.

4.2. Agriculture – Veterinary

4.2.1. Alternatives

The Parties worked cooperatively to develop capacity through information exchange, outreach and education, and transfer of knowledge for the adoption of safer and cost effective alternatives to lindane for veterinary uses through the workshop held in Mexico in 2005. An updated list of alternatives for veterinary uses of lindane in Canada, Mexico and the United States can be found in Table 3.

Table 3. Available Alternatives to the Pesticidal Uses of Lindane in Canada, Mexico and the United States—Livestock

Use Site	Pest	Canadian Registered Alternatives	Mexican Registered Alternatives	US Registered Alternatives
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⁷¹ USFDA. Drugs. Lindane Shampoo and Lindane Lotion. <<http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm110452.htm>>.

Use Site	Pest	Canadian Registered Alternatives	Mexican Registered Alternatives	US Registered Alternatives
Beef Cattle	Hornfly, lice, tick	Carbaryl Diazinon Dichlorvos Malathion Phosmet Tetrachlorvinphos Cyfluthrin Cypermethrin Permethrin Pyrethrin Rotenone Rotenone/Sulphur Lambda-cyhalothrin Veterinary Drugs: Eprinomectin Ivermectin Doramectin Moxidectin	Alpha- cypermethrin, Amitraz Cypermethrin Coumaphos Deltamethrin Fipronil Fluazeron Flumethrin Lambda-cyhalothrin, Flumethrin + Cyfluthrin, Cymiazol + Cipermethrin Chlorpyrifos + Permethrin Veterinary Drugs: Doramectin Ivermectin + Abamectin Moxidectin	Carbaryl Coumaphos Cyfluthrin Cypermethrin Diazinon Dichlorvos Fenvalerate Lambda-cyhalothrin Malathion Permethrin Phosmet Pyrethrin Tetrachlorvinfos Trichlorfon Veterinary Drugs: Eprinomectin Ivermectin Doramectin Moxidectin Methoprene

Use Site	Pest	Canadian Registered Alternatives	Mexican Registered Alternatives	US Registered Alternatives
Swine	lice, mange mite, flea	Carbaryl Malathion Phosmet Rotenone Veterinary Drugs: Doramectin Ivermectin	Alpha- cypermethrin, Amitraz Cypermethrin Coumaphos Deltamethrin Fipronil Fluazeron Flumethrin Lambda-Cyhalothrin Flumethrin + Cyfluthrin, Cymiazol + Cypermethrin Chlorpyrifos + Permethrin Veterinary Drugs: Doramectin Ivermectin + Abamectin Moxidectin	Amitraz Coumaphos Malathion Methoxychlor Phosmet Permethrin Tetrachlorvinfos Veterinary Drugs: Doramectin Ivermectin

[February 2012]

4.3. Agriculture – Pesticide

4.3.1. Inventory of lindane products used for agricultural pesticide purposes

There are no current registered suppliers or formulators of lindane pesticide products in Canada or the United States. No lindane is being imported into Canada, Mexico or the US for agricultural uses.

4.3.2 Alternatives

The alternatives workshop held in Mexico in 2005 identified alternatives to lindane for previously registered pesticide uses. This information has been updated and compiled into Tables 4 and 5.

Canada, through the PMRA, and the United States, through the Pesticide Environmental Stewardship Program,⁷² coordinate and facilitate the development of voluntary, national Integrated Pest Management (IPM) strategies in cooperation with a range of partners including grower organizations, manufacturers, other federal government departments, provinces, research establishments and other nongovernmental organizations. Sagarpa in Mexico has published guidance information⁷³ that promotes the implementation of IPM strategies in the country.

The US government and industry developed the PBT Profiler,⁷⁴ a web-based evaluation tool to assist companies to develop new chemicals without PBT properties.

Further, the US EPA has exchanged information with other Parties on new alternatives registered by US EPA for seed treatment use and formed partnerships⁷⁵ with a wide range of organizations to explore pest control practices that reduce pesticide risk.

Table 4. Available Alternatives to the Pesticidal Uses of Lindane in Canada, Mexico and the United States—Seed Treatments

Use Site	Pest	Canadian Registered Alternatives	Mexico Registered Alternatives	US Registered Alternatives
Canola*	Flea beetle	Acetamiprid Clothianidin Thiamethoxam Imidacloprid	Not applicable	Clothianidin Thiamethoxam Imidacloprid

⁷² EPA. 2012. PestWise. US Environmental Protection Agency. <<http://www.epa.gov/pestp/>> (consulted July 2012).

⁷³ Sagarpa. n.d. Manejo Integrado de Plagas, 11. *Secretaría de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación* <<http://www.sagarpa.gob.mx/desarrolloRural/Documents/fichasaapt/Manejo%20integrado%20de%20plagas.pdf>> (consulted July 2012).

⁷⁴ EPA. 2010. PBT Profiler. US Environmental Protection Agency. <<http://www.pbtprofiler.net/>> (consulted July 2012).

⁷⁵ EPA. Pesticides: grants and partnerships. Partnerships. <www.epa.gov/pesticides/grants/partnerships.htm> (consulted June 2013).

Use Site	Pest	Canadian Registered Alternatives	Mexico Registered Alternatives	US Registered Alternatives
Corn	Wireworm, Mexico (general category incl:) <i>Phyllophaga</i> spp. (scarab beetles), <i>Agriotes</i> spp. (cutworms), <i>Acanthoscelides obtectus</i> (bean weevil), <i>Ephestia kuehniella</i> (Mediterranean flour moth), <i>Oryzaephilus surinamensis</i> (sawtoothed grain beetle), <i>Plodia interpunctella</i> (Indian meal moth), <i>Rhizopertha dominica</i> (Lesser grain borer), <i>Sitophilus granarius</i> (wheat weevil), <i>Sitophilus oryzae</i> (rice weevil), <i>Sitophilus zeamais</i> (maize weevil), <i>Tribolium castaneum</i> (red flour beetle), <i>Prostephanus truncatus</i> (Larger grain borer), <i>Sitotroga cerealella</i> (Aungoumois grain moth), <i>Tribolium confusum</i> (confused flour beetle), <i>Zabrotes subfasciatus</i> (Mexican bean weevil)	Clothianidin Imidacloprid Tefluthrin (granular in furrow treatment), Thiamethoxam	Acephate Bifenthrin Cadusafos Carbofuran Chlorpyrifos ethyl Clothianidin Deltamethrin Diazinon Ethoprofos Fenitrothion Fipronil Sulphuryl fluoride Fonofos (Dyfonate) Magnesium phosphide Phoxim Imidacloprid Isazophos Isofenphos Malathion Permethrin Pirimiphos-methyl Tebupirimphos Tefluthrin Terbuphos Thiametoxam Thiodicarb	Imidacloprid Thiamethoxam Permethrin Tefluthrin Clothianidin

Use Site	Pest	Canadian Registered Alternatives	Mexico Registered Alternatives	US Registered Alternatives
Barley	Wireworm, Mexico (general category incl:) <i>Sitophilus oryzae</i> (rice weevil), <i>Tribolium confusum</i> (confused flour beetle)	Thiamethoxam Imidacloprid	Chlorpyrifos-methyl Deltamethrin Sulphuryl fluoride Malathion Carbofuran Clothianidin Fonofos Malathion Thiodicarb	Thiamethoxam Imidacloprid
Wheat	Wireworm, Mexico (general category incl:) <i>Tenebroides mauritanicus</i> (Cadelle beetle), <i>Tribolium castaneum</i> (red flour beetle), <i>Sitophilus zeamais</i> (maize weevil)	Thiamethoxam Imidacloprid	Chlorpyrifos methyl Deltamethrin Fenitrothion Sulphuryl fluoride Phoxin Malathion Pirimifos	Thiamethoxam Imidacloprid
Oat	Wireworm, Mexico (general category incl:) <i>Plodia interpunctella</i> (Indian meal moth), <i>Sitophilus granarius</i> (wheat weevil), <i>Sitotroga cerealella</i> (Aungoumois grain moth)	Thiamethoxam Imidacloprid	Chlorpyrifos-methyl Deltamethrin Sulphuryl fluoride Malathion Carbofuran Clothianidin Fonofos Malathion Thiodicarb	Imidacloprid
Rye*	Wireworm	Thiamethoxam	Not applicable	Imidacloprid

Use Site	Pest	Canadian Registered Alternatives	Mexico Registered Alternatives	US Registered Alternatives
Sorghum	Wireworm, Mexico (general category incl:) <i>Agrotis</i> spp. (cutworms), <i>Sitophilus granarius</i> (wheat weevil), <i>Sitophilus oryzae</i> (rice weevil)	Thiamethoxam	Bacillus thuringiensis Carbofuran Chlorpyrifos-ethyl Clothianidin Deltamethrin Fonofos (Dyfonate) Malathion Thiodicarb	Thiamethoxam Imidacloprid
Bean**	(Mexico) <i>Acanthoscelides obtectus</i> (bean weevil)	Not applicable	Deltamethrin Malathion	Not applicable

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*Canola was never a registered use in the United States.

*Canola and rye were never registered uses in Mexico.

**Beans were never a registered use in Canada and the United States.

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

Table 5. Available Non-chemical Alternatives to Agricultural Seed Treatment Uses of Lindane

Cultural Methods
<p>Site selection and monitoring</p> <p>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 from wireworm infestation. Assessment methods include soil sampling, use of bait traps, and adult trapping. Should wireworm infestation exist, a number of methods are available to reduce and effectively control the population.</p>
<p>Fallowing</p> <p>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.</p>

<p>Crop rotation</p> <p>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.</p>
<p>Timing of seeding and planting</p> <p>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.</p>
<p>Shallow cultivation</p> <p>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.</p>
<p>Soil packing</p> <p>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 for 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.</p>
<p>Biological Methods</p> <p>Research at Pacific Agri-Food Research Centre, in Agassiz, Canada, is examining the use of <i>Metarhizium anisopliae</i>, an insect fungal pathogen, to control wireworms. Results are promising so far but no commercial product currently exists.</p>

4.3.3. Outreach and Education

Because lindane is no longer used as a pesticide in Canada or the United States and almost all pesticide uses in Mexico are being phased out, there were no further efforts to exchange information on this topic. The US EPA's decisions and actions on lindane are publicly available (Docket numbers OPP-2002-0202, OPP-2006-0034, and OPP-2004-

0246). Further, the US EPA has prepared a fact sheet on the voluntary cancellation and Reregistration Eligibility Decision addendum⁷⁶ for the public.

Due to the cancellation of or phase out of pesticide uses of lindane in all three countries, extra efforts were not undertaken to convey the possible risks associated with pesticide uses of lindane under this action. Rather, efforts were increased to ensure information was passed regarding risks associated with pharmaceutical use. See section 4.1.3.

4.4. Trade Issues

Crompton Co. (Chemtura), which had sold lindane as a seed treatment in Canada, filed a claim for arbitration on 10 February 2005, in accordance with NAFTA Chapter 11, for compensation and damages related to the discontinuance of lindane sales in Canada. The Tribunal issued its final ruling on 2 August 2010, finding that Canada had not breached the provisions of NAFTA, and determined that Chemtura would bear the entire costs of the arbitration (\$688 000) and so be liable for one-half the fees and costs of the Government of Canada (C\$2.9 million). More information can be found on the Foreign Affairs and International Trade Canada website.⁷⁷

4.5. Waste Management Issues

4.5.1. Water contamination

The Canadian drinking water guideline for lindane was archived because lindane was no longer found in Canadian drinking water supplies at levels that could pose a risk to human health.⁷⁸

If waste that contains lindane reaches a drinking water source, then it has the potential to cause contamination. In the United States, lindane has an enforceable standard (Maximum Contaminant Level (MCL) of 0.0002 mg/L) in drinking water under the Safe Drinking Water Act⁷⁹ for public water systems. If a public water system is in violation of the MCL for lindane, it must take action to address the contamination.⁸⁰

The Safe Drinking Water Act (SDWA) requires the United States Environmental Protection Agency (US EPA) to conduct a periodic review of the existing National Primary Drinking Water Regulations (NPDWRs) that include MCLs and determine which,

⁷⁶ EPA. 2006. Pesticides: Reregistration. Lindane Voluntary Cancellation and RED Addendum Fact Sheet. (July) <http://www.epa.gov/oppsrrd1/REDs/factsheets/lindane_fs_addendum.htm> (consulted June 2013).

⁷⁷ Foreign Affairs and International Trade Canada. See <<http://www.international.gc.ca/international/index.aspx>>.

⁷⁸ Health Canada. Environmental and Workplace Health. Guidelines for Canadian Drinking Water Quality - Summary Table <http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2012-sum_guide-res_recom/index-eng.php>.

⁷⁹ EPA. 2012. Safe Drinking Water Act (SDWA). US Environmental Protection Agency. <<http://water.epa.gov/lawsregs/rulesregs/sdwa/index.cfm>> (consulted July 2012).

⁸⁰ For contaminants and their MCLs, see <www.epa.gov/safewater/mcl.html#listmcl>.

if any, need revision. During the second round of this review (completed in March 2010), US EPA determined that a revision to the NPDWR for lindane was not required at that time, based on the low occurrence of this contaminant in source and finished drinking water samples.

Mexico continues to monitor levels of lindane and other isomers of HCH in environmental media.

4.5.2. Production residues

Lindane was never produced in Canada or Mexico, although it was produced in the United States in the mid-20th century. However, historical records are sparse. The US EPA's Superfund Program⁸¹ was established in 1980 to locate, investigate, and clean up the worst hazardous waste sites nationwide. As of 2010, there are approximately a dozen sites being cleaned up under that program that have lindane listed as a contaminant.

In 2010, the National Programme for the Remediation of Contaminated Sites was published in Mexico. One year later, an online information system was made available (*Sistema Informático de Sitios Contaminados—Sisco*).⁸² The objective of this information system is to register all contaminated sites considered as environmental liabilities and to serve as a tool to identify, characterize and prioritize sites, following a preliminary risk assessment phase. It is also considered a valuable instrument that will assist in the formulation and implementation of regulatory instruments for the environmental management of these sites.

4.5.3. Existing Stocks

Since the onset of the NARAP, there have been no pesticide uses of lindane in Canada nor, as of 1 October 2009, in the United States. In Mexico, companies associated with AMIFAC reported that neither do stocks exist for the formulation of lindane, nor are there stocks of active ingredient for pesticide uses.

4.6. 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 have contributed to national, bilateral and trilateral monitoring efforts.

4.6.1. Environmental Monitoring and Modeling

The Parties have worked nationally and collaboratively to improve knowledge in the field of monitoring and modeling of lindane in environmental media of North America.

⁸¹ EPA. Superfund: Cleaning up the Nation's Hazardous Wastes's Sites. <<http://www.epa.gov/superfund/>>.

⁸² Semarnat. n.d. Sistema Informático de Sitios Contaminados (SISCO), *Secretaría de Medio Ambiente y Recursos Naturales* <http://www.semarnat.gob.mx/temas/gestionambiental/Materiales_y_Actividades_Riesgosas/sitioscontaminados/sisco/sisco.pdf> (consulted July 2012).

Canada has developed regional and global numerical models, CanMETOP (Canadian Model for Environmental Transport of Organochlorine Pesticides) and MEDIA (Multi-compartment Environmental Diagnosis and Assessment) respectively, for simulating the environmental transport of pesticides. These models can be used to simulate the transport of lindane and the other isomers of HCH both regionally in North America and globally. Canada and the US have continued to implement monitoring programs and have undertaken monitoring studies to better understand the trends and cycling of HCHs in the environment. Canada has undertaken monitoring studies to understand the air/water exchange of HCHs in Canada's north and the Great Lakes region.^{83,84,85} The US EPA and Canada have continued to cooperate on the monitoring of lindane and α -HCH in air and precipitation in the Great Lakes region. The US EPA has also continued to monitor for the presence of lindane and α -HCH in Great Lakes top predator fish through the Great Lakes Fish Monitoring and Surveillance Program (GLFMSP). Spatial and temporal trends are reported in peer-reviewed literature, program reports, and through the State of the Great Lakes reports.

Both Canada and the US undertook initiatives with China to prepare and improve the use of emissions information on lindane in China, and thus assess their impact on the North American environment.⁸⁶ Total depositions of lindane due to global sources in 2005 were 30 tonnes in Canada, 12 tonnes in the United States, and 1 tonne in Mexico. In Canada, some 93% of the deposition was traced to major foreign sources: 7% from China, 8% from India, 3% from Europe, and 2% from the former Soviet Union, and 72% from elsewhere in North America. In the United States, 83% of total lindane deposition was due to global sources: 17% from China, 31% from India, 6% from Europe, and 4% from the FSU and 25% from North America. In Mexico, global sources contributed 71% of total deposition with 11% from China, 39% from India, 9% from Europe, 2% from the former Soviet Union, and 10% from elsewhere in North America. The authors noted that global sources have a strong influence on lindane levels in North America and specifically in the North American Arctic.

⁸³ Jantunen, L.M., P.A. Helm, H. Kylin, and T.F. Bidleman. 2008. Assessment of HCH air-water gas exchange in the Canadian Archipelago as affected by ice cover; Hexachlorocyclohexanes (HCHs) in the Canadian Archipelago. 2. Air-water gas exchange of α - and γ -HCHs. *Environ. Sci. Technol.* 42: 465–470.

⁸⁴ Bidleman, T.F., H. Kylin, H., L.M. Jantunen, L.M., P.A. Helm, P.A., 2007. Macdonald, R. Assessment and publication of HCH spatial distribution and air-water gas exchange in the Canadian Archipelago, based on 1999 data; Hexachlorocyclohexanes (HCHs) in the Canadian Archipelago. 1. Spatial distribution of α -, β -, and γ -HCHs. *Environ. Sci. Technol.* 41: 2688–2695.

⁸⁵ Jantunen, L.M., P.A. Helm, J.J. Ridal, and T.F. Bidleman. 2008. Assessment and publication of air-water gas exchange of HCHs in lakes Superior and Ontario, based on 1996-2004 data; Air-water gas exchange of chiral and a chiral organochlorine pesticides in the Great Lakes. *Atmos. Environ.* 42: 8533–42.

⁸⁶ Ma, J. and S. Venkatesh. 2008. Impact of intercontinental atmospheric transport of lindane on North American environment. Environment Canada. See http://www.epa.gov/bns/reports/stakejun2008/Lindane_Venkatesh_08.pdf.

The United States and Canada also contributed to the development of information on long-range transport of POPs through participation in the development of the OECD multimedia model for screening long-range transport potential and overall persistence of POPs.⁸⁷

Although originally considered for action under the NARAP, further investigation into the issue of isomerization was not undertaken since the Risk Profile on Lindane,⁸⁸ as developed by Mexico and adopted by the POPRC, concluded that isomerization was not considered a significant pathway for HCH conversions. The risk profile identified the environmental effects of lindane, which were also well summarized in the US EPA's Reregistration Eligibility Document on Lindane, Section III, Part B, Environmental Risk Assessment.⁸⁹

Canada continues to support the Global Atmospheric Passive Sampling (GAPS)⁹⁰ study to investigate the atmospheric concentrations and transport of POPs on a global scale. Canada, Mexico and the United States all have sampling sites in the study, and lindane and α -HCH are among the substances measured. Data from GAPS were a key contribution to the first global monitoring report under the Stockholm Convention on POPs adopted at COP4 in May 2009. Data from the GAPS network will contribute to the second global monitoring report that is due at COP7 in 2015.

INE, in connection with Proname, has conducted studies for determining the presence of POPs, including lindane, in the Valle de Yaquí, Sonora, and Coatzacoalcos, Veracruz.⁹¹ Low levels of lindane were reported in both sites, in soils and in sediment layers, although quite diffuse. Other studies have also indicated the presence of lindane and other HCH isomers in soils and sediments.⁹²

In the framework of Lindane Task Force, two studies were carried out in different environmental and biological matrices. In 2008, a pilot study was developed, in collaboration with the Autonomous University of San Luis Potosí (UASLP) to assess the levels of lindane and its alpha and beta isomers in samples of commercial cow milk in 11 Mexican cities⁹³ Also in 2009, another study was done to determine whether the consumption of unprocessed milk and the pharmaceutical use lindane could be

⁸⁷ OECD: OECD Pov and LRTP Screening Tool, <<http://www.oecd.org/env/ehs/risk-assessment/oecdповandlrtpscreningtool.htm>>.

⁸⁸ See source cited in footnote 7, *supra*.

⁸⁹ EPA. Pesticides: Reregistration. Lindane. Reregistration Eligibility Document on Lindane. <<http://www.epa.gov/opp00001/reregistration/lindane/>>.

⁹⁰ Environment Canada. 2010. Global Atmospheric Passive Sampling (GAPS) Network. <<http://www.ec.gc.ca/rs-mn/default.asp?lang=En&n=22D58893-1>> (consulted July 2012).

⁹¹ See sources cited in footnotes 21 and 22, *supra*.

⁹² See footnote 24, *supra*.

⁹³ Yáñez-Estrada, L. and N.E. Rivero-Pérez. 2009. Assessment of concentrations of lindane and other HCH isomers in milk in different regions of Mexico, Technical research report submitted to the Commission for Environmental Cooperation. Universidad Autónoma de San Luis Potosí (UASLP).

significant routes of exposure for residents (children) of three Mexican communities with a history of exposure to such pesticides.⁹⁴

4.6.2. Human Monitoring and Modeling

The Parties worked collaboratively to support a *Trinational Biomonitoring Study* including subjects from the three countries.⁹⁵ This study provides the first North American data set for some environmental contaminants, including the HCH isomers β -HCH and lindane plus polychlorinated biphenyls (PCBs) and dioxins/furans, as well as metals like lead and mercury, in the blood of women of childbearing age. Between 2005 and 2007, 125 Canadian women in five cities—Calgary, Halifax, Hamilton, Ottawa and Vancouver—participated in the study. In Mexico, 250 women were recruited in 10 cities: Córdoba, Coatzacoalcos, Salamanca, Tultitlán, Ciudad Obregón, Guadalajara, Hermosillo, Mérida, Monterrey, and Querétaro. For the United States, existing data from the NHANES conducted between 2001 and 2004 were used. It was noted that Mexican mothers had higher concentrations of β -HCH, due to the more recent use of these products in Mexico. Very few of the mothers from any country had detectable concentrations of lindane.

In Canada, the Northern Contaminants Program (NCP) evaluates contaminants in human tissues and traditional foods. The most recent NCP report, which included data on a range of contaminants, was released in the Canadian Arctic Contaminants and Human Health Assessment Report,⁹⁶ June 2009. Data on various HCH isomer concentrations are available in various reports to the NCP and future monitoring programs are being considered.

In 2009 the US Centers for Disease Control and Prevention published the Fourth National Report on Human Exposure to Environmental Chemicals.⁹⁷ Results for lindane and β -HCH, based on serum concentrations, are presented by age group and ethnicity.

Dietary patterns focused on the seasonally available subsistence foods for Arctic indigenous populations and eaten by different age groups in Alaska and Canada have been documented as. The creation of these databases and exposure/risk assessment models subsequently derived were supported in part by the US EPA and Health Canada's First Nations and Inuit Health Branch and are freely available through The

⁹⁴ Ize, I. 2010. Análisis de resultados del monitoreo de lindano e isómeros alfa y beta de HCH en leche bronca de vaca y en sangre de niños. Commission for Environmental Cooperation (CEC)

⁹⁵ CEC. 2011. Trinational Biomonitoring Study: Assessment of Persistent Organic Pollutants and Selected Metals in the Blood of First-Birth Mothers in Southern Canada and Mexico and in Women of Reproductive Age in the United States. See <<http://www.cec.org/Storage.asp?StorageID=10143>> (consulted July 2012).

⁹⁶ Aboriginal Affairs and Northern Development Canada. 2009. Canadian Arctic Contaminants Health Assessment Report, see link at <<http://publications.gc.ca/pub?id=351816&sl=0>> (consulted July 2012).

⁹⁷ CDC 2009. Fourth National Report on Human Exposure to Environmental Chemicals. Centers for Disease Control and Prevention. <<http://www.cdc.gov/exposurereport/>> (consulted July 2012).

Lifeline Group,⁹⁸ whose LifeLine™ Community-based Assessment Software® (C-BAS) Software provides a tool for researchers interested in community public health to utilize the valuable array of existing information to compile an exposure/risk assessment by population level, down to that of an individual community. A series of dietary profiles have already been created by The LifeLine Group and can be used for the exposure and risk assessments for those communities. LifeLine™ profiles can easily be modified using the Dietary Record Generator (DRG)⁹⁹ and the assessor's information or completely new community-specific dietary profiles created with the DRG.

The Parties considered investigation of human dietary exposure and direct exposure to lindane as a result of veterinary use as originally suggested in the NARAP. Shortly after the NARAP was published, all veterinary uses of lindane were either phased out (Canada and the United States) or in the process of being phased out (Mexico), and as such the Lindane Task Force agreed that limited resources would not be used to research this further.

4.6.3. Building capacity

As part of the trilateral biomonitoring study,¹⁰⁰ the CEC worked closely with two Mexican analytical laboratories to draw on experiences in Canada and the United States around blood monitoring techniques and analytical procedures. Among other benefits, this has enhanced the capacity of Mexico's analytical facilities to monitor POPs as part of the country's obligations under the Stockholm Convention.

The Lindane Task Force also engaged the Environmental Monitoring and Assessment Standing Committee of the CEC to increase laboratory capacity and gather data on levels of lindane and other isomers of HCH in Mexico, through analysis of samples of blood and unpasteurized cow's milk from San Luis Potosí, Querétaro and Chiapas. The purpose of this project was to conduct an inter-calibration exercise with the participation of several laboratories in Mexico, and to standardize a quantification method for these types of samples.¹⁰¹

4.7. Outreach and Education

As the three countries have either phased out (Canada and the United States) or are in the process of phasing out (Mexico) agriculture and veterinary uses of lindane, no work was undertaken to encourage lindane manufacturers, formulators, and distributors to develop publicly available best practices for lindane use and application in these areas as originally considered under the NARAP.

⁹⁸ The Lifeline Group. <<http://www.thelifelinegroup.org/>>.

⁹⁹ EPA. n.d. Dietary Record Generator, Tribal LifeLine™ Project. <http://www.epa.gov/osp/tribes/NatForum06/3_25c.pdf> (consulted July 2012).

¹⁰⁰ See footnote 95, *supra*.

¹⁰¹ See sources cited in footnotes 93 and 94, *supra*.

Both Canada and the United States have extensive programs for outreach and education regarding pharmaceutical uses of lindane in their respective countries. Please see actions under section 1.3.

As noted in Section 3.2, Mexico formed an inter-secretarial working group towards obtaining and disseminating information on the additional POPs added to the Stockholm Convention, including lindane and the alpha- and beta-isomers of HCH. Also in 2010, the booklet "Learning to take care of the environment" was published by Semarnat; it is aimed to children to make recommendations that enable them to take care for the environment and health in different topics, including pesticide POPs.

4.8. Ensuring Compliance

4.8.1. Enforcement

Neither Canada, nor the United States were informed of any illegal, unauthorized uses or illegal imports and exports of lindane and lindane containing products. Both countries utilize compliance monitoring programs to assure compliance by the regulated community with environmental laws and regulations through inspections, field monitoring, and other investigations. There are no specific compliance monitoring programs at the national level for lindane in Mexico. Mexico complies with its enforcement obligations as required under the Stockholm and Rotterdam Conventions

Pesticide regulatory officials from the United States and Canada have agreed on measures to enhance coordination of enforcement and compliance activities for pesticide regulation. These measures include the scheduling of regular conference calls, sharing of information and intelligence, including plans and reports, communications materials, alerts and bulletins. When mutual concerns are identified, enforcement and compliance offices coordinate activities. Stakeholders are informed of these activities through newsletters and reports to the NAFTA Technical Working Group on Pesticides.¹⁰²

4.8.2. Measuring Success

Both regionally and internationally, lindane use has decreased significantly over the past decade. The phase-out for agricultural use in North America has contributed to the decrease in concentrations in the North American environment. Canada, Mexico and the United States continue to monitor levels of HCH isomers in environmental media and human samples through national monitoring programs. Recent evidence shows levels of α -HCH and lindane decreasing in the environment¹⁰³ and humans, while in the Arctic, levels of β -HCH have increased in some environmental media.¹⁰⁴

¹⁰² Health Canada. Consumer Product Safety. North American Free Trade Agreement Technical Working Group on Pesticides. <http://www.hc-sc.gc.ca/cps-spc/pest/part/int/_nafta-alena/index-eng.php>.

¹⁰³ Venier, M., and R.A. Hites. 2010. (See fn 10, *supra*).

¹⁰⁴ Becker, S., et al. 2008. (See fn. 4, *supra*).

The Parties will continue to monitor for lindane and other HCH isomers under their national and regional monitoring programs, such as AMAP, IADN, NHANES, Canada Food Basket, and Proname, to ensure a continuing decline in levels of HCH in the North American environment and people. The Parties will endeavor to support the efforts of the CEC Environmental Monitoring and Assessment Standing Committee to advance information collection and comparability of data at the North American regional level.

With the inclusion of lindane in the Stockholm Convention in 2009, the Parties saw the work in support of regional and international activities under the NARAP come to fruition. They agreed that the actions under the NARAP had been reasonably fulfilled and proposed the drafting of a status report to verify if this were in fact the case. In 2010, the Parties provided updates on the status of lindane in each country, and those updates have been integrated into this final report. The Parties will continue to work together but henceforth share information regarding lindane products, regulations, and uses through international fora rather than through the CEC.

4.9. Leveraging Resources

4.9.1. Financial Resources

Many actions under this NARAP required financial resources that were leveraged through sources outside the CEC. Funding for some actions was provided by the Secretariat, by an individual country, or by a combination of sources. The CEC Secretariat worked with the Parties to secure funds from the World Bank to undertake the Trilateral Biomonitoring Study.¹⁰⁵ The Secretariat and the Parties also contributed funding and in-kind support for this large study.

The Secretariat also worked with the Parties to secure funding for Proname: a key tool in obtaining environmental data on substances of concern in the country. Under the coordination of the Secretariat and the CEC's Environmental Monitoring and Assessment Standing Committee, Proname has benefited from activities that have strengthened technical and human capacities in the Mexican laboratories participating in the associated projects.

Proname has limited multi-year funding from INE. This support from the federal government has helped to support program operations, including five monitoring sites in Mexico. Lindane and other HCH isomers are on the list of substances monitored at these sites.

4.9.2. Human Resources

The actions under this NARAP could not have been completed without the countless hours of support from experts within the Governments of Canada, Mexico and the United States, including experts from the scientific communities and stakeholders in

¹⁰⁵ See footnote 95, *supra*.

each country. The Secretariat acted to assist these experts and provide overall coordination for implementation of actions under the NARAP.

4.10. Integration with International Activities

Recognizing potential of lindane and other HCH isomers' for regional and global long-range atmospheric and oceanic transport, the Parties worked with other countries through international initiatives and organizations to reduce lindane releases to all media.

Canada and the United States work with the UNECE POPs protocol and Canada has contributed information and expertise to the review of sufficiency and effectiveness of the protocol, including emissions and ambient levels and trends of HCH and other POPs in the environment. Results of this can be found in the 2005 chair's reports of the UNECE Working Group on Strategies and Review.^{106 107}

Canada and Mexico are Parties to the Stockholm Convention. The United States, although not a Party to the Convention, attends and contributes to meetings of the Conference of the Parties (COP) and the POPs Review Committee (POPRC).

Canada and the United States will continue to collect data and report out on lindane and other HCH isomers in the context of the POPs Protocol to the UNECE CLRTAP.

In efforts to support the international activities under the NARAP, the Secretariat compiled information on production and use of lindane in China. Information on previous production in various countries was compiled and included in Annex A of the NARAP on Lindane and other HCH Isomers.

The Parties, independent of the CEC, supported risk reduction activities in China and India (two of the remaining producers of lindane in 2006) building on projects such as those that have been initiated by the US EPA.

In 2004, the US EPA initiated bilateral projects with China and India to promote risk reduction in those countries from lindane emissions. China has stopped all production and use of lindane and is now focusing on the cleanup of contaminated POPs sites, including former lindane manufacturing sites. This project with China was completed in 2006. India has reduced the use of lindane but did not pursue other projects with the US EPA regarding lindane.

In September 2006, the US EPA participated in an international workshop in China focused on lindane and the cleanup of contaminated sites. With the support of the

¹⁰⁶ UNECE. 2005. Technical Input for Reviewing the Protocol on Persistent Organic Pollutants. United Nations Economic Commission for Europe, Working Group on Strategies and Review, <<http://www.unece.org/fileadmin/DAM/env/documents/2005/eb/wg5/eb.air.wg.5.2005.1.e.pdf>> (consulted July 2012).

¹⁰⁷ UNECE. Environmental Policy. Treaties. Air Pollution. Convention Bodies. EMEP Steering Body. Outputs. Chair's Report. <<http://www.unece.org/env/lrtap/taskforce/tfiar/chairs-reports.html>>.

United States, China's Ministry of Environmental Protection identified their remaining stocks of lindane and prohibited use of the substance. The next phase of the work will be support for the cleanup of lindane and HCH-contaminated sites.

The US EPA signed a letter of intent with the Institute for Control of Agrichemicals, Ministry of Agriculture (ICAMA) in China to work cooperatively on pesticide management, which could include substances that could have the characteristics of POPs. An extensive work program was agreed to and is being carried out. Projects include human health and environmental risk assessment methodologies and harmonization of pesticide residue standards for foods. In 2010, the US EPA and the Ministry for Environmental Protection of China renewed the Memorandum of Understanding, giving continued broad authority to work on POPs and other substances of concern.

5. Conclusions

5.1. Benefits Derived from the Lindane NARAP

In concurrence with the NARAP, agricultural and veterinary uses of lindane have been phased out in Canada and the United States and are being phased out in Mexico. Lindane's pharmaceutical uses are being phased out in Mexico, will be phased out in Canada by 2016, and will be allowed only for second line treatment against lice and scabies in the United States.

The ability to phase out veterinary uses and reduce pharmaceutical uses of lindane was due in part to the sharing of information at the successful Lindane Task Force Workshop on Alternatives to Lindane Use, held in Mexico in 2005. Representatives from the environment and health departments of the three countries met with stakeholders to discuss and exchange available information on alternatives to pharmaceutical and agricultural lindane use. The results from this meeting are incorporated into Tables 2–5 of this report; the listed alternatives are considered by their respective governments to be viable replacements for lindane for these applications.

The Parties worked together to develop the first North American data set for some environmental contaminants, including lindane, in the blood of women of childbearing age. Results of the study can be found on the CEC website. The Parties worked together through this initiative and others to increase capacity in Mexico in the field of sample gathering and laboratory analysis of lindane and other POPs in different environmental media and human samples.

The CEC worked with Canada, the United States and China to prepare and improve the usage and emissions information on lindane in China and thus assess the impact of these emissions on the North American environment. A summary was included in the 2009 Biennial Progress Report for the Great Lakes Binational Toxics Strategy, and the

authors of the summary concluded that global sources have a strong influence on lindane levels in North America and specifically in the Arctic.¹⁰⁸

One significant benefit of development and implementation of the NARAP is the experience gained by Mexico in the course of drafting a national profile on lindane and supporting the nomination of lindane and related compounds as candidates for substances to be controlled under the Stockholm Convention on POPs. Mexico showed leadership during the POPs committee's review process by actively participating in scientific discussions and providing information to develop the risk profile and risk management evaluation for these compounds.

Additionally, Mexico was able to share the methodology that was used to collect data at the national level with the international community. This methodology was later incorporated into a handbook to support effective participation in the work of the POPs Review Committee. Mexico also had the opportunity to participate in international forums to share its experiences and lessons learned, including contributions to online seminars (webinars) organized by the Secretariat of the Stockholm Convention.

The activities implemented and efforts made by Mexico through this regional action plan have benefited the country with relevant lessons learned. As the positive issues that allowed the commitments of the NARAP, the following strengths can be mentioned

- All society sectors, including government, NGOs, academy and industry got involved in various ways in the NARAP actions.
- According to their specific functions, each institution was responsible for certain actions, this allowed a division of tasks and greater efficiency in the NARAP implementation process
- Even with its limitations, the national legal framework and tools led to the cancellation of lindane registries
- With some exceptions, importers and formulators of pesticides showed willingness and acceptance of the cancellation of lindane registries
- With the financial support from the CEC and other international organizations, it was possible to perform various monitoring and biomonitoring studies, as well as capacity building
- Information and knowledge exchange was a key point to comply with several NARAP commitments.

On the other side, the following weaknesses in the implementation of the NARAP could be identified:

- The complicated coordination between sectors and agencies involved

¹⁰⁸ See footnote 6, *supra*.

- In the context of research and monitoring, insufficient human and financial resources and limited analytical infrastructure and trained personnel were major obstacles.
- Finally, the absence of legal tools to request and track information on the use of lindane was also a significant limitation.

Such lessons learned have been replicated in other efforts conducted by Mexico, such as the development of a national profile and diagnostic for Endosulfan.

5.2. Ongoing Implementation of Actions in Mexico

Although the Lindane Task Force considers the actions under the NARAP to be relatively complete, there remain concerns regarding lindane and other HCH isomers in Mexico. Certain items in the NARAP were identified by Mexico as points in need of further consideration in order to effectively complement the achievements obtained through the lindane NARAP. Detailed below are the outstanding actions as they relate to the identified action items.

1. As per NARAP section 4.2.1.1. *Pharmaceutical: Inventory of lindane products used for pharmaceutical purposes*; there is no legal mechanism in place to generate an inventory of lindane products or stocks for pharmaceutical purposes in Mexico. At this time, Mexico cannot accurately verify trends in usage or quantify existing stocks.
2. As per section 4.2.1.2. *Pharmaceutical: Alternatives, on promoting research to investigate the safety and efficacy of alternatives and assess existing information*; Further exchange of information on substitutes and alternatives to lindane that allow for decreased risks in applications and uses, with a focus on their advantages and cost effectiveness is needed in Mexico.
3. As per NARAP section 4.2.5.1. *Waste Management Issues: Water contamination, on assessing the exposure of surface and ground water to lindane*; further work is required in Mexico to determine if and where sources of lindane and other HCH isomer contaminated water exist and whether they might pose a risk of exposure to the Mexican population.
4. As per NARAP section 4.2.6.1. *Science and Research: Environmental Monitoring and Modeling, on promoting research and to determine to what extent the use of lindane contributes to the atmospheric, terrestrial and aquatic burden of all HCH isomers in North America; on and supporting and promoting the development of scientific expertise in the field of modeling of pathways in the atmosphere, terrestrial, and aquatic systems*; more work is required in Mexico in the field of monitoring and biomonitoring of matrices for determining the levels of lindane and other isomers of HCH, as well as capacity building in these same areas, standardization of methods for environmental and biological matrices that have not yet been analyzed and finally, creation of a database to manage data from Mexican studies and monitoring programs. Some of these requirements can be met by the continued

implementation of Proname, which requires efforts to ensure funding is maintained to support the development of long-term results and allow for time trend analyses.

5.3. NARAP Closure

The present report ends the activities under the Lindane NARAP. The SMOC Working Group is responsible for setting strategic priorities for chemicals-related work under the CEC. Accordingly, should a need be identified for future trilateral work on this substance, the SMOC Working Group should develop the appropriate policy direction within the context of the CEC's regular operational planning process.

As the actions under the lindane NARAP are considered to have been accomplished, the Lindane Task Force will consider itself to be dissolved upon the SMOC Working Group's approval of the present report.