Commission for Environmental Cooperation
of North America

North American Regional Action Plan on Lindane

Background Document

The purpose of this paper is to introduce and provide context for the issues to be addressed at the North American Lindane Task Force meeting. It is not intended to be a comprehensive review of the current state of the science nor debate. This paper was prepared by the Secretariat of the Commission on Environmental Cooperation (CEC). The views presented here do not necessarily reflect those of the CEC, or of the governments of Canada, Mexico, or the United States.

Introduction

Lindane is an organochlorine insecticide. It has been widely used throughout North America and the world for decades. Lindane (γ-HCH) and the alpha and beta isomers of hexachlorocyclohexane (α-HCH and β-HCH) have been targeted for the development of a North American Regional Action Plan (NARAP) through which the three North American countries will review the current status of this pesticide and its uses and will propose recommendations for reducing the risks which lindane poses to human health and to the environment. The Lindane Task Force is a group of experts and citizens from the three countries who have a specific interest in reducing the risk to human health and the environment associated with exposure to the pesticide lindane. They report through a chairperson to the Sound Management of Chemicals (SMOC) Working Group of the Commission for Environmental Cooperation of North America.

International Status of Lindane

Lindane use has been restricted by at least two international treaties. The first is the 1998 Aarhus Protocol on Persistent Organic Pollutants (POPs) to the 1979 Convention on Long-Range Transboundary Air Pollution (LRTAP). The LRTAP region includes the Russian Federation, Central Asia, Europe and North America. Lindane is among the 16 POPs substances listed in this legally binding protocol. The Protocol restricts lindane to six specific uses. In October 2003, the Protocol entered into force. To date, 18 countries

have ratified the Protocol. For additional information on the POPs Protocol, go to: <http://www.unece.org/env/lrtap/pops_h1.htm>.

The second is the Rotterdam Convention on Prior Informed Consent (PIC), which has 56 parties and will enter into force in February 2004. The PIC includes lindane, reflecting that lindane has been banned or severely restricted by at least one or more countries in two or more regions of the world. Currently 45 countries have banned all import of lindane and more than 20 have restricted or severely restricted its use. Under the PIC, when an importing country indicates that no consent for import is provided, exporting countries are obligated to prevent export of that chemical to that country. To view the list of countries that do not allow the import of lindane, go to: <http://www.pic.int>.

The Stockholm Convention on POPs was signed by 151 nations in May 2001 and has been ratified by 45 nations. It will enter into force once at least 50 nations have ratified it. The Stockholm Convention is a legally binding treaty that calls for the eventual global elimination of an initial list of 12 POPs with specific criteria and guidelines for adding new POP substances. While there are many criteria to satisfy for adding additional substances to the Convention, based on the criteria for persistence and toxicity, lindane could be considered a candidate for addition. For additional information on the Stockholm Convention, go to: <http://www.pops.int>.

Much of the international action on lindane revolves around the risks it can pose to human health and the environment. While lindane is persistent in the environment, toxic and bioaccumulative, there are also indications that it may be an endocrine disruptor. To address these risks, it is important to identify and develop safer alternatives and control strategies that build on innovative practices including organic agriculture, integrated pest management, and the use of medicinal plants.

Development of the Initiative

Under the guidance of the SMOC Substance Selection Task Force, a substance of concern is nominated by one of the three countries for consideration. Each country then prepares a national evaluation and determines if they have an interest in pursing an action plan, based on domestic needs and the mutual concern of the three Parties. Once the mutual concern among the three Parties has been established, the SMOC Working Group prepares a recommendation to the Council to approve development of a North American Regional Action Plan. Lindane has followed this path and a subsequent decision document and terms of reference have been authorized.

The task force is composed of the six national representatives, three indigenous peoples' representatives, one from each country, and one each from the environmental community, the industrial sector and the academic sector. A unique aspect of this task force includes an option for expanding the participation of the academic, environmental and industrial representatives to allow an alternate to represent each of these sectors, depending on where meetings are held. The academic representatives were also selected because of their expertise in the area of children's health. As a consequence, there are two environmental representatives, two academic representatives and two industry

representatives who will alternate their attendance at meetings depending on locale, availability and venue. The federal government representatives retain voting rights in the event that consensus cannot be established among the full task force membership.

The Task Force has scheduled public meetings in Guadalajara, Mexico (29-30 September 2003) and Anchorage, Alaska (12-13 February 2004) in order to provide opportunities for meaningful interventions by citizens and groups who are most impacted by the use and distribution of this toxic substance. All interventions are valued and will be considered for applicability to the development of the North American Regional Action Plan.

Technical Summary: Characteristics of γ-Hexachlorocyclohexane (Lindane)[1]

Lindane is an organochlorine insecticide that has been used for control of a wide range of soil-dwelling and plant-eating (phytophagous) insects. It is commonly used on a wide variety of crops, in warehouses, on livestock, in public health to control insect-borne diseases, and as a seed treatment, often mixed with fungicides.

Lindane is also currently used in lotions, creams, and shampoos for the control of lice and mites (scabies) in humans.

Technical-grade lindane is composed of over 99 percent of the gamma-isomer of hexachlorocyclohexane (γ-HCH). Frequent reference is also made to technical-grade HCH (commonly referred to in the past as technical-grade BHC), which contains five other isomers (molecules with a unique structural arrangement, but identical chemical formulas). Data presented in this profile are for technical-grade lindane, (99% γ-HCH) unless otherwise stated. γ-HCH has been shown to be the insecticidally effective isomer of HCH.

It is of considerable importance to note that γ-HCH is "refined" from technical HCH resulting in a significant quantity of waste HCH consisting primarily of the alpha, and beta isomers. These other isomers don't have any direct pesticidal or industrial uses. Disposal is becoming an increasingly complex problem as environmental concerns and costs have increased significantly.

Status of Lindane

General Considerations for North America

- There is no primary production of lindane in North America; however there are formulation plants which prepare end-use products for registered uses.
- Work was completed between Canada and the United States in order to reevaluate lindane, using the most current available information databases.

[1] See <http://ace.ace.orst.edu/info/extoxnet/pips/lindane.htm>.

- Mexico is conducting a national diagnostic on lindane as part of its National Implementation Plan to meet the requirements of the Stockholm Convention.
- Tracking of imports and exports of technical lindane and the formulated products needs further assessment

Canada

Agricultural and Other Uses

- The only agricultural use is for seed treatment on wheat, barley, oats, rye, flax, corn, beans, soybeans and peas for control of wireworms.
- All remaining uses of lindane will stop on 31 December 2004, and the revocation of all lindane maximum residue limits (MRLs) will be considered.

Public Health Use

- In Canada, lindane is approved for lice and scabies treatment.
- In human health applications, six companies currently market 14 products containing one percent lindane in solution.

Canada is reviewing the regulatory history and current status of lindane, and is preparing a preliminary action plan involving a review of case histories, a benefit/risk assessment, current marketing data, alternative therapies, product monographs, prescription status and external consultation.

Mexico

Agricultural and Other Uses

- Lindane is used mostly on livestock (cattle and pigs, for ticks, fleas, common fly larvae, etc.) and as a seed treatment (oats, barley, beans corn, sorghum and wheat).
- It is used as a crop treatment for wheat and sorghum.
- Other uses include flea treatment for domestic animals and pest control on ornamental plants.

Public Health Uses

- Human health uses include scabies and lice treatment and for scorpions

United States

Agriculture and Other Uses

- Lindane Re-registration Eligibility Decision ("RED"), completed in 2002, specifies the remaining requirements for the registrant to re-register lindane for six remaining seed treatment uses (corn, wheat, barley, oats, rye, sorghum).[2]
- Currently, 99 percent of lindane used in US agriculture is for the pre-plant seed treatment of corn and wheat.

[2] See <http://www.epa.gov/oppsrrd1/REDs/factsheets/lindane_fs.htm>.

- Four other grain crops (barley, oats, rye, and sorghum) represent the remainder of the residual agricultural seed treatment uses.

Public Health Uses

- Approved by the US Food and Drug Administration (FDA) for lice and scabies treatment.
- In 2003, action taken to reduce and improve package size and warning notices as a result of reassessment of risk factors.[3]
- FDA has established a process for approving the use of botanicals for public health purposes, thereby encouraging the use of alternatives.
- Annual use is less than one metric ton of pharmaceutical-grade lindane.
- Lindane accounts for under a million treatments out of 10–20 million cases of lice and scabies.

[3] See <http://www.fda.gov/cder/drug/infopage/lindane/>.

Key Issues Related to Lindane in the North American Region

For discussion purposes at the public meeting in Anchorage, Alaska, February 12, 2004

1) **Science and Research Issues**
    a. Pesticide-related research in Mexico
    b. Unique ecosystem properties in the Arctic support bioaccumulation and bioconcentration
    c. Long-range atmospheric transport
        a) The Arctic is particularly relevant as it is considered a globally important indicator zone due to the global distillation phenomenon.

        b) The high levels of lindane in the northern hemisphere, especially in the Arctic, may result from long-range atmospheric transport. There are some uncertainties involved in the source inventories.

        c) Measurements from five circumpolar arctic monitoring stations reported by the Arctic Monitoring and Assessment Program show that, HCH is the most predominant organochlorine in air (AMAP 1997 and 2002).

        d) Other sources are important, not just those in North America.

        e) Stockpiles and storage of waste product HCH's

    d. The stereochemistry of HCH isomers indicates the gamma isomer may convert naturally to the beta isomer.

    e. Furthermore, the following trend in decreasing carcinogenicity is noted: alpha> beta> gamma

    f. Exposure to lindane
        a) There are concerns related to occupational exposure to lindane. EPA Risk Assessments can be reviewed at the following web site: <http://www.epa.gov/pesticides/reregistration/lindane/or_ra.pdf>
        b) Human exposure
            1. Levels of lindane in breast milk
            2. Children 7 to 12 years of age showed lindane intake levels 52 percent higher than that of adults, raising concerns about increased relative exposure
            3. Impacts on other vulnerable populations
            4. Dietary exposure
            5. Relevance of inert ingredients (formulants)
            6. Considerations for endocrine disruption
            7. Impacts of synergistic effects of other substances
        c) Water and wastewater
        d) Runoff and aquatic ecosystems
            1. There are sources of unpublished data relating particularly to marine mammal tissue assessments in the North that should be acquired and reviewed

e) Understanding the impacts of the various isomers on different populations
    1. Because of its persistence, beta-HCH exhibits the highest concentration of the isomers normally reported in human samples.
    2. In 1997, the Canadian Arctic Contaminants Assessment Report of the Northern Contaminants Program indicated that 15 to 20 percent of Inuit women on southern Baffin Island exceeded the tolerable daily intake of lindane, with unknown but worrying health implications

2) Uses Related to Agricultural /Veterinary Applications

a. What are the actual uses of lindane as opposed to registered uses and its importance in the agriculture/veterinary sectors
    a) Mexico uses 80% for veterinary applications
    b) Canada/USA mostly for seed treatment

b. Many farmers in the US have relied on natural agricultural control practices (i.e., crop rotation) and other non-chemical methods in place of using lindane.

c. Need to investigate other alternatives being used by growers and lindane users.

d. Toxicity/safety of alternatives and their availability in relation to lindane needs to be assessed.
    a) There are alternative methods that can be employed for terrestrial food crops, livestock, lawn and ornamentals, dogs and dog kennels, and structural applications.
    b) There are alternatives to lindane for seed treatment. One benefit of using the substitute “diazinon” for agricultural seed treatment has been significantly reduced cost.

e. Product reserves and stockpile management

f. Share info on bilogical and chemical alternatives as stratgies for organic agriculture

g. Consider phase out strategies for agricultural uses
    a) Establish guidelines for phase-out of uses for lindane

h. Development of a comparative matrix for 3 countries listing lindane uses, pests, products, alternatives, human and environmental effects, and costs

3) Uses Related to Public Health

a. Efficacy of lindane for scabies and head lice.

b. Scabies is among the 10 most important causes of disease (morbidity) in indigenous communities in Mexico. Infants are more exposed to lindane than adults by over 30-fold. Based on consumption of milk products and water, the

estimated average daily intakes calculated for lindane were 0.02 µg/kg/day for adults and 0.66 µg/kg/day for infants.

c. Pharmaceutical alternatives include permethrin and pyrethrins
    a) Evaluate resistance of lice and scabies

d. Promote appropriate hygiene techniques, mechanical alternatives include combing, hand picking of lice, enzyme use.
e. Consider lindane as the option of last resort

4) Alternatives

a. Use of traditional knowledge of allelopathic plants and their toxic effects on insects may provide alternatives to lindane uses for scabies and lice.

b. Natural alternatives include: wet combing, formic acid preparations, topical vinegar and mineral oil, tea tree oil, acetic acid, citronella oil, camphor, sodium lauryl ether sulfate (SH-206). Concerns with the use of alternatives are: treatment resistance, lack of efficacy, and toxicity.

c. Alternative pesticides are registered in the US and Canada for historical pet, flea and tick control uses, and termite control.

d. Consideration of registration incentives for alternatives, e.g. IPM,, Organic agricultural practices

e. Investigate safety and efficacy of alternatives
f. Develop a bibliography of alternatives to lindane

5) Outreach and Education

a. More research is needed on human health effects of lindane and other HCH isomers to better understand the relationships between exposure and effects.

b. Communicating human health effects to the public will be an important consideration for the NARAP
    a) Community right to know
    b) Equal access to information in appropriate languages
    c) Utilize most appropriate media
    d) Support national programs for training and information dissemination
    e) Educate health care providers to alternatives to lindane

c. Outreach and education can also inform decisions of growers and consumers in terms of choices with respect to the use of lindane.
d. Possible options for discussion:
    i. Establish national public education campaigns to raise awareness about risks of lindane.
    ii. Emphasize adoption of safe alternatives to lindane.
    iii. Discourage illegal uses of lindane.

Lindane users/formulators need to have access to training and awareness campaigns

6) **Capacity Building Tools—What are the needs among the three countries? Considerations**

a. Development and use of computer-based modeling has been undertaken to estimate the concentration of lindane in the environment, wastewater and drinking water.
   1. water: <http://www.epa.gov/oppt/exposure/docs/episuitedl.htm>
   2. <http://www.epa.gov/opptintr/exposure/docs/efast.htm>

b. Mexico is conducting a "national diagnostic" on lindane that will help identify opportunities for capacity building

c. Aligning with the CEC Environmental Monitoring and Assessment Task Force to complement its blood biomonitoring program and include alpha and beta isomers in the sampling and analysis
   a) Enhancing analytical capacity and sampling protocols
      1. interchange of expertise (University of Laval, Quebec and Centers for Disease Control, Georgia)
      2. QA/QC
   b) Enforcement issues in different sectors
      1. Regulatory framework
      2. Prevention of illegal use and imports
      3. coordination with Customs officers
      4. implement PIC Convention
      5. Share information on national enforcement strategies
      6. Develop and enforce appropriate labelling
      7. Monitoring for residues in food, i.e. corn, meat and dairy products, especially if consumed by children
   c) Monitoring imports of treated seed and other food products
   d) Is there a need for lindane analysis under programs like NHANES?

Global monitoring, Stockholm convention

Need linkages and human and monetary resources

Study hotspots with high application of lindane (e.g., Livestock operations)