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November 4, 2005

Luke Trip, Commission for Environmental Cooperation
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Dear Mr. Trip,

The undersigned 61 organizations from Canada, the United States and Mexico submit these comments in response to the draft *North American Regional Action Plan (NARAP) on Lindane and Other Hexachlorocyclohexane (HCH) Isomers*. In short, we believe the Action Plan fails to adequately address the urgent need to eliminate the use of lindane throughout North America and fails to acknowledge the numerous public comments provided to the North American Task Force on Lindane from Indigenous peoples and organizations, health professionals, and environmental groups overwhelmingly supporting rapid elimination of lindane in North America.

A substantial body of evidence indicates that lindane and the other HCH isomers have significant adverse effects on human health and ecosystems. Lindane is a persistent, bioaccumulative, and toxic compound. The NARAP documents many of the serious risks associated with lindane use, and we applaud Mexico for acting on this evidence to set in motion a rapid phase-out of pharmaceutical, veterinary, and agricultural uses of lindane with the goal of eliminating all lindane use.

Unfortunately, the United States and Canada have not committed to similar actions to eliminate lindane use. According to the NARAP, the U.S. plans to review the remaining six seed treatment uses approved for lindane (an estimated 65-106 metric tons

per year) with no commitment toward a phase-out. In a footnote, the NARAP confirms that the U.S. is in fact considering a significant *expansion* of lindane seed treatment use with the pending registration for canola. The U.S. also plans to continue allowing the use of an estimated 1,000 kilograms of lindane per year in pharmaceutical products. Canada will continue to use a small amount of lindane for pharmaceutical purposes with no plans to implement an elimination program.

The actions proposed by the U.S. and Canada to reduce exposure to lindane and other HCH isomers are entirely inadequate, ignoring the significant body of scientific evidence - much of which is documented in the NARAP itself - regarding the health and environmental impacts of lindane and the availability of safer alternatives. We highlight below only a portion of this evidence, specifically focusing on the human health effects of lindane, environmental impacts from use and production, and the documented dangers and ineffectiveness of lindane in pharmaceutical products.

Human Health Effects

Lindane and the other HCH isomers have significant impacts on human health. Evidence from animal studies and limited evidence from human exposures indicate that lindane is a potent neurotoxin and with potential to affect the reproductive and immune systems. As is noted in the NARAP, lindane is also a suspected endocrine disruptor. Highlighted below is some of the compelling evidence about the carcinogenic, neurotoxic and reproductive effects of lindane and the other HCH isomers.

Carcinogenic Effects

As reported in the NARAP, the International Agency for Research on Cancer (IARC) has determined that there is sufficient evidence demonstrating that lindane and technical HCH are carcinogenic in mice and, based on these observations, IARC has classified lindane and the other HCH isomers as possibly carcinogenic to humans.¹ EPA has classified lindane as “suggestive evidence of carcinogenicity, but not sufficient to assess human carcinogenic potential” based on an increased incidence of benign lung tumors in female mice. The Agency for Toxic Substances and Disease Registry (ATSDR) and the World Health Organization consider lindane a liver carcinogen, as is noted in the NARAP.

A 1999 report from the Austrian government cited "lack of adequate data" on lindane's carcinogenicity as the basis for a recommendation to suspend use of the pesticide across the European Union. In response to this report, most lindane uses were banned throughout Europe by 2000.² This precautionary action in the face of a data gap stands in stark contrast to U.S. inaction in the face of EPA's assessment that the data are "not sufficient to assess" lindane's cancer causing effects in humans.

Neurotoxic Effects

A review of the neurological effects of lindane exposure found that lindane can interfere with learning. These conclusions were based on evidence that repeated exposure to lindane increased the number of errors made by mice in a food-reinforced maze.³ The

authors support this claim with evidence that lindane may interfere with the ability to process new information through effects in the hippocampus.

Additional studies have shown that exposure to low doses of lindane can interfere with an individual's ability to process new information by altering GABA. GABA is an amino acid derivative that inhibits pre-synaptic transmissions in the central nervous system (CNS). Lindane is a powerful convulsant in humans as a result of its impact on the CNS where it increases the release of neurotransmitters.⁴ Acute exposure to lindane may cause seizures of varying degrees (grand mal, petit mal, myoclonus etc.), memory impairment, hyperactivity, irritability, and aggression.⁵

Reproductive Effects

A summary of observed lindane toxicity in rats found that exposure to the chemical led to impairment of testosterone metabolism and could lead to an alteration of male reproductive systems during prenatal development.⁶ Other animal studies show that high doses of lindane can alter oocyte maturation in mice and marine invertebrates.⁷ A recent study indicated that prenatal administration of lindane may induce long lasting effects of spermatogenesis in mice. Researchers found experimental lindane exposure resulted in reduced sperm counts, changes in the pattern of testicular germ cell distribution, and abnormalities in chromatin in the sperm cells of mice.⁸

A study examining the effects of lindane exposure on the reproductive systems of mice concluded that developing oocytes exposed to lindane in vivo had an increase of irreversible damage in two-cell embryos.⁹ The authors report that the observed effects occurred at lindane concentrations that greatly exceed the concentrations measured in the human population, but they caution that the cumulative effect of lindane stored in the adipose tissue and exposure to other chemicals with similar mechanisms of toxicity might lead to clinically significant effects on reproduction.

Reproductive effects of HCH isomers during fetal development is of particular concern given the recent findings of the U.S. Centers for Disease Control and Prevention that more than half the participants in a national survey of chemicals in blood and urine carried beta-HCH in their blood,¹⁰ with the highest levels found among women of childbearing age.¹¹ Analysis of maternal and umbilical cord blood shows that HCH isomers are some of the chemicals detected in the highest concentrations among residents of the Arctic.¹² EPA has also noted that lindane is "efficiently transmitted" from mother to child through breastmilk. When women carry HCH isomers in their bodies, infants may be exposed to their damaging reproductive effects both inside and outside the womb.¹³

Environmental Impacts

Atmospheric Transport of HCH

The atmospheric transport of lindane is a serious concern for residents of arctic regions and for residents of areas in close proximity to agricultural lindane applications. A recent study measured the volatilization and transport of lindane from the Canadian prairies where lindane was commonly used as a seed treatment on canola fields.¹⁴ This study is particularly relevant considering the U.S. decision to continue to permit use of

lindane for seed treatments. Waite et al. determined that 12 - 30% of the lindane applied as a canola seed treatment volatilized and was released to the atmosphere.

Volatilized lindane may enter aquatic or non-target terrestrial ecosystems through precipitation or dry deposition where it can have adverse effects on the ecosystem. It is particularly important to consider the impact of such deposition on species that are highly susceptible to lindane toxicity, including fish and aquatic invertebrate species and bees.

As is noted in the NARAP, HCH is one of the most abundant pesticides measured in the Arctic atmosphere and in Arctic ocean surface water, where it accumulates in the fatty tissue of marine mammals and fish.¹⁵ A study of pesticide occurrence in air and precipitation in Quebec, Canada showed that lindane was also one of the major organochlorine pesticides dominating the air and precipitation there.¹⁶ The authors of this study concluded that the high levels of technical HCH, used in large quantities in the region prior to its ban in 1978, were evidence of active long-range distance transport or volatilization of previously used chemicals from soil or water. Ongoing lindane use for seed treatment has the same potential to result in long-range transport, volatilization, and persistence.

In the Action Plan the U.S. commits to "consider" including all isomers of HCH in its upcoming reevaluation of the seed treatment uses of lindane. It is essential that all isomers of HCH be included in this reassessment. Indigenous populations are exposed to high levels of all HCH isomers through the bioaccumulation of these chemicals in native food sources. This contamination does not occur from the use of lindane by indigenous populations—it is the result of lindane production and use globally. Although gamma-HCH is less bioaccumulative than the other two isomers of HCH, alpha and beta isomers are transported to arctic communities where they precipitate and accumulate as a result of cold temperatures.

HCH and Groundwater

The NARAP fails to address the potential for lindane used in seed treatments to reach groundwater supplies. Lindane may contaminate groundwater in areas where seed treatment has occurred or in regions with high levels of atmospheric deposition. It is highly persistent in soils with a half-life of 15 months and a low affinity for soil binding. Some studies indicate that lindane may pose a risk for groundwater contamination, particularly in soils with low organic matter content and high levels of precipitation.¹⁷

Dirty Production

As is noted in the NARAP, large quantities of waste are created as a byproduct of lindane production. These tons of waste products pose threats to workers, local communities, and globally through atmospheric transport of the tons of HCH isomers produced. The NARAP calls for projects in China and India that will reduce use and emissions that result in long range transport of lindane and its waste isomers. It does not address, however, production issues in Romania—the source of all imports to the U.S. The U.S. and Canada should agree to stop purchasing lindane from all sources in an effort to halt production of lindane and its waste isomers.

Dangers of Continued Pharmaceutical Use

The American Academy of Pediatrics released a statement on the diagnosis and treatment of head lice that was published in the September 2002 issue of *Pediatrics*. The report included the following statement about lindane, “resistance has been reported worldwide, and it has low ovicidal activity. It is only available by prescription and should be used cautiously because several cases of seizures in children have been reported.¹⁸” The NARAP mentions head lice resistance in its discussion of lindane alternatives, but fails to include information about documented resistance in lindane itself.

In a recent study comparing the efficacy of lindane, malathion, pyrethrin, and permethrin in treating head lice, lindane was the least effective and slowest working product. The authors reported that after the recommended ten minute application time no lice had been killed and after 3 hours of exposure, only 17% of the lice had died.¹⁹ Decreased efficacy of the lindane products may increase the likelihood of incorrect application of the product, which can have serious health consequences.

The Food and Drug Administration (FDA) evaluated reports of adverse effects from lindane use and determined that most occurred when the chemical was misused or used in excessive amounts. When lindane is applied too frequently or for prolonged periods of time, it can result in seizures, dizziness, headache, and paresthesia. In extreme cases, improper lindane use has resulted in death.²⁰ The most common reason for the misuse of lindane is reapplication after the first treatment failed— a situation that will increase in frequency as lindane efficacy declines.

FDA has issued an advisory for lindane use and recommended that it only be considered as a second line treatment after initial treatments have failed. The advisory stresses that it should not be reapplied if initial treatment fails. FDA also noted that certain populations are at increased risk for adverse effects from lindane. These populations identified are infants, children, elderly persons, persons with skin conditions that might increase absorption, and persons who weight less than 49.5kg.²¹ A review of pesticide exposures from 1997-2000 among children under age six along the Texas-Mexico border reported 8% of the children who experienced clinical effects from pesticides were exposed to lindane. Five of these 10 children developed moderate to major effects. Of the 49 total lindane exposures covered in the study, 5% resulted in clinical toxicity.²²

The potential for adverse effects and the failure of lindane as an effective treatment for head lice are sufficient reasons for it to be removed from the pharmaceutical market. There are safer and more effective alternatives that can replace lindane as a pediculicide. Effective non-toxic treatments for head lice exist.²³ Alternatives to pesticide treatments include dry-on, suffocation-based pediculicide and mechanical lice removal tools such as the licemeister. The action plan should include a commitment to additional research on non-toxic alternatives for the treatment of lice and scabies.

In conclusion, the NARAP on Lindane and Other Hexachlorocyclohexane (HCH) Isomers does not include adequate measures to protect health and the environment in the North American region. As early as 1962, with the publication of *Silent Spring* by Rachel Carson, the serious environmental and health effects of lindane were well-documented. She reviews research documenting that lindane adversely affects soil health by

preventing beneficial nitrogen-fixing bacteria from “forming the necessary root nodules on leguminous plants.” Later in the book, Carson documented that plants treated with lindane “became monstrously deformed with tumor-like swellings on their roots. Their cells grew in size, being swollen with chromosomes which doubled in number.” In a review of the medical literature, Carson notes that [lindane] is “stored in significant amounts in the brain and functioning liver tissue and may induce ‘profound and long-lasting effects on the central nervous system.’” She also reported about research linking exposure to lindane with aplastic anemia and other blood disorders.²⁴

We note that this Regional Action Plan is the first that targets a chemical still in use in all three countries of the region, while previous Action Plans have focused on chemicals already banned in the U.S. and Canada (e.g., DDT and chlordane). Given the fact that lindane is banned in 52 countries throughout the world and is now nominated as a chemical for listing in Annex A of the Stockholm Convention, it is unconscionable that the U.S. and Canada delay action to eliminate this dangerous chemical. For the CEC-driven NARAP process to be considered an effective vehicle for addressing chemicals of concern that are in use throughout the region, the U.S. and Canada must follow the example of the Mexico in taking concrete action to eliminate all uses of lindane in the region.

We look forward to a revised final version of the NARAP that includes the steps necessary to protect the health and environment of all North Americans from the dangers of lindane.

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