INITIAL ENVIRONMENTAL EXAMINATION: AMENDMENT

SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR PRESIDENITAL MALARIA INITIAVE- INDOOR RESIDUAL SPRAYING (IRS) FOR MALARIA CONTROL IN MALAWI

PROGRAM/ACTIVITY DATA:

Program/Activity Number: GH-I-00-06-00002-00
Country/Region: Malawi, Africa Bureau, Southern Africa
Program/Activity Title: SO8 Health, Population and Nutrition 612-0246

Sub-activity: IRS Pilot Program for Malaria Control in Malawi (Nkhotakota District)

Funding Begin: FY07 **Funding End:** FY08 **LOP Amount:** $700,000

SEA Prepared By: Melanie Biscoe, RTI International
Current Date: August 29, 2007

IEE Amendment (Y/N): Y
Filename & date of original IEE: Community Health Partnerships (CHAPS, USAID/Malawi) and Blantyre Integrated Malaria Initiative, BIMI (AFR/SD and G/PHN)

ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion: ____ Negative Determination: _X__
Positive Determination: ____ Deferral: ____

ADDITIONAL ELEMENTS: (Place X where applicable)

CONDITIONS: _X__ PVO/NGO: ____

Other Relevant Environmental Compliance Documentation: This IEE references the following USAID environmental compliance documentation that is already in effect for ongoing activities globally under USAID:

- Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment: 03/2007

This IEE references the following USAID environmental compliance documentation that is already in effect for ongoing activities under USAID/MALAWI SO 3:

- Insecticide Treated Mosquito Net Programs in Malawi: Pesticide Evaluation Report and Safer Use Action Plan: 12/2000

SUMMARY OF FINDINGS:

The U.S. President's Initiative on Malaria (PMI) in Africa seeks to reduce malaria mortality by 50% in 15 countries in sub-Saharan Africa in five years. The United States will work in partnership with host country governments and build on existing national malaria control plans, policies and resources. The Initiative will support and complement efforts of the Global Fund (GFATM), the World Bank, and other members of the Roll Back Malaria (RBM) Partnership. The Initiative will include detailed reporting on inputs, outputs, and results. Malawi was one of the first seven countries selected for this Initiative.

As part of PMI, the United States Agency for International Development (USAID) proposes to implement a pilot Indoor Residual Spraying (IRS) program in Malawi for malaria vector control during the 2007 spray season. USAID is obligated to comply with the Code of Federal Regulations Title 22 Section 216 (22 CFR 216). 22 CFR 216 mandates that detailed pesticide procedures are addressed prior to direct or indirect support of pesticide use. This document fulfills this legal obligation. Additionally, this document seeks to fulfill the Environmental Impact Assessment requirements of the government of Mozambique. This document relies heavily upon USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment* (PEA), the primary resource for providing guidance for IRS implementation that maximizes the safety of workers and beneficiaries and minimizes environmental contamination.

The pilot IRS program will utilize one of the five pyrethroid insecticides currently registered by the Malawi Bureau of Standards. The program will be targeted around Illovo Sugar (Dwangwa Estates) in Nkhotakota District, and include areas both north and south of the Estates. Approximately 26,000 households will be sprayed during the pilot program, including households on Dwangwa Estates where IRS using lambda-cyhalothrin has taken place since 2000.

A **negative determination with conditions** is recommended for this project. The conditions are that USAID, USAID contractors, and the MOH implement the risk reduction actions outlined in the Environmental Management Plan (EMP). USAID will discuss the compulsory nature of EMP implementation with the MOH; and the development of an Implementation Letter between USAID and MOH assigning roles and responsibilities for these risk reduction actions.

Any support by USAID to expand the pilot IRS program in 2008 would require USAID development an additional EIA to be approved by the Government of Malawi, according to their national laws. So long as this Malawian EIA is completed and the expansion activity proposes the use of registered pyrethroid chemicals addressed in this document, USAID will not require an additional SEA or SEA amendment for IRS pilot program expansion. If non-pyrethroid chemicals or alternative pyrethroids not addressed in this document are proposed for use in program expansion, USAID will require an additional SEA or SEA amendment that takes into account these chemicals.

As required by USAID's Automated Directives System (ADS) 204.5.4, the USAID/Malawi Health Team will actively monitor ongoing activities for compliance with the recommendations in this SEA, and modify or end activities that are not in compliance.

APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:

CLEARANCE:
Mission Director, USAID/Malawi: _____Date: _____
Curt Reintsma

CONCURRENCE:
Environmental Officer, Bureau of Global Health: _____Date: _____
Michael Zeilinger

ADDITIONAL CLEARANCES:

Mission Environmental Officer
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Autman Tembo

PMI Advisor: _____Date: _____
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Environmental Officer
Africa Bureau: _____Date: _____
Brian Hirsch

SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR INDOOR RESIDUAL SPRAYING (IRS) FOR MALARIA CONTROL IN MALAWI

by

Melanie Biscoe, RTI International

ACKNOWLEDGEMENTS, PREPARATION METHODOLOGY AND PUBLIC COMMENT

This assessment is based on research conducted in Malawi from June 2 to 16, 2007, including consultations with several IRS program stakeholders. Major stakeholder concerns about the project included:

- The need to fulfill local environmental review requirements
- Potential impact on agricultural crop exports, including tobacco, ground nuts, soybeans, rice and maize
- Potential impact on fisheries and fish exports, including aquaculture
- The critical need to inform target communities about the project
- The need to assist the elderly and disabled in moving household goods
- Issues surrounding DDT (note that DDT is currently not registered in Malawi and was not considered for use in the pilot IRS program)

The following individuals and institutions were consulted and their comments and concerns about the pilot IRS program were integrated into this document:

1. Aaron Glyn Sosola, (Pharmacy, Medicines and Poisons Board). BSc (MW); B.Pharm (RSA); MPH (MW), Deputy Registrar and Head of Technical Services Tel 256-1-755-634 and 265-755-166 Cel 265-8-202-930 and 265-9-564-777 sosola@malawi.net sosola@pmpb.malawi.net P.O. Box 30241 Capital City Lilongwe 3
2. Dr. Aloysius Kamperewera, Deputy Director, Environmental Affairs Department Tel 256-1-771111 and 265-8-869446 Aloysius@SDWP.org.mw P/B 394, Lilongwe 3
3. John Chipwhanya, National Malaria Control Program Director.
4. Carl Campbell, US Centers for Disease Control, Blantyre
5. John Gimnig, US Centers for Disease Control, Atlanta, United States
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9. Jefrey H. Luhanga, PhD, Controller of Agricultural Extension and Technical Services, Ministry of Agriculture, Tel 265-01-789-072 DL 265-01-789-033 Cel 265-08-823-353 xtluhanga@yahoo.com P.O. Box 30134 Capital City, Lilongwe 3
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16. Mr. Kadyampskeni, Nkhotakota District Environmental Health Officer 08662496
17. Mr. Msiska, Nkhotakota District Malaria Coordinator
18. Mr. Phiri, Nkhotakota District ITN Coordinator
19. Illovo Sugar (Dwangwa Estate) Health Officer
20. Illovo Sugar (Dwangwa Estate) IRS Program Coordinators
21. Evans Kapeya, Registrar of Pesticides, Pesticides Control Board ekapeya@yahoo.com, pesticideboard@malawi.net
22. Jones T. Chidothe, Sales Manager, Farmers Organization, Ltd. Tel 01873088 or 01873745 Fax 01873452 Cel 09954594 Res 01684328 farmorg.sales@broadbandmw.com P.O. Box 1916 Blantyre, Malawi
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26. Dr. Themba Mzilahowa, Liverpool Associates in Tropical Health, Blantyre
27. Dr. Somanje, Permanent Secretary for Preventive Health Services, Ministry of Health
28. Todd Johnson, Development Alternatives Inc., todd_johnson@dai.com (impact on beekeeping interventions)
29. Trent Bunderson, Director, East and Southern Africa, WSU/Total LandCare, Lilongwe, Malawi Cell (265) 8 838 072 Roaming Cell (265) 9 838 072 tbunderson@yahoo.com (impact on beekeeping interventions)

The individuals listed above graciously provided their input to a three-person team consisting of:

Ms. Melanie Biscoe	RTI International
Mr. Jake O'Sullivan	RTI International
Mr. Autman Tembo	USAID/Malawi
Ms. Catherine Chiphazi	USAID/Malawi

Additionally, government documents concerning pesticide use, the environment, and malaria control were reviewed and incorporated into this EA (see Bibliography).

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ACRONYMS

ADS	Automated Directives System
CDC	Centers for Disease Control
EIA	Environmental Impact Assessment
DSOER	District State of the Environment Report
EMP	Environmental Management Plan
FAO	Food and Agriculture Organization of the United Nations
HPLC	High Performance Liquid Chromatography
IEC	Information, Education and Communication
IEE	Initial Environmental Examination
IRS	Indoor Residual Spraying
ITNs	Insecticide Treated Nets
IUCN	International Union for Conservation of Nature and Natural Resources
LLINs	Long-Lasting Insecticidal Nets
IVM	Integrated Vector Management
LATH	Liverpool Associates in Tropical Health
MOU	Memorandum of Understanding
NBS	Malawi National Bureau of Standards
NGOs	Non-Governmental Organization
NMCP	National Malaria Control Program
PCB	Malawi Pesticides Control Board
PSCs	Pyrethrum Spray Catches
PEA for IVM	Programmatic Environmental Assessment for Integrated Vector Management
PMI	Presidential Malaria Initiative in Africa (U.S.)
PPE	Personal Protective Equipment
RBM	Roll Back Malaria
RTI	Research Triangle Institute
USAID	United States Agency for International Development
USEPA	United States Environmental Protection Agency
WP	Wettable Powder
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

EXECUTIVE SUMMARY

The Malawi National Malaria Control Program and the President's Malaria Initiative propose a pilot IRS program in Nkhotakota District to determine the feasibility and desirability of IRS in Malawi as a major public health intervention. Research Triangle Institute International (RTI), a USAID contractor, is responsible for providing substantial technical assistance to the National Malaria Control Program and the Nkhotakota District Health Office to plan and implement the pilot IRS program. Major components of program implementation that will be supported by PMI through RTI include:

- Purchase of insecticide, spraying equipment, and adequate amounts of personal protective clothing and equipment for staff;
- Financial support for trainers and spray teams;
- Technical advisors to plan the program, train field staff, and supervise field operations;
- Information, Education and Communication (IEC) campaigns to inform beneficiaries, raise public awareness, promote behavior change and promote cooperation;
- Financial support for renting a storage facility for the insecticide, empty sachets, spray and cleaning equipment; and
- Additional human health and environmental safety components as described in the Environmental Management Plan (EMP).

The pilot IRS program will utilize one of the five pyrethroid insecticides registered by the Malawi Bureau of Standards. The program is targeted around Illovo Sugar (Dwangwa Estates) in Nkhotakota District and includes areas to the north up to Dwambazi river and south up to Nkhotakota district headquarters. The boundary on the western side is Nkhotakota Wildlife Reserve while the eastern side is the lake. Approximately 26,000 households will be sprayed during the pilot program, including the 4,000 households on Dwangwa Estates where IRS using lambda-cyhalothrin has taken place since 2000. Illovo Sugar will take primary responsibility for operations on the Dwangwa Estates, and RTI and Illovo will work together to ensure that operations within and outside the Estate are streamlined and adhere to best practices.

The potential negative health impacts of the intervention include transitory, acute health impacts on beneficiaries and spray operators as a result of unintentional pesticide exposure. Environmental impacts are expected to be minimal but, if they occur, would most likely include negative impacts on fish, aquatic invertebrates, and bees. The EMP in the next section details the mitigation requirements for the pilot program to minimize these risks to human health and the environment. Mitigation measures include substantial training for all individuals involved in implementation, community education,

utilization of personal protective equipment, and best practices for re-use/disposal of contaminated water from operations.

Compliance with measures described in the EMP will be monitored on a regular basis by the Government of Malawi's Department of Environmental Affairs and relevant Nkhotakota District Officials. RTI International will also conduct an internal compliance inspection and submit a compliance report to major program stakeholders. Finally, USAID health and environment staff will visit the program site periodically to determine the progress of the IRS campaign as well as to assess compliance with this SEA.

This assessment is based on research conducted in Malawi from June 2 to 16, 2007, including consultations with several IRS program stakeholders. Additionally, government documents concerning pesticide use, the environment, and malaria control were reviewed and incorporated into this EA (see Bibliography).

ENVIRONMENTAL MANAGEMENT PLAN (EMP)

Table 1 summarizes the required mitigation actions according to the time that the actions should be taken. Bolded indicators are those that are considered "minimum requirements" for all IRS programs, and are used to compare IRS programs funded through PMI through time; these indicators are also listed in the environmental compliance monitoring checklist in Appendix 1. USAID and the Malawi Department of Environmental Affairs will discuss the compulsory nature of EMP implementation with the Ministry of Health; the Ministry of Health must be committed to the implementation of the EMP. A memorandum of understanding (MOU) detailing the commitments, roles and responsibilities will be negotiated and signed between GOM/MOH and USAID/Malawi. Key institutions and collaborators who will assist in the implementation of the project include:

- Malawi National Malaria Control Program
- USAID Health Team
- CDC
- RTI International
- Malawi National Bureau of Standards
- Malawi Pesticides Control Board
- Pharmacy, Medicine and Poisons Board of Malawi
- Malawi Department of Environment
- Nkhotakota District Health Office
- Illovo Sugar (Dwangwa Estate)
- Nkhotakota District Assembly
- Nkhotakota Environment Office

- Nkhotakota Agriculture Office
- Nkhotakota Fisheries Office
- Liverpool Associates in Tropical Health (LATH)
- USAID Apiary Support Project
- USAID Aquaculture Support Project
- Croplife

These institutions should be brought together in an IRS coordination committee to resolve program issues on a regular basis. Roles played by each of these collaborating institutions are identified in the EMP table under "Implementation Responsibility."

Table 1. Required Mitigation Activities for Pilot IRS Program, Nkhotakota District, Malawi

Negative Impact	Activities	Frequency	Program targets	Indicators	Source of Information	Implementation Responsibility
Fetal Exposure	Pregnancy tests to ensure pregnant women are not on the spray teams; prohibition of breastfeeding women on spray teams; education of women regarding risk and presentation of consent forms	Once prior to campaign of less than 1 month For campaigns of more than 1 month, once every 30 days	potential female spray operators	● **Percentage female spray operators who took pregnancy tests** ● **Percentage female spray operators who indicated they were not breastfeeding** ● Percentage female spray operators who have signed consent forms	Medical Exam Records	Health District Office, RTI, Illovo Sugar

Spray Operator and Community Exposure, Environmental Contamination	Training of spray operators, team leaders and supervisors according to WHO and EA guidelines; training of storekeepers, drivers and health workers.	Once prior to campaign	spray operators team leaders supervisors storekeepers drivers health workers	● All outlines for training exercises include components described in the text of this EA, as well as the EMP ● **Lack of vehicle accidents** ● **Lack of major spill during insecticide transport** ● **Health workers trained** ● **Storekeepers trained** ● **Drivers trained** (see guidelines in Pesticide Procedures E) Spray Operators conduct the following activities during spraying: ● **Frequently agitate spray can** ● **Hold pump such that compression gage can be seen** ● **Stands parallel to wall being sprayed** ● **Stands 45 cm from wall** ● **1m/2.5 sec spray rate** ● **75 cm swatch width and 5 cm overlap** ● **Nozzle not dripping** ● **All house wall surfaces sprayed** Storage facilities contain the following components (see rows below for additional details): ● **Stock records up-to-date**	Training exercise outlines Trip reports describing training activities and exercises Inspection Reports	RTI, Illovo Sugar, Croplife, Pharmacy, Medicine and Poisons Board

				● First in, first out stock rotation system in place **● Empty sachets collected and counted** **● Temperature recorded** **● Stocks orderly** **● No leaks or spills evident** **● Insecticide stored separate from food/medicine/human habitation** **● Soap and water available**		

Spray Operator and Community Exposure, Environmental Contamination	Procurement of sprayers manufactured according to WHO specifications; procurement and proper use of PPE by spray operators, team leaders and supervisors (cotton overalls, face shield, dust mask, broad-rimmed hat, rubber gloves, gum boots) procurement of PPE for wash persons	Once prior to campaign	spray operators team leaders supervisors storekeepers wash persons	● **PPE in good condition** ● **All necessary PPE worn by all relevant personnel** ● When asked, personnel know signs and symptoms of poisoning, emergency treatment and referral protocol (see Appendix 9)	Inspection reports	RTI, Illovo Sugar
Residential Exposure	Procure one or two cloths per spray operator to cover furniture in households	Once prior to campaign	spray operators	● Ratio cloths procured/spray operator ● System in place to wash contaminated drop cloths	RTI procurement documents Inspection reports	RTI, Illovo Sugar
Acute Effects of Pesticide Go Untreated	Ensuring treatment medicines for insecticide exposure listed in EA are available at the District level; registration, procurement and distribution of Lorazepam,Vit E and Salbutamol 100mcg, sustained release aerosol which are currently not available in Malawi	Once prior to campaign	relevant health facilities	● **Percentage treatment medicines available at health facilities** ● Availability of first aid kits in storage facilities and hired vehicles	Inspection reports	MOH Pharmacy, Medicine and Poisons Board (first indicator), RTI and Illovo Sugar (second indicator)
Staff and Community Exposure	Procurement and use of gloves for washing interior and exterior of program vehicle	Once prior to campaign	driver	● Drivers wear gloves while washing vehicle	RTI procurement documents Inspection reports	RTI, Illovo Sugar

Spray Operator Exposure	Organization of a drill for carrying out and supervising personal hygiene, regular washing of protective clothes and cleaning of equipment according to WHO guidelines	Once prior to campaign	spray operators	● **No eating, drinking or smoking witnessed during operations** (and washing conducted prior to any eating, drinking or smoking) ● **Facilities available for daily wash-up** ● **All working clothes must be removed at the end of each day's operations and a shower or bath taken-- in circumstances where a full-body shower or bath is not feasible, face/neck and hands must be washed with soap and water.** ● Spraying staff provided with at least two uniforms to allow for frequent changes. ● Washing facilities with sufficient water and soap made available in the field at appropriate locations (previously mentioned) ● Working clothes regularly washed ● Gloves washed during clean-up	Inspection reports	RTI, Illovo Sugar

Spray Operator and Community Exposure	Procurement and distribution of barrels for progressive rinse, and wash-tubs for personal hygiene; inscription of program barrels and tubs as District Health Office property to deter sale and domestic use in event of pilferage	Once prior to campaign	spray operators team leaders supervisors	● **Rinse-water recycled and remainder disposed of according to EA guidelines** (see Pesticide Procedures J)	Inspection reports	RTI, Illovo Sugar
Environmental Contamination	Locate district storage facilities on high ground, outside of floodplains	Once prior to campaign	n/a, sets example for campaign scale-ups	● Storage facility outside of floodplain	Inspection reports	District Health Office
Community Exposure	IEC Campaign, instruct residents to: ● clear homes of mats or rugs, furniture, cooking implements and foodstuffs prior to spraying ● if furniture cannot be moved out of the home, then move it to the center of the room if possible ● stay outside the home during spraying and for two to four hours after spraying ● move and keep all animals outside the home during spraying, and for four hours after spraying ● sweep up any insects killed from the spraying and drop them in latrine pits ● sweep floors free of any residual insecticide that may remain from the spraying ● not re-plaster or paint over the sprayed walls after	Once prior to campaign	residents	● IEC materials developed and inclusive of specific instructions ● IEC materials delivered in appropriate fashion ● **Residents outside house during spraying** ● **Food and goods outside house during spraying** ● **Furniture covered during spraying** ● **Residents stay outside for four hours after spraying** ● **Residents sweep floor** ● **Occurrence of skin/eye/throat irritation or any type of poisoning**	Inspection reports	RTI, Illovo Sugar

	spraying ● keep using bed nets for protection against malaria ● if skin itches after re-entrance into home, wash with soap and water; for eye irritation, flush eyes with water; for respiratory irritation, leave the home for fresh air; for ingestion, if soap and water are unavailable, or if symptoms persist, contact program staff or go to nearest health facility					
Community Exposure	Through IEC exercises, determine best means of assisting the elderly and disabled in removing goods from the household	Once prior to campaign	residents	● IEC campaign adequately addresses issues surrounding the elderly and disabled (spray operators to enforce removal of household goods during campaign)	End of round report, Inspection report	RTI
Apiary Contamination	IEC Campaign, to inform beekeepers of the nature of the program and request proper cleaning of beekeeping equipment stored indoors, and air-tight storage of honey if it is stored indoors	Once prior to campaign	beekeepers in target area	● Acceptance of Nkhotakota honey exports in importing markets	USAID Apiary Support Project, District Agriculture Office	USAID Apiary Support Project, District Agriculture Office

Aquaculture Contamination	IEC Campaign, informing farmers involved in aquaculture in the target areas of Nkhotakota District to clean any aquaculture equipment stored in their home before use in ponds, and to ensure disposal of floor residue and dead insects as a result of IRS in pit latrines or a hole especially dug for the purpose of disposal	Once prior to campaign	farmers involved in aquaculture in target area	● Number of post-spraying complaints from farmers involved in aquaculture in target area	USAID Aquaculture Support Project, District Fisheries Office	USAID Aquaculture Support Project, District Fisheries Office
Potential Exposure without Impact on Vector	Collection of insecticide samples and lab-testing of insecticide to ensure quality control	Once prior to campaign	n/a, sets example for campaign scale-ups	● Moisture content ● 75% active ingredient present	NBS report	RTI, Pesticides Control Board, National Bureau of Standards
Potential Exposure without Impact on Vector	Entomological monitoring	Continuous monitoring conducted before and after the campaign.	n/a, sets example for campaign scale-ups	● Monitoring results presented in end-of-round report and monitoring reports submitted after end-of-round report	End of round report	LATH, NMCP
Fetal Exposure	Reassign women spray operators who become pregnant the campaign to tasks that minimize occupational exposure to insecticides	During campaign	Female spray operators	● Number of females reassigned	Supervisors	District Health Officials, RTI, Illovo Sugar

Community Exposure, Fetal Exposure	Prohibition of spraying in homes where sick persons or pregnant women are living and cannot move outside the home *and* stay outside the home during and 4 hours after spraying	Daily throughout campaign	spray operators	● Residents outside house during spraying (previously mentioned) ● Residents stay outside for four hours after spraying (previously mentioned) ● Occurrence of skin/eye/throat irritation (previously mentioned)	Inspection reports	Supervisors, Team Leaders
Community Exposure	Prohibition of spraying in homes where food, utensils and flooring have not been removed from the house, and where furniture has not been removed outside *or* moved to the middle of the room and covered with a cloth by the spray operator	Daily throughout campaign	spray operators	● Food and goods outside house during spraying (previously mentioned)	Inspection reports	Supervisors, Team Leaders
Spray Operator Exposure	Prohibition of eating, drinking and smoking during work; prohibition of eating before washing	Daily throughout campaign	spray operators	● No eating, drinking or smoking witnessed during operations (previously mentioned)	Inspection reports	Supervisors, Team Leaders
Community Exposure	Prior to spraying, covering furniture that cannot be moved with cloths provided by the Program	Daily throughout campaign	spray operators	● Furniture covered during spraying (previously mentioned)	Inspection reports	Spray Operators
Spray Operator and Community Exposure, Environmental Contamination	Reprimanding of spray operators that do not follow proper procedure in all aspects of operations (handling, spraying, hygiene, cleanup)	Daily throughout campaign	supervisors team leaders	● **Adequate Supervisor/Team Leader Ratio** ● **Adequate Team Leader/Spray Operator Ratio** ● Number and severity of incidents reported by campaign leadership	Inspection Reports Monthly Reports	Supervisors, District Officials, RTI, Illovo Sugar

Pilferage and Community Exposure, Environmental Contamination	Daily tracking of insecticide sachets used, spray-operator sign-out of sachets, return of empty sachets to supervisors, etc. (Indicators are equivalent to procedures listed in Pesticide Procedures J)	Daily throughout campaign	storekeeper team leaders supervisors	● At reception at provincial warehouse lot numbers of insecticide and quantities are registered on shelf inventory card ● District requisitions are approved at the program office where copies are maintained ● Requisition goes to provincial warehouse where distribution takes place and signed for, based on sachet numbers (if provincial warehouse present) ● On reception at district office, all sachets are counted and stamped with the relevant district stamp and registered on stock card. ● 5-6 can refills/day are issued to each spray operator, with their code written on the sachet. (e.g. M= Matutuine, 49 = no. spray operator João. On the can refills issued to João are written M49). These sachets are signed out buy the spray operator ● At the end of the day, empty and full sachets are returned and number checked against what was signed for ● The next day all	Inspection Reports Monthly Reports	Storekeepers, Team Leaders, Supervisors, RTI, Illovo Sugar

				previously signed but unused sachets are re-issued and again signed for by the relevant spray operator ● **Spray operator performance, number of structures sprayed versus can refills used is calculated to see if there is an over or under application** ● At the end of the spray round, [stock remaining] = [stock at start] - [no of sachets distributed]. No. sachets distributed should be equal to no. can refills used.		
Spray Operator and Community Exposure, Environmental Contamination	Daily sprayer maintenance, sprayer progressive rinse, spray operator bathing, washing of overalls, PPE and cloths used to cover furniture, latrine disposal of laundry wash-water	Daily throughout campaign	storekeeper spray operators team leaders supervisors	*Indicators described in previous rows*	*Sources described in previous rows*	*Implementers described in previous rows*

Community Exposure, Environmental Contamination	Storage of empty sachets until manufacturer recapture or disposal option selected by PCB, per PCB instruction	Daily throughout campaign and after campaign until empty sachets returned to manufacturer or disposed per PCB instruction	storekeeper	● Empty sachets collected and counted, stored in sealed drums	Inspection Reports Monthly Reports	Storekeepers, RTI, Illovo Sugar
Pilferage and Community Exposure, Environmental Contamination	Keep storage facilities up to standards described in Pesticide Procedures J; Storage of all insecticides, empty packaging, barrels and tubs in storage facilities, reducing use of contaminated goods domestically	Daily prior to, throughout and after campaign	logistics officer storekeeper	● Presence of a dedicated and trained storekeeper ● Thermometer installed/temperature recorded (previously mentioned) ● Insecticide stored separately from food and medicine (previously mentioned) ● Stock records up-to-date (previously mentioned) **● Facility double-padlocked and guarded** **● Facility physically secure** ● Soap and clean water available at all times (previously mentioned) ● Adequate numbers of shower/bathing facilities available for spray operators (designated wash basins at a minimum) (previously	Inspection Reports	Storekeepers, District Health Office, RTI, Illovo Sugar

				mentioned)		

Non-Compliance with Occupational Safety, Health and Welfare Act	Ensure storage conditions comply with OSHW Act (other conditions covered in other aspects of this EMP)	Daily prior to, throughout and after campaign	logistics officer storekeeper	● Every area for the bulk storage of dangerous substances is • Constructed and maintained with suitable material; • Adequately ventilated; • Has adequate storage space; • Is capable of containing not less than seventy-five percent of spillage; • Has an inventory of the substances in storage maintained and prominently displayed.● There are adequate and suitable means for extinguishing fire, which are readily accessible provided and maintained in every workplace.● Chemical fire extinguishers are freshly charged at intervals not greater than those specified by the manufacturers, or otherwise once annually, and tested by the application of such hydraulic pressure thereto are suited to the type of extinguisher tested, at intervals of not more than four years; and the dates of recharging the extinguisher and the last hydraulic test are clearly marked on the body of	Inspection Reports	Storekeepers, District Officials, RTI, Illovo Sugar

				the extinguisher or on a tab securely attached thereto.● No fire, flame, open light or other agent likely to ignite volatile and inflammable substances is allowed or used in any part of a workplace in which volatile and inflammable substances are used.● No person is witnessed smoking in any part of a workplace where volatile and inflammable substances are used, and a notice prohibiting smoking shall be posted in a conspicuous place in every such part of the workplace.		

Worker Exposure, Community Exposure, Environmental Contamination	Improvement of Illovo Sugar (Dwangwa Estate) Storage Facility (Recommended, not required)	Daily prior to, throughout and after campaign	Illovo Sugar	● Facility expanded to accommodate maximum capacity expected for all pesticide commodities Install bottom vents for better ventilation ● Wire mesh installed on vents to prevent vermin from entering ● Sump and bunds constructed ● Exhaust system installed to remove dust and ash emitted from the plant ● Insecticide placed on pallets in case of flooding or spillage ● Floor free of dust and dirt ● Daily records show temperature ● Temperature less than 40 degrees C	Inspection Reports	Illovo Sugar (Dwangwa Estate)
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	Train district and/or national environmental compliance inspectors in Training of Trainers (TOT) and spray operator training course	Once prior to campaign	Malawian environmental compliance inspectors	● Malawian Environmental Compliance Inspectors trained on IRS	TOT/Spray Operator training attendance lists	RTI, Croplife
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	RTI Inspectors engage relevant Malawi environmental personnel in inspection exercise	Once during campaign	RTI compliance inspector Malawian environmental compliance inspectors	● Qualitative feedback from Malawian environmental compliance inspectors	Inspection Trip Report, Inspection Reports	District Environment Office, District Agriculture Office, District Fisheries Office, Department of

						Environment, RTI, USAID
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	Environmental compliance inspections and reporting by district environmental officers, RTI and USAID	Once during campaign (RTI), and frequently during campaign	n/a, sets example for campaign scale-ups	● Inspections conducted and reports completed detailing compliance with indicators	Inspection Reports	District Environment Office, District Agriculture Office, District Fisheries Office, Department of Environment, RTI, USAID
Community Exposure	End-of-program cleaning/decontamination of interior and exterior of vehicles	Once after campaign	driver	● Interiors and exteriors of vehicles cleaned	End of round report	Drivers/Rental company
Community Exposure, Environmental Contamination	In the event of unused pesticide, transfer remaining unused pesticide to Illovo Sugar (Dwangwa Estate) to manage and use in subsequent spray round(s) subject to USAID concurrence, Illovo has a permanent storage facility and has their own spray program.	Once at end of campaign	logistics officer Illovo Sugar	● Remaining unused pesticide transferred to Illovo Sugar at end of spray round. ● Minimize amount of unused stock by proper planning and procuring just enough pesticides to cover the targeted 26,000 HHs.	End of round report	RTI

Ensure efficacy of pyrethroids in malaria vector control	Development of protocol/implementation of measures to mitigate mosquito resistance to insecticides-- pesticide rotation or mosaicing.	Initial development or protocol and continuous re-assessment of measures to be taken based on entomological monitoring	n/a	● Protocol developed	Protocol Report	NMCP
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	Submission of end-of-spraying environmental compliance reporting to USAID	Once at end of campaign (RTI); periodically through campaign (Department of Environmental Affairs)	n/a	● Compliance reports submitted	Environmental Compliance Reports	District Environment Office, District Agriculture Office, District Fisheries Office, Department of Environment, RTI, USAID

BACKGROUND AND PURPOSE

Need for Action and the Preferred Alternative

PMI Background

The IRS program in Malawi is associated with the U.S. President's Initiative on Malaria in Africa, which was announced 30 June, 2005, and seeks to reduce malaria mortality by 50% in up to 15 countries (total population: 175 million) in sub-Saharan Africa in five years. This will be accomplished by rapidly scaling up the following proven malaria prevention and treatment interventions in each country to reach 85% coverage of vulnerable groups (children under five, pregnant women, and people living with HIV/AIDS):

- treatment of malarial illnesses with artemisinin-based combination therapies (ACTs);
- intermittent preventive treatment (IPT) of pregnant women with effective antimalarial drugs, currently sulfadoxine-pyrimethamine;
- distribution of insecticide-treated bed nets (ITNs); and
- indoor residual spraying (IRS).

In implementing these interventions, the United States, through USAID and CDC, will work in partnership with the Government of Malawi and build on existing national malaria control plans, policies and resources. The Initiative will support and complement efforts of the Global Fund (GFATM), the World Bank, and other members of the Roll Back Malaria (RBM) Partnership. The Initiative will include detailed reporting on inputs, outputs, and results.

Malaria Burden in Malawi

Malaria is the most frequently reported cause of morbidity in both adults and children in Malawi. In 2003, 40% of all outpatient visits were attributed to malaria, comprising of 3.5 million recorded visits. However, after accounting for the large number of untreated cases, the National Malaria Control Programme estimates that the total number of outpatient cases was over 6 million (GOM 2004).

The *Malaria Strategic Plan 2001-2005* aimed to reduce the burden of malaria using multiple strategies. First, increased collaboration between Technical Committees and the National Malaria Advisory Committee and hiring of personnel strengthened the management of the health system. Second, an emphasis on disease management led to increased access to antimalarial drugs and the standardization of training for health care workers. Donor agencies supported the procurement of sulfadoxine-pyrimethamine (SP) and the expansion of laboratory services. Approximately 2.7 million mosquito nets were distributed throughout the country – half of which were distributed in 2004 alone – to address disease prevention. In addition, ITN re-treatment increased from 7% in 2002 to

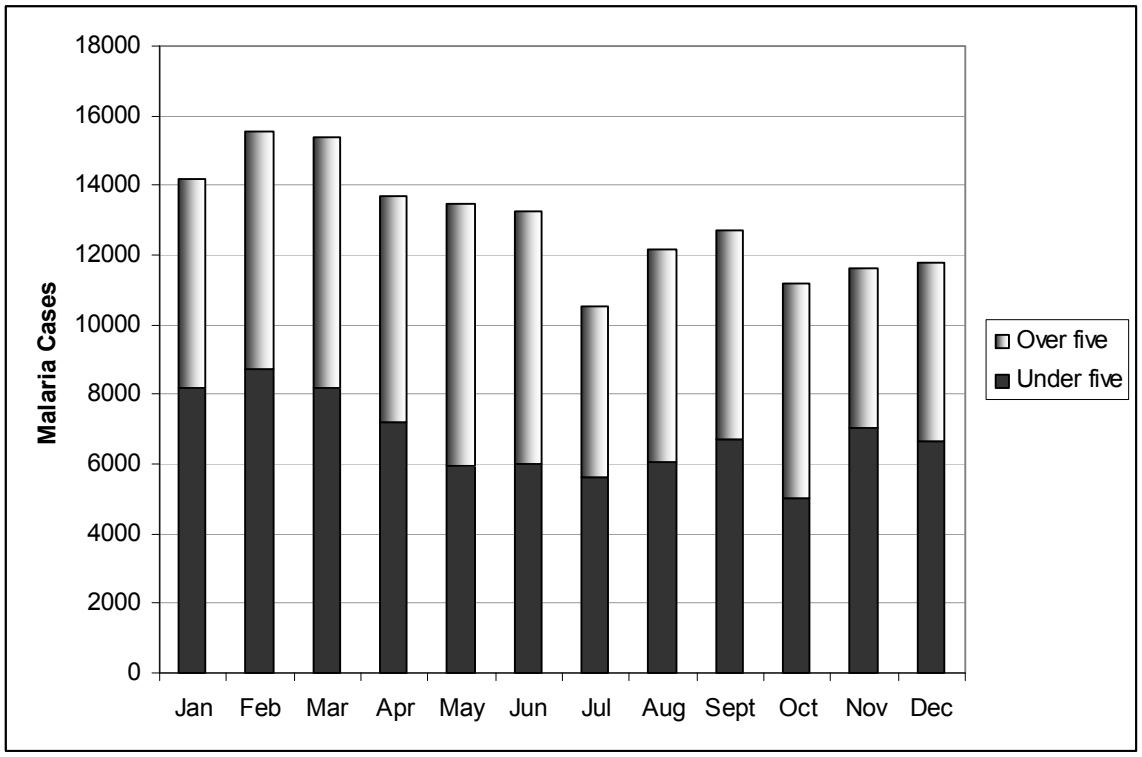
61% in 2004. Community-level data was collected on a monthly basis as part of the surveillance, epidemic preparedness, and response component. Completing the Strategic Plan were communication campaigns, human resource development, and increased opportunity for operational research.

Despite the successes mentioned above, several barriers to malaria prevention and control were acknowledged in the *Malaria Strategic Plan 2005-2010*, including a shortage of antimalarials; emerging resistance to SP; limited supply of nets and failure to reach the poorest communities and stop divergence of nets to untargeted groups; improper use of and failure to retreat nets; and shortage of staff in the health system. As such, the *Strategic Plan 2005-2010* revised the policies of the NMCP to include case management, intermittent preventive treatment (IPT), and scaling up of ITNs distribution. The NMCP also proposed IRS in four selected areas. These strategies, in concert with surveillance, epidemic preparedness, communication campaigns, human resource development, and operational research, were selected with the goal of halving malaria morbidity and mortality by 2010 per the Abuja Declaration.

Pilot Project Justification

The Nkhotakota District, situated between Lake Malawi to the east and Dwambadzi Forest and Nkhotakota Wildlife Reserve to the west, has experienced 100,000 to 200,000 malaria cases annually over the past six years (District Malaria data). The burden is approximately 25% higher among children under five. In 2006, 134 deaths occurred due to malaria.

Figure 1. Typical Malaria Caseload in Nkhotakota District



Additionally, malaria is the most prevalent environmental health related disease in Nkhotakota District with a higher percentage of cases than cholera, diarrhea and skin diseases as evidenced by the table below.

Table 2. Cases of Environmental Health Related Diseases (%) in Nkhotakota District

Year	*Malaria*	*Cholera*	*Diarrhea*	*Skin diseases*
1994	*60*	*0.2*	*44*	*4.1*
1995	*61*	*1*	*40*	*5.3*
1996	*60*	*1*	*42*	*7.6*
1997	*59*	*0.9*	*41*	*8.8*
1998	*59*	*0.9*	*39*	*24.1*

1999	*56*	*1*	*39*	*24*
2000	*54*	*0.5*	*40*	*41.2*
2001	*53.1*	*1*	*39*	*61.9*
2002	*33.5*	*1*	*30*	*19.1*
2003	*32.7*	*1*	*41*	*17.9*
2004	*30*	*1*	*30*	*15*

Source: DSOER 2005.

Use of ITNs, the primary vector control method of Nkhotakota, has had limited success. Despite the distribution of 126,609 nets from 2004 to 2006, and the corresponding increase in household net usage from 55% to 67%, the percentage of nets being re-treated with insecticides has decreased 19% over the same time period. Malawi supports an ITN delivery model with three distribution channels: highly subsidized distribution managed by health personnel through the antenatal health facilities for pregnant women and children under five, community-based distribution managed by Health Surveillance Assistants (HSAs) for all family members, and private sector distribution through commercial channels for those with an ability to pay full price. The health facility model was adopted as a national model in 2002 in partnership with the MOH, The United Kingdom Department for International Development (DFID), the United Nations Children's Fund (UNICEF), the World Health Organization (WHO), the United States Agency for International Development (USAID), the U.S Centers for Disease Control and Prevention (CDC), and other partners. ITNs are procured through UNICEF with DFID financing (now provided through the SWAp basket funding mechanism beginning in 2005), are distributed and marketed by PSI, and are supported at district level by the District Health Management Teams.

As of September 2006, the ITN policy has changed to include long-lasting ITNs (LLINs). The IRS will combine with the distribution of LLINs which minimizes the need for re-treatment.

The health office of Illovo Sugar's Dwangwa Estate, located in Nkhotakota, records approximately 2,000 confirmed cases of malaria per month. Illovo has been maintaining IRS operations since 2000. Spraying occurs three times per year.

Because of the aforementioned factors – the district's intense malaria transmission, clear geographic boundaries, and declining rates of net re-treatment – along with Nkhotakota's representative rural districts and the history of IRS driven by the informal public-private partnership with the sugar estate, Nkhotakota District was chosen for the IRS pilot project.

Alternatives Considered and Not Considered

Alternatives Considered and Preferred

Pilot IRS Campaign using Registered Pyrethroids, including: alpha-cypermethrin bifenthrin cyfluthrin deltamethrin lambda-cyhalothrin	USAID support would include the following components: • Purchase of insecticide, spraying equipment, and adequate amounts of personal protective clothing and equipment for staff; • Financial support for trainers and spray teams; • Technical advisors to plan the program, train field staff, and supervise field operations; • IEC to inform beneficiaries, raise public awareness, promote behavior change and promote cooperation; • Financial support for renting storage facilities for insecticide, spraying equipment, personal protective clothing and empty insecticide sachets • Financial support and technical assistance for additional human health and environmental safety components, including updating infrastructure for responsible disposal of contaminated wash-water (e.g. evaporation tank, ablution block and/or soak pit) at Illovo. Illovo has an existing disposal facility which needs upgrading to ensure that proper safeguards are in place. This will be done in full consultation with USAID mission and Pesticide Board. • Financial and technical support for empty sachet disposal as needed according to the requirement of the Pesticide Board and international guidelines

Alternatives Not Considered and Rejected

ITN/LLIN Program	USAID is committed to continuing support for ITN and LLIN scale-up activities within Malawi. To that end, the following PERSUAP was developed prior to this SEA: • Insecticide Treated Mosquito Net Programs in Malawi: Pesticide Evaluation Report and Safer Use Action Plan. Malaria prevention through scaling up the use of treated mosquito nets (ITN, LLIN) is a key strategy of the NMCP. USAID has supported ITN use from its inception as a pilot intervention in Blantyre to its adoption across Malawi. With USAID assistance, overall ITN ownership in Malawi rose to 50% in 2006, with 60% of households with children under five owning a net. Recent data indicate that over 80% of children under two are protected by ITNs.
Pilot IRS Project using other Insecticide	Available data indicate that malaria vectors in Malawi are fully susceptible to all classes of pesticides that could be used in IRS. Pyrethroids are being proposed for the pilot project due to their safety compared to other pesticides registered in Malawi. Additionally, pyrethroids have been used for isolated IRS as part of donor programs. They have also been used by Illovo Sugar for the malaria control

	program on its estates since 2000.
Larviciding and Environmental Management	Larviciding and environmental management are strategies not currently listed in the National Malaria Strategic Plan.
No Action	According to USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment*, the no action alternative will not be considered; the risks posed by IRS are acceptable to USAID in light of the risks posed by malaria.

The Preferred Alternative

Human Health and Environmental Effects of Preferred Alternative

As a consequence of implementing the Preferred Alternative, approximately 300,000 people in Nkhotakota District will be covered by this vector control program. This protection will reduce the incidence of adult morbidity, miscarriages, low birth-weight, and adverse effects on fetal neurodevelopment due to malaria. It will also reduce incidence of malaria-related childhood anemia, complications, organ failure, and death.

Few adverse human health or environmental effects are anticipated as result of occupational, residential, and/or environmental exposure to pyrethroids due to mitigation efforts. Effects from occupational exposure could include eye, skin and respiratory irritation, although personal protective equipment should minimize such effects. These acute effects can also occur in the resident population up to 24 hours after spraying; however, residents typically do not experience these effects if they re-enter their residences four hours after spraying.

In the past, Dwangwa Estate IRS program managers documented respiratory and skin irritation in residents who re-enter their homes after a two hour period. As a result, the Dwangwa Estate IRS program managers recommend that residents stay outside the home for four hours after spraying. The program managers believe that the occurrence of reactions after two hours may be a result of high temperatures that cause the insecticide to settle out of the air at a slower rate. In the most recent spray round at the Illovo Sugar Dwangwa Estates, four people re-entered their houses too soon after spraying and experienced respiratory and skin irritation. Since 2000 when the Dwangwa Estates program started, the program has documented one asthma attack. There have not been any reactions documented after 24 hours post-spraying. Further discussion on the acute human health impacts of pyrethroids and proposed mitigation for those impacts is included in the Pesticide Procedures section.

AFFECTED ENVIRONMENT

The total population living in Nkhotakota District is approximately 300,000 inhabitants. The pilot IRS program however is targeting only 26,000HHs living north of Nkhotakota boma up to Dwambazi river. Details are given in Table 2 below.

Table 3: Areas and Population of targeted district

Districts	Surface (km²)	Estimated # Homes	Population
Nkhotakota	4,358	60,000	300,000
Targeted in Pilot Campaign		26,000	130,000
Percent		43.3	43.3

Source: PMI planning materials provided by Carl Campbell, US Centers for Disease Control (CDC)/Malawi

Housing on Dwangwa Estates is primarily plaster and paint, but also include mud, brick, cement and straw. Housing outside of Dwangwa Estates in Nkhotakhota district is constructed primarily of mud and locally-fired brick.

According to the 2005 District State of Environment Report, "There has been a significant transition from traditional and from less formal to formal housing, and from semi permanent, to permanent housing. More houses have burnt bricks and the traditional houses made of poles and mud are now diminishing. However, number of squatter settlements is increasing in the urban areas of Nkhotakota Boma and Dwangwa…. The local government is encouraging the use of concrete blocks for buildings."

Nkhotakota District lies in the African Rift Valley on Lake Malawi, and is thus subject to extreme heat and humidity. Temperatures for the past twelve years have remained consistent with a minimum of 20 and a maximum of 29 degrees Celsius. The hottest season of the year occurs from October through December; the highest recorded temperature in Nkhotakota District is 35 degrees Celsius in November of 1996. The following tables and figures further describe Nkhotakota's temperature and relative humidity throughout the year.

Table 4. Nkhotakota District Minimum Temperatures

YEAR	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL	MEAN
1992	21,9	22,0	21,9	21,8	19,5	15,7	15,5	19,9	18,3	21,1	22	21,7	241,3	20,1
1993	20,8	21,2	21,1	21,2	18,5	16,3	16,1	16,2	17,4	20,5	22,5	23,4	235,2	19,6
1994	22,3	21,4	21,3	20,7	17,8	16,2	16,0	17,5	18,7	21,2	22,8	22,1	238,0	19,8
1995	21,7	21,5	21,8	20,2	18,7	15,8	16	18,2	18,8	21,6	23,2	22,7	240,2	20,0
1996	21,8	21,2	20,9	20,2	19,0	15,9	14,8	15,8	18,7	20,8	23	22,2	234,3	19,5
1997	21,7	21,2	21,9	20,4	17,2	16,9	15,9	16,8	16,9	22,1	23,4	21,5	235,9	19,7
1998	22,3	22,4	22,3	20,9	16,1	16,4	15,5	17,6	19,0	20,8	23,0	23,3	239,6	20,0
1999	21,7	20,9	21,4	19,9	18,1	16,4	16,2	17,2	18,6	20,3	22,5	22,5	235,7	19,6
2000	22,1	21,4	21,0	20,9	18,5	16,9	15,8	17,8	19,0	21,6	21,9	21,4	238,3	19,9
2001	21,6	21,0	21,5	20,7	18,3	16,6	16,2	16,5	18,5	21,8	23,0	22,8	238,5	19,9
2002	21,8	21,8	21,5	20,7	17,5	15,8	16,2	17,4	19,5	21,8	23,0	22,1	239,1	19,9
2003	22,3	22,3	21,9	20,5	18,3	17,3	16,2	16,4	19,0	21,5	24,0	22,3	242	20,2
2004	21,9	21,5	22,1	20,9	17,9	16,6	0,0	0,0	0,0	0,0	0,0	0	120,9	20,2

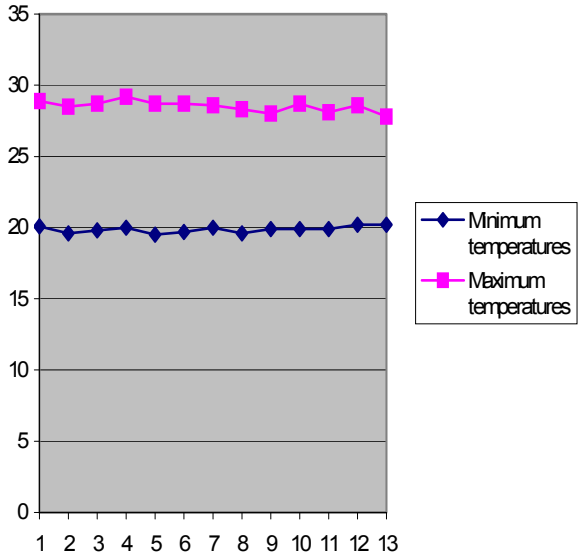
Source: Nkhotakota District DSOER 2005.

Table 5. Nkhotakota District Maximum Temperatures

YEAR	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC	TOTAL	MEAN
1992	29,3	29,0	29,7	29,1	26,8	26,1	26,1	26,8	30,3	32,2	31,8	29,9	347,1	28,9
1993	29,3	28,4	27,9	28,5	27,5	25,4	25,5	26,2	27,8	32,0	31,9	32,4	342,8	28,5
1994	29,4	28,3	28,8	28,7	27,2	26,1	25,5	26,7	28,0	31,1	33,6	30,6	344,0	28,7
1995	28,2	28,5	29,2	28,3	27,6	25,9	26,4	28,4	30,6	33,3	33,4	30,0	349,8	29,2
1996	28,8	28,3	27,9	27,7	27,1	26,0	25,3	27,5	30,2	31,8	34,5	29,8	344,9	28,7
1997	30,0	28,3	30,7	26,7	26,7	27,2	25,6	27,8	29,7	30,5	32,9	27,8	343,9	28,7
1998	29,3	29,3	29,6	28,2	25,2	25,2	25,9	26,9	29,7	31,9	28,6	32,8	342,6	28,6
1999	28,6	28,3	28,3	27,2	25,8	25,8	25,4	26,5	29,2	30,9	32,2	31,4	339,6	28,3
2000	28,8	28,6	28,4	28,2	25,9	25,0	25,2	26,3	29,8	31,7	29,7	28,5	336,1	28,0
2001	28,0	28,7	28,3	28,5	25,1	25,9	25,7	28,0	30,0	31,4	33,4	31,1	344,1	28,7
2002	28,5	28,2	28,7	28,2	26,9	25,6	27,3	27,2	29,2	26,0	31,9	29,3	337,0	28,1
2003	28,9	29,0	29,0	27,9	27,1	26,0	25,2	25,5	29,8	32,3	33,0	29,6	343,3	26,1
2004	29,2	28,7	29,4	28,2	26,1	25,4	0,0	0,0	0,0	0,0	0,0	0,0	167,0	27,8

Source: Nkhotakota District DSOER 2005.

Figure 2. Nkhotakota District Average Temperatures from 1992 to 2004



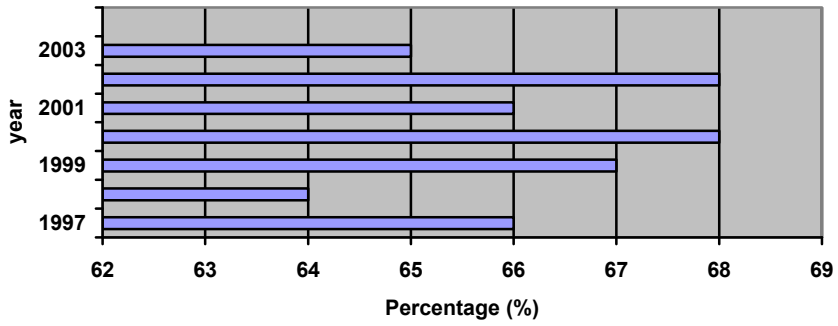
Source: Nkhotakota District DSOER 2005.

Table 6. Nkhotakota District Relative Humidity

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Total	Average
1997	78	80	73	76	66	63	53	54	54	57	57	82	793	66 %
1998	77	76	80	73	55	58	57	61	56	51	57	62	763	64 %
1999	80	82	82	75	71	63	62	63	57	52	57	64	808	67 %
2000	77	79	81	75	72	66	65	63	55	52	54	79	818	68 %
2001	80	78	81	74	66	61	63	55	53	54	53	71	789	66 %
2002	81	82	80	75	64	64	66	60	58	52	58	74	814	68 %
2003	79	80	79	71	64	63	60	55	52	50	54	75	782	65 %
2004	78	77	78	78	70	66	0	0	0	0	0	0	447	75 %

Source: Nkhotakota District DSOER 2005.

Figure 3. Nkhotakota District Relative Humidity



Source: Nkhotakota District DSOER 2005.

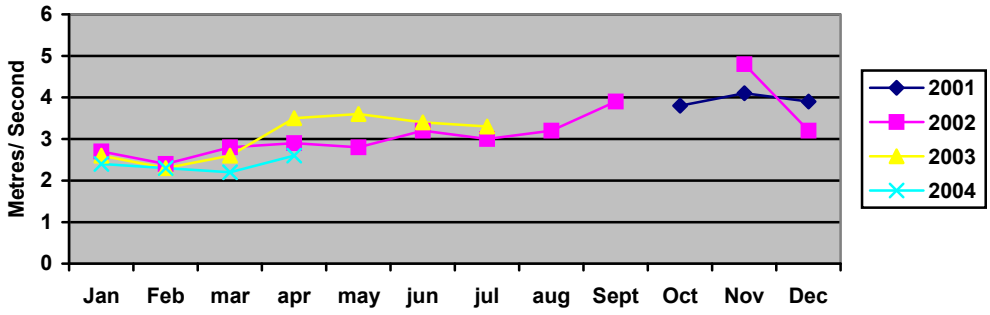
Nkhotakota District also experiences "strong Southeasterly winds," or Mwera, between May and September. The occurrence of "gusty stormy winds" coincides with the hottest months of the year, October and November. The following table and figure describe Nkhotakota's wind speed in greater detail.

Table 7. Nkhotakota District Wind Speed m/s (2001 – 2004)

Year	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
2001	-	-	-	-	-	-	-	-	-	3.8	4.1	3.9
2002	2.7	2.4	2.8	2.9	2.8	3.2	3.0	3.2	3.9	-	4.8	3.2
2003	2.6	2.3	2.6	3.5	3.6	3.4	3.3	-	-	-	-	-
2004	2.4	2.3	2.2	2.6	-	-	-	-	-	-	-	-

Source: Nkhotakota District DSOER 2005.

Figure 4. Nkhotakota District Wind Speed m/s



Source: Nkhotakota District DSOER 2005.

In addition to wind and heat, November also marks the start of the rainy season in Nkhotakota District. According to precipitation data from 1992 to 2004, rains can peak any time from December to April, subsiding substantially in May. Figure 2, which can be found under Pesticide Procedures H, describes the precipitation patterns in Nkhotakota District from 1992 to 2004.

ENVIRONMENTAL CONSEQUENCES

Unavoidable Adverse Effects

The risk of vehicle accidents and consequent insecticide spillage is always present. Such spillage could expose both humans and aquatic environments to pyrethroids with adverse consequences. It is also possible that the impacts of normal residential exposure of pregnant women could include neurological effects on unborn fetuses, but further research is necessary to test this hypothesis (Berkowitz, et al. 2003). This fetal exposure in the home would be an unavoidable risk of the IRS operation. Human inhalation of toxic fumes in the event of a storehouse fire is also an unavoidable risk. Information on the combustion byproducts of pyrethroids can be found in below (taken from USAID's Integrated Vector Management Programs for Malaria Vector Control: Programmatic Environmental Assessment (IVM PEA), pages 57-58) as well as fire-fighting instructions from Material Safety Data Sheets.

Table 8. Insecticide, Combustion Byproduct, and Extinguishing Instructions

Insecticide	Combustion Byproduct	Extinguishing Instructions (from MSDS)
Alpha-cypermethrin	Combustion and/or pyrolysis of alpha-cypermethrin can lead potentially to the production of compounds such as formaldehyde, acrolein, and hydrogen cyanide (UK PID, 2006)	Extinguishing media: Dry powder, CO_2 or alcohol-resistant foam. Special exposure hazards: None found. Protective equipment: Wear full protective clothing and self-contained breathing apparatus. Special precautions: Confine the use of water to the cooling of unaffected stock, thus avoiding the risk of accumulation of polluted run-off from the site.
Bifenthrin	Not available	Suitable extinguishing media: Carbon dioxide (CO2), Foam; Powders Not suitable extinguishing media: Water (the product is hazardous for the environment - do not dilute it) Specific fire fighting methods: Isolate fire area. Evacuate downwind. Contain the extinguishing fluids by bunding (the product is hazardous for the environment). Do not attempt to fight the fire without suitable protective equipment. Do not breathe fumes Protection of fire-fighters: Self-contained breathing apparatus and complete protective clothing

Insecticide	Combustion Byproduct	Extinguishing Instructions (from MSDS)
Cyfluthrin	Combustion and/or pyrolysis of cyfluthrin can lead potentially to the production of compounds such as formaldehyde, acrolein, hydrogen cyanide, hydrogen chloride, and hydrogen fluoride (UK PID, 2006)	Not available to-date.
Deltamethrin	Combustion and/or pyrolysis of deltamethrin can lead potentially to the production of compounds such as formaldehyde, acrolein, hydrogen cyanide, and hydrogen bromide (UK PID, 2006)	Suitable extinguishing media: Water spray jet, carbon dioxide (CO_2), dry powder, foam. Extinguishing media which should Product itself is non-combustible Not be used for safety reasons: Fire extinguishing measures to suit surroundings. Specific hazards during fire fighting: In case of fire the evolution of dangerous gases is possible. Special protective equipment: In the event of fire and/or explosion do not breathe fumes. Fire-fighters should wear self contained breathing apparatus for fire fighting if necessary. Further information: Remove product from areas of fire, or otherwise cool containers with water in order to avoid pressure being built up due to heat. Whenever possible, contain fire-fighting water by binding area with sand or earth.
Lambda-cyhalothrin	Open-burning of lambda-cyhalothrin creates nitrogen oxides, hydrogen chloride, and hydrogen fluoride (WHO, 1997)	Extinguishing media: For small fires use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. For large fires, use Alcohol-resistant foam, Water spray. Extinguishing media which must not be used for safety reasons: Do not use a solid water stream as it may scatter and spread fire. Specific hazards during fire fighting: As the product contains combustible organic components, fire will produce dense black smoke containing hazardous products of combustion. Exposure to decomposition products may be a hazard to health. Special protective equipment for firefighters: Wear full protective clothing and self-contained breathing apparatus. Further information: Do not allow run-off from fire fighting to enter drains or water courses. Cool closed containers exposed to fire with water spray.

Irreversible or irretrievable commitments of resources

All financial costs of this program are irretrievable. It is important to note that, after implementation of this proposal, Nkhotakota district would acquire new spray pumps that could be used in future IRS interventions not supported by the US government and the required environmental analysis. The storage facilities will also contain barrels or tubs used for rinsing sprayers and cleaning overalls, face shields, gloves, and boots. If not secured, these barrels or tubs may be pilfered and used for drinking water or food storage.

Environmental impacts of the proposed action

The primary environmental risks include negative impacts on bee hives and pollination, as well as contamination of aquatic ecosystems, which could have a transitory adverse effect on freshwater fish and invertebrate species. Training and supervision of spray personnel according to best practices should adequately address this risk.

Direct and indirect effects and their significance

Direct Effects

USAID will directly support the use of pyrethroids for malaria vector control in Malawi. This support will likely have few adverse human health and environmental effects, while providing protection against malaria to approximately 130,000 people. This protection will reduce the incidence of adult morbidity, miscarriages, low birth-weight, and adverse effects on fetal neurodevelopment. It will also reduce incidence of malaria-related childhood anemia, complications, organ failure, and death.

Indirect Effects

Through this action, USAID will be providing the District Health Office with backpack compression sprayers. Upon completion of this program, USAID will no longer supervise the use of this capital.

Complementary and Conflicting Policies, Plans or Controls for the Areas under Consideration

Apart from the Government of Malawi National Environmental Policy (Act No. 23 of 1996) and the Guidelines for Environmental Impact Assessment (published December 1997) which guide the development of this environmental assessment document, two other regulations need to be considered in the implementation of the pilot IRS program: Pesticides Act (Act No. 12 of 2000) and Occupational Safety, Health and Welfare Act (Act No. 21 of 1997). After review of the Pesticides Act (Act No. 12 of 2000), relevant mitigation measures were included in the EMP, with the exception of additional labeling and import requirements which must be followed by any pesticide importer and/or distributor. Functions of the Malawi Pesticides Control Board are described in the Malawi Pesticides Act and can be found in Appendix 3.

The following bullets summarize the activities the program must conduct to remain in compliance with Malawi's Occupational Safety, Health and Welfare Act:

- *Every area for the bulk storage of dangerous substances shall—*
    - *Be constructed and maintained with suitable material;*
    - *Be adequately ventilated;*
    - *Have adequate storage space;*

        - *Be capable of containing not less than seventy-five percent of spillage;*
        - *Have an inventory of the substances in storage maintained and prominently displayed.*
    - *There shall be provided and maintained in every workplace, adequate and suitable means for extinguishing fire, which shall be readily accessible.*
    - *Chemical fire extinguishers shall be freshly charged at intervals not greater than those specified by the manufacturers, or otherwise once annually, and tested by the application of such hydraulic pressure thereto shall be suited to the type of extinguisher tested, at intervals of not more than four years; and the dates of recharging the extinguisher and the last hydraulic test shall be clearly marked on the body of the extinguisher or on a tab securely attached thereto.*
    - *No fire, flame, open light or other agent likely to ignite volatile and inflammable substances shall be allowed or used in any part of a workplace in which volatile and inflammable substances are used.*
    - *No person shall smoke in any part of a workplace where volatile and inflammable substances are used, and a notice prohibiting smoking shall be posted in a conspicuous place in every such part of the workplace.*

These are included in the EMP. Additionally, the program should be aware of the following legal requirements and prospects for inspection and reporting as part of the Pesticides Act:

- *No person shall compel an employee to use any pesticide in a manner or for a purpose contrary to the manner or purpose permitted by the Board on the registration of the pesticide or as may be prescribed.*
- *Every employer who requires or permits an employee to use a pesticide shall provide and require the employee to use facilities, equipment and clothing conducive to the safe handling of the pesticide.*
- *The Registrar may by written notice require any employer to take steps to reduce the risks to the health of employees from pesticides, including requiring the employer to monitor the health of employees exposed to insecticides.*
- *If a person dies, becomes ill or is injured and there are grounds for believing that this was wholly or partially caused by exposure to a pesticide, the Registrar shall be notified immediately by*
    - *The owner or person in charge of premises, land or a vessel, aircraft, vehicle or other mode of transport, where the exposure occurred;*
    - *The employer of a person who was or may have been exposed to the pesticide in the course of his employment;*

- *Any registered medical practitioner who, upon examination of a person, has reason to believe that such a person has died or suffered injury as a result of exposure to pesticide; or*
- *Any public health officer who has reason to believe that exposure to a pesticide may be linked to any death or detrimental effects on human health in an area for which the officer is responsible.*

- *No person shall dispose of any pesticide container of or packaging in a manner that is unduly hazardous to human or animal health or the environment or is contrary to any written law.*
- *An inspector [designated by the Pesticides Control Board] may:*
  - *Enter on any land, premises, aircraft, vessel or vehicle, at or in which any pesticide is or may be reasonably suspected to be manufactured, stored, transported, sold, distributed or used to determine whether the provisions of this Act are being complied with;*
  - *Carry out periodic inspections of all establishments which manufacture, import, export, store, sell, or distribute or use pesticides to determine whether the provision of this Act are being complied with;*
  - *Seize any equipment, pesticide, document, record or other things which the inspector believes has been used in, or which appears to afford evidence of, a contravention of this Act;*
  - *Cause a police officer to investigate any person whom the inspector on reasonable grounds suspects of having committed an offence against this Act.*

Occupational exposure of pregnant women is not addressed in the above-described acts explicitly but is still a concern and will be minimized through exposure prevention and mitigation activities described in the EMP.

In addition to these Acts, the Government of Malawi is in the process of finalizing Environment Management (Waste Management and Sanitation) Regulations, as well as Environmental Management (Chemicals and Toxic Substances Management) Regulations. Once these acts are finalized, the pilot IRS program as well as future IRS programs may need to take into consideration additional regulatory compliance measures, particularly with respect to disposal of hazardous waste, container re-use, treatment of chemical wastes, and transboundary movement of wastes and prior informed consent procedures.

USAID Pesticide Procedures, 22 CFR Part 216.3(b)

A. The USEPA registration status of the requested pesticide

The registration status of the proposed pyrethroids is summarized in the following table.

Table 9. Registration Status of Suggested Pesticides

Is the pesticide…	Alpha-cypermethrin	Bifenthrin	Cyfluthrin	Deltamethrin	Lambda-cyhalothrin
Registered by the host country (for public health use)?	YES	YES	YES	YES	YES
Registered by EPA for "same or similar use"?	Not Registered—but other forms of cypermethrin registered for residential uses	YES	YES	YES	YES
WHO-recommended?	YES	YES	YES	YES	YES

B. The basis for selection of the requested pesticide

The chemicals used in IRS all have different properties and are more or less appropriate in different circumstances. The following threshold criteria must be met in making decisions on pesticides used in malaria vector control:

- Pesticide registration in the host country

As indicated in Pesticide Procedures A, the proposed pesticides are registered in Malawi.

- Acceptability of the pesticide to the National Malaria Control Program

Pyrethroid use in IRS is acceptable to the NMCP.

- Risk to human health—pesticides must be approved by the WHO and should be preferred based on their safety as described in USAID's *Programmatic Environmental Assessment for Integrated Vector Management*.

The following table illustrates the potential for exposure above levels of concern based on results from a screening risk assessment conducted for *USAID's Programmatic Environmental Assessment for Integrated Vector Management*. The screening risk assessment was a conservative assessment of chemicals used in IRS, examining worst-case scenarios of occupational and residential exposure. The assessment compared estimated exposures to US EPA human health benchmarks for each chemical. Additional details can be found in Chapter 5 of the *PEA for IVM*.

Table 10. Non-Cancer Health Risks from Pyrethroids Used in IRS

Occupational Exposure				Residential Exposure			
Risk Below Levels of Concern	**Low Risk**	**Moderate Risk**	**High Risk**	**Risk Below Levels of Concern**	**Low Risk**	**Moderate Risk**	**High Risk**
Alpha-cypermethrin				Alpha-cypermethrin			
Bifenthrin	Cyfluthrin			Bifenthrin			
	Lambda-cyhalothrin			Cyfluthrin			
Deltamethrin				Deltamethrin			
				Lambda-cyhalothrin			

- Risk to environment, livestock and/or agricultural trade

See Pesticide Procedures G.

Beyond these four threshold considerations, technical and logistical factors must be addressed in comparing and selecting insecticides for malaria vector control. The primary factor to be addressed is:

- Vector resistance

According to NMCP data emerging from 2007 sentinel site susceptibility testing, malaria vectors across the country are susceptible to pyrethroids. Illovo Sugar also conducted susceptibility testing in 2002-3 that indicated 97-99 percent susceptibility to pyrethroids.

Secondary factors include:

- Appropriateness of surface for spraying

Housing on Dwangwa Estates is primarily plaster and paint, but also include mud, brick, cement and straw. Housing outside of Dwangwa Estates in Nkhotakhota district is constructed primarily of mud and locally-fired brick.

According to the 2005 District State of Environment Report, "There has been a significant transition from traditional and from less formal to formal housing, and from semi permanent, to permanent housing. More houses have burnt bricks and the traditional houses made of poles and mud are now diminishing. However, number of squatter settlements is increasing in the urban areas of Nkhotakota Boma and Dwangwa…. The local government is encouraging the use of concrete blocks for buildings."

- Duration of effectiveness (and implications for cost)

According to WHO, all pyrethroids listed are expected to have a duration of 3 to 6 months; however, the duration of effectiveness varies under different climatic conditions as well as surfaces. Technical information on duration of effectiveness on the primary wall surface types in Nkhotakota will be considered when selecting insecticides during the procurement process.

- Cost of insecticide

The cost of pyrethroids are approximately 4 to 6 USD per sachet. Additional cost considerations, taking into account in-kind product support, will be considered during the procurement process.

Tertiary factors include:

- The need for an insecticide of a different class to prevent resistance

If IRS is pursued by the NMCP in the medium to long term, Malawi will need to develop and implement a resistance management program; however, for a one-time pilot program, exclusive use of pyrethroids is an acceptable course of action as it is not expected to stimulate additional vector resistance in Nkhotakota District (conclusion based on communication with Dr. Janet Hemingway, LATH).

- Major classes of insecticides used in other vector control interventions that could promote resistance

ITNs and LLINs are used widely throughout Malawi. The Nkhotakota District ITN Utilization Report indicates that 69% of households use an ITN, and that 62.25% of households retreat their nets. The ITNs and LLINs that are distributed are primarily treated with deltamethrin, a pyrethroid insecticide. In the medium to long term, IRS using pyrethroids combined with ITN utilization could promote pyrethroid resistance in the vector population.

- Major classes of insecticides used in the agricultural sector that could promote resistance

Pesticide use varies throughout Nkhotakota District. In the southern part of the district, cotton farming is prevalent and necessitates high use of pyrethroid pesticides, including cypermethrin. However, the IRS target area focuses in the central and northern part of Nkhotakota District, where cotton farming is not prevalent and the primary pesticides used include only Dakonel (250 g) and M-45 (250 g). Of these specific formulations, only 13 bottles of Dakonel and 8 bottles of M-45 were used in the whole of Nkhotakota District from 2006 to 2007. Thus it is not expected that agricultural use of pyrethroids would contribute to vector resistance in the areas targeted for IRS this year. If the program is expanded and expected to continue for several years, it is advisable to take into account agricultural pesticide use in the development of a resistance management scheme for malaria vector control.

- Host-country capacity to prevent pilferage

Compared to most countries where IRS is being implemented, Malawi has substantial capacity to prevent pilferage of insecticide in an IRS program, provided that the appropriate infrastructure and personnel for pesticide storage is provided (see Pesticide Procedures J). District officials and the NMCP can benefit from lessons-learned at Illovo Sugar's Dwangwa Estates, as well as expertise that can be provided through CropLife and the Pesticides Control Board.

C. The extent to which the proposed pesticide use is part of an integrated vector management program

Currently, the NMCP exclusively utilizes ITNs and LLINs in malaria vector management. The proposed pesticide use is intended to examine the possibility of expanding this uni-dimensional approach to encompass two complementary vector-control measures. To-date, the NMCP has not included larviciding or environmental management in its strategy for malaria vector management.

D. The proposed method or methods of application, including availability of appropriate application and safety equipment

The proposed method of application is Indoor Residual Spraying, or IRS. IRS is a commonly-used malaria vector control method that is particularly effective in preventing malaria epidemics. It is implemented by the application of residual insecticides, to which *Anopheles* female mosquitoes have been demonstrated to be susceptible, to the interior walls of houses and other structures. The insecticide remains on the treated surfaces upon which the mosquitoes will rest before or after taking a blood meal. Several formulations of insecticides are available for this purpose; those that may be used for this pilot project include alpha-cypermethrin, bifenthrin, cyfluthrin, deltamethrin, and lambda-cyhalothrin.. The residual effect of the aforementioned insecticide is sufficient to kill resting mosquitoes for a period ranging from three to nine months depending on the insecticide and its formulation, the surface on which it is applied, and local conditions. The objective of IRS programs is to reduce the mean life-span of the female mosquito population below the duration required for development of the parasite life phases that occur in the mosquito and, thereby, to substantially reduce the population's ability to sustain malaria transmission. IRS is most effective in areas with seasonal malaria transmission and is typically implemented by teams of spray operators who spray houses in at-risk localities prior to the rainy season, as heavy rains prompt increases in the *Anopheles* vector population. To be effective, IRS must attain coverage rates of at least 85% of the houses in a target area. To-date, there are no plans for USAID support for re-application of the insecticide, as one of the motives for conducting this pilot program is to conduct entomological monitoring activities to determine the duration of effectiveness for the chosen insecticide.

The spray operators who implement IRS use compression sprayers to apply a measured amount of insecticide on the interior walls of houses and structures. A water-soluble insecticide is added to the sprayer containing a pre-measured amount of water, the prayer is pressurized, and the material is then applied to the interior walls of targeted homes and structures. After the day's spraying is complete, spray operators must clean the sprayer following the manufacturer's recommendations to ensure their proper operation and calibration.

The spray equipment used for IRS will be manufactured according to WHO specifications for compression sprayers for IRS operations. District Health Officers will determine mechanisms by which potential spray operators will be chosen. Spray operators will initially be chosen based on their completion of primary school. Their ability to read, write and make calculations, as well as a medical exam to determine fitness for implementation of the activity. Pregnancy tests will be conducted as part of the medical exam to ensure that pregnant women are not included on the spray teams. The MOU between GOM/MOH and USAID will place the responsibility on MOH to ensure commitment and enforcement.

The individuals recruited for IRS campaigns will receive intensive training on the use, operation, calibration and repair of the sprayer and practical exercises during a 5-day period prior to the beginning of the spraying campaign. They will also receive training to understand proper hygiene, to recognize the signs and symptoms of poisoning, and to understand the referral procedure for any incidents involving poisoning. This training will be conducted in accordance with WHO's "Manual for Indoor Residual Spraying" (WHO 2002). Potential spray operators must also pass written and practical tests at the end of training. In this way, spray operators will be prepared to conduct appropriate application of the insecticide.

Each spray team will consist of six or seven spray operators. Each spray operator will be provided with the following safety equipment, in accordance with WHO and FAO specifications:

- Broad-rimmed hat/helmet
- Face shield or goggles (face shield preferable)
- Dust mask or filtered mask
- 2 or 3 cotton overalls per spray operator
- Nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm
- Rubber boots

Supervisors will observe two spray teams to ensure spraying occurs according to best practices. Supervisors will travel between spray teams and will observe spray operators and team leaders in the preparation, spray technique, and sprayer and PPE cleanup during

the IRS campaign, as well as compile all data collected by their respective teams. Supervisors and additional district and national malaria program personnel will receive a 5-day "training of trainers course" according to WHO best professional practices, and will also receive additional training on personnel management, environmental aspects, entomological monitoring, geographical reconnaissance, and data recording and analysis. After each day's spray activities, supervisors will collect sachet packing material to track the amount of insecticide used, and ensure that spray operators practice proper personal hygiene to avoid prolonged insecticide exposure. The insecticide is packaged in water-soluble sachets, minimizing pesticide exposure to spray operators during sprayer preparation.

Scrupulous attention to personal hygiene is an essential component of the safe use of pesticides. For spray operators, safety precautions will depend largely on personal hygiene, including washing and changing clothes. A schedule for carrying out and supervising personal hygiene, regular washing of protective clothes and cleaning of equipment will be organized along the following lines (WHO 2006):

- Spraying staff should be provided with at least two uniforms to allow for frequent changes.
- Washing facilities with sufficient water and soap should be made available in the field at appropriate locations.
- All working clothes must be removed at the end of each day's operations and a shower or bath taken—in circumstances where a full-body shower or bath is not feasible, face/neck and hands must be washed with soap and water.
- Working clothes must be washed regularly.
- Particular attention should be given to washing gloves, as wearing contaminated gloves can be more dangerous than not wearing gloves at all.
- Spray operators must wash before eating.
- Eating, drinking and smoking during work must be strictly forbidden.

A drop-cloth and overalls wash-person will be hired and provided with his/her own protective gear. Wash persons will wash overalls at a central location in tubs used exclusively for overall washing. Spray operators must also wash themselves (at least face/neck, and hands) after each day's operations using wash basins specifically procured for that purpose or in a shower or bathing area. Spray operators should never wash themselves, their overalls, or their PPE in any water bodies. All wash-water should be disposed of in a concrete evaporation tank covered with a locked grate, an ablution block, or a soak pit, and improvement of existing infrastructure at Illovo for proper disposal of contaminated water (see Pesticide Procedures J for more detail on wash-water disposal options).

If USAID does not continue its support for the IRS program, program materials must be distributed or destroyed accordingly. All personal protective equipment (PPE), spray equipment, and environmental compliance equipment would be provided to the District Health Office for its use in future spray programs. Insecticide would be provided to Illovo Sugar's Dwangwa Estate, which conducts IRS on a regular basis, to ensure that the insecticide is used prior to its expiration date. Rented warehouses would be decontaminated with water and detergent and revert to their owners. There are two options once the empty sachets are returned to the district storage facility. First, the empty sachets may be returned to the manufacturer for disposal. This proposal will be included in tender documents. If manufacturer recapture is not feasible, then USAID will be obligated to store the empty sachets in sealed drums until such time that the Pesticides Control Board can arrange for proper incineration along with obsolete pesticide stocks. Burning or burial of empty sachets are not an acceptable form of disposal according to the Malawi Pesticides Control Board. Non-contaminated pesticide packaging (e.g., boxes or paper) can be disposed of locally—WHO recommends that this packaging be returned to a supervisor for "safe" disposal, and UNFAO recommends disposal at a landfill or "recycling" the packaging as fuel for a cement kiln or power plant (WHO, 2002; Thompson, 2004). UNFAO's "Draft Guidance Document on the Selection of Waste Management Options for the Disposal of Obsolete Pesticides and Contaminated Materials" says that, "The material, from which the containers and packaging are constructed, is generally environmentally harmless in itself and is suitable for recycling or disposal within the country. The degree of residual pesticide contamination within the materials is the only issue that may prevent this from occurring" (Thompson, 2004:60). Any packaging or personal protective equipment (PPE) that has been heavily contaminated should be triple-rinsed, shredded or punctured, and taken to a hazardous waste facility.

E. Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use and measures available to minimize such hazards

For acute and long-term toxicological hazards, see the toxicological profiles for pyrethroids from USAID's Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment that can be found in Appendices 4-8, as well as on USAID's Environmental Health Project website: http://www.ehproject.org/PDF/ehkm/ivm-env_assessment.pdf

Residential Exposure. The steps to mitigate, to the fullest extent possible, occupational exposure to pyrethroids are mentioned in the preceding section and described fully in the WHO's "Manual for Indoor Residual Spraying" (WHO 2002). However, as in all IRS operations, the risk of residential exposure is also present. District authorities and program staff will work with relevant boards, committees, and non-governmental organizations to carry out an IEC campaign to sensitize residents to IRS activities, in accordance with WHO guidelines. The IEC campaign (as well as IRS Program team

leaders and supervisors who will also instruct residents on best practices prior to spraying) should focus on the following elements of residential safety during an IRS program:

- clear homes of mats or rugs, furniture, cooking implements and foodstuffs prior to spraying
- if furniture cannot be moved out of the home, then move it to the center of the room if possible
- stay outside the home during spraying and for four hours after spraying
- move and keep all animals outside the home during spraying, and for four hours after spraying
- sweep up any insects killed from the spraying and drop them in latrine pits
- sweep floors free of any residual insecticide that may remain from the spraying
- do not replaster or paint over the sprayed walls after spraying
- keep using bednets for protection against malaria
- if skin itches after re-entrance into home, wash with soap and water; for eye irritation, flush eyes with water; for respiratory irritation, leave the home for fresh air; for ingestion, if soap and water are unavailable, or if symptoms persist, contact program staff or go to nearest health facility.

The IEC component for IRS will coordinate closely with other PMI IEC initiatives.

Pesticide Exposure and Treatment. USAID will work with the Pharmacy, Medicine and Poisons Board of Malawi and District Health Officials to ensure that the medicines in Table 11 are available in all relevant Nkhotakota District health facilities, hospitals and health centers. USAID will assist in registration and distribution of Lorazepam,Vitamin E and Salbutamol 100mcg, sustained release aerosol, which are currently not available in Malawi.

Table 11. Drugs Recommended for Treatment of Pyrethroid Exposure

Name of drug	Active ingredients
Promethazine	Promethazine Hydrocloride
Panadol	Paracetamol
Diazepam	Benzodiazapine/Diazapam
Lorazepam	Lorazepam
Calamine cream	Calamine, zinc oxide, glycerol, phenol, purified water, sodium citrate, betonite,

Vit E	Tocopherol, fragrance, mineral oil, deionized water, sodium hydroxide, stearic acid
Hydrocortisone cream	1% hydrocortisone
Salbutamol	Salbutamol 100 mcg, suspended inert aerosol
Salbutamol tablets	Salbutamol sulphate 4 mg
Activated Charcoal	Activated Charcoal

Safe Pesticide Transport. Prior to long-distance transport of the insecticide from the customs warehouse/central storage facility to the District, drivers will be informed about general issues surrounding the insecticide and how to handle emergency situations (e.g. road accidents). Training for long-distance transport from the distributorship to the district storage facilities will include the following information:

- For what use the insecticide is intended
- Toxicity of the insecticide
- Understanding security issues, implications of the insecticide getting into the public
- Handling an accident or emergency (according to FAO standards)
- Combustibility and combustion byproducts of insecticide

Drivers hired specifically for the two-month spray campaign period will receive:

- Training provided to spray operators (with the exception of sprayer operation and spray practice)
- Handling an accident or emergency (according to FAO standards)
- Handling vehicle contamination (see below)

Because vehicles will be rented for the program, it is important to ensure that pesticide contamination in the vehicle does not have negative impacts when the vehicle is subsequently used for another purpose (e.g. food transport). To prevent pesticide runoff from vehicle washing, drivers will also be responsible for wiping the vehicle bed with a damp cloth prior to washing the exterior of the vehicle. Finally, drivers will be responsible for cleaning and decontaminating the interior of the vehicle and exterior bed at the end of the spray campaign. Drivers will be provided with gloves to wear for cleaning the vehicle. All cloths used in wiping down the interior and bed of the vehicle should be washed with spray operator overalls.

F. The effectiveness of the requested pesticide for the proposed use

Vector Resistance

Liverpool Associates in Tropical Health (LATH) and Medical Research Council of South Africa (MRC) conduct susceptibility testing every three years in Malawi, the most recent testing having taken place in 2007 in the six sentinel districts representing the three regions of the country. Preliminary results indicate that malaria vectors in each region in Malawi are 100 percent susceptible to pyrethroids, carbamates, organophosphates, and organochlorines (personal communication with NMCP, IVCC and CDC). Illovo Sugar (Dwangwa Estates) also conducts susceptibility studies. Illovo's last susceptibility study was conducted in 2002 or 2003, and indicated that malaria vectors are 97 to 99 percent susceptible to pyrethroids.

Residual Persistence

The WHO Pesticide Evaluation Scheme (WHOPES) has published the duration of effective action of IRS Insecticides (Najera and Zaim 2002), which are indicated in the following table.

Table 12. WHOPES Duration of Effective Action of IRS Insecticides

Active Ingredient	Recommended Dose (mg/m^2)	Duration of Effective Action (Months)	WHOPES Comment
Alpha-cypermethrin WP and SC	20-30	4-6	
Bifenthrin WP	25-50	3-6	
Cyfluthrin WP	20-50	3-6	
Deltamethrin WP and WG	20-25	3-6	
Lambda-cyhalothrin WP	20-30	3-6	
Lambda-cyhalothrin CS	20-30	3-6	Not recommended for cement-plastered surfaces

Additional data on the residual persistence of insecticides can be found in published literature and additional field trials and disaggregated based on the wall surface. The insecticide procurement process will take into account these additional data in selecting one of the pyrethroids registered in Malawi for the IRS activity.

Insecticide Quality

USAID support for IRS will require that insecticide procurements will be accompanied by a Certificate of Analysis, assuring that the formulation was tested and that the appropriate amount of active ingredient is present in the formulation.

Demonstrations of Effectiveness

Illovo Sugar has been using lambda-cyhalothrin wettable powder in IRS since 2000, and has found the formulation to be effective in reducing the number of malaria cases treated at Illovo's on-site health center. To-date, Illovo has sprayed four times per year (recently

switching to three times per year), and has not conducted bioassays to determine the duration of effectiveness on different wall surfaces. Just recently, Illovo used lambda-cyhalothrin capsule suspension. Anecdotally, Illovo considers both lambda-cyhalothrin formulations to be effective for at least four months.

G. Compatibility of the proposed pesticide with target and nontarget ecosystems

Outside Environment

All pyrethroids considered are toxic to bees, and fish and other aquatic organisms. Thus the primary concern in pyrethroid use for IRS would be the following scenarios:

- ***Release of sprayer rinse-water into water bodies.*** Sprayer rinse-water should be re-used for the next day's operations. If this is not logistically possible, supervisors and spray operators must be trained to dispose of sprayer rinse-water in pit latrines.
- ***Spray operators washing themselves, overalls and PPE in water bodies.*** Spray operators should wash themselves, and wash persons should wash overalls and PPE at the local or central meeting point for IRS operations.
- ***Accidental spraying of apiaries (beehives).*** Accidental spraying of apiaries would kill bees residing therein. Use of pyrethroids for IRS is not expected to adversely impact beehives for the following reasons:
    - Pyrethroids will be sprayed on the inside walls of houses where bees are unlikely to land (compared with use in agriculture, where bees may come into frequent contact with pesticides)
    - Bee hives are typically not present near or on sprayed homes.
    - Preliminary data from the International Union for Conservation of Nature and Natural Resources (IUCN) environmental monitoring in Uganda indicate that even beehives in close proximity to pesticide storage facilities, sprayer clean-up sites, and targeted households were not be affected by use of lambda-cyhalothrin.

The primary route of beehive contamination from IRS would likely be from insecticide residue contaminating implements that are stored inside the household and used in collecting honey. Additional risk to the honey export market may exist from contamination of honey storage containers that were not removed from the household prior to spraying. The IEC campaign will address these issues and emphasize the importance of removing all household goods prior to spraying so that such contamination does not occur, and should advise beekeepers to clean beekeeping equipment before use to avoid honey contamination. Beekeepers should also keep honey in air-tight containers to avoid contamination.

According to United States Code of Federal Regulations Title 22 Section 216, "to the extent feasible and relevant, projects and programs for which Environmental Impact Statements or Environmental Assessments have been prepared should be designed to include measurement of any changes in environmental quality, positive or negative,

during their implementation." Monitoring of changes in environmental quality as a result of this pilot IRS activity is not relevant for the following reasons:

- Pyrethroids do not bioaccumulate or persist in the environment.
- Pyrethroids will not be sprayed on agricultural fields or in the environment, and substantial releases of the pesticide into the environment as a result of project activities are improbable.
- Impacts of pyrethroids on non-target organisms are acute and transitory.
- Spraying will not occur in any national park or conservation area.

Organic Crop Exports

Pyrethroids are expected to be compatible with households in Nkhotakota District, as organic export crop production is not prevalent in Nkhotakota District or throughout most of Malawi.

Aquaculture

The Lake Malawi Fishery is not expected to experience any impact from the IRS operations. Any negative impact on Lake Malawi fishery itself should be transitory and exceptionally limited given the type and quantities of pesticides involved, and any monetary impact would be spread out over the larger fishing population. However, smallholder aquaculture is privately owned and any impact on one aquaculture operation could negatively impact one fishing family. Farmers involved in aquaculture in the target areas of Nkhotakota District should be informed to clean any aquaculture equipment that is typically stored in the home before use in ponds, and to ensure disposal of floor residue and dead insects as a result of IRS in pit latrines or a hole especially dug for the purpose of disposal.

Table 13. Number of Fish Farms in Nkhotakota District 1986-2004

Year	Kafuzira	Kanyenda	Mphonde	Malengachanzi	Mwadzama	Mwansambo
1986	1	-	-	-	-	-
1998	-	-	-	5	-	-
1999	-	7	1	6	-	-
2000	3	4	9	10	-	4
2001	-	28	6	41	-	6

2002	5	21	8	27	-	2
2003	7	2	11	32	1	1
2004	10	8	26	6	-	2
Total	26	70	51	127	1	15

Source: DSOER 2005

Livestock

Pyrethroids are generally considered the safest insecticides that can be used in IRS, although individual pyrethroids' impacts on mammals range from low to high toxicity. As a general precaution, all livestock must exit the house for four hours after spraying. After re-entering the home, dead insects from home should be collected and thrown into a pit latrine to prevent pets and livestock (particularly chickens and guinea-fowl) from eating them. The table below notes the prevalence of different livestock species in Nkhotakota District from 2001 to 2004.

Table 14. Livestock Population 2001-2004

Year	Cattle	Goats	Sheep	Pigs	Dogs	Rabbits	G/fowls	Chicken
2001/02	8913	32146	9205	10132	9904	948	2913	186299
2002/03	6116	30380	6586	5576	7994	1156	4687	169883
2003/04	5739	30466	7158	7909	7877	1589	8022	206961
% Change	-35.6	-5.2	-22.2	-21.9	-20.5	+67.6	+175.3	+11.1

Source: DSOER 2005

H. The conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils

In November 2005, the Ministry of Local Government and District Administration published the *Nkhotakota District Assembly: District State of Environment Report 2004-2007* (DSOER). This report is the basis for the vast majority of information in this section. Paragraphs taken directly from the report are italicized.

In the majority of the district, soil is sandy. Dambo areas contain alluvial soils as a result of upstream erosion and subsequent sedimentation in dambo areas. The following table describes the predominant soil types in Nkhotakota District:

Table 15. Nkhotakota District Soil Types

Soil Types	Description	Properties
Lithic	Have 20% fine earth to a depth of 30-500cm above the hard rock below which roots can not penetrate.	It has varying properties.
Vertic	Have more than 30% clay in the upper 18cm and mostly deep.	Cracks due to the montimorilllonitic clay minerals.
Euric Ferracic	It has no specific characteristics.	Have low CEC in most of the upper 100cm.
Fluvic	Continuously rejuvenated through the deposition of sediments transported by water, derived from alluvium and deep.	Very rich in nutrient content.
Parralithic	Have highly weathered rock particles to a depth of atleast 150cm.	Have low nutrient and moisture holding capacity.

Source: Chitedze soil analysis reports/DSOER 2005

Nkhotakota district has four ecological zones: Lake Malawi, comprising 82,559 nautical miles, riverine wetlands, Nkhotakota wildlife reserve (180,000 hectares), and Dwambadzi forest reserve (36,660 hectares). Compared to other districts in Malawi, Nkhotakota District has a high percentage of forested land area (52%). Most of the forested land is protected in Dwambadzi forest reserve and Nkhotakota wildlife reserve. The reserves comprise approximately 75% of the total land area covered by indigenous (miombo) forests. The forests in both reserves, however, continue to be encroached upon by human settlements. According to the 2005 DSOER:

> *The forest cover is predominantly miombo woodlands. The indigenous trees are mostly found in the protected areas of Nkhotakota game and Dwambadzi forest reserves. Patches of miombo woodlands are also found in the customary lands that are bordering the protected areas…. Small portions of exotic trees such as pinus patulla, eucalyptuses are found in the Dwambadzi forest reserve. Acacia, eucalyptus and others are mostly found in the homesteads planting and individual woodlots.*

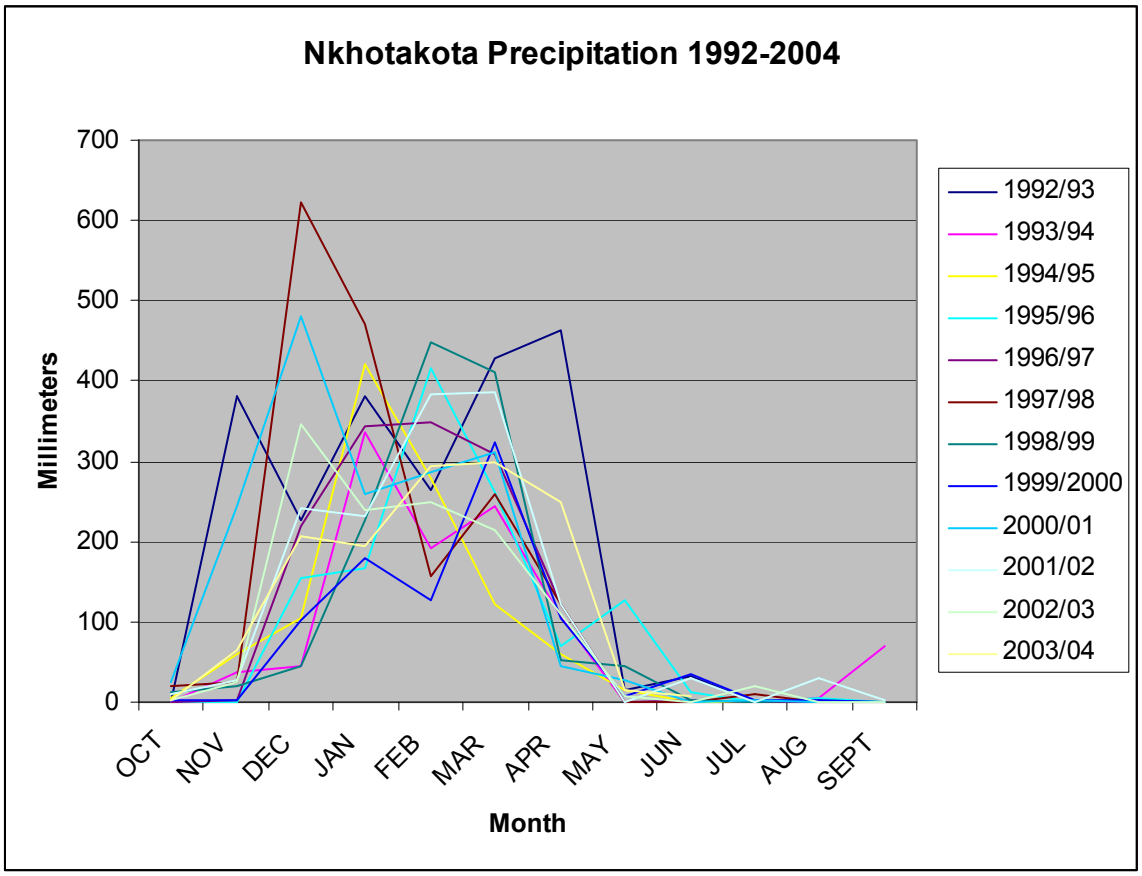
Nkhotakota District lies in the African Rift Valley on Lake Malawi, and is thus subject to extreme heat and humidity. Temperatures for the past twelve years have remained consistent with a minimum of 20 and a maximum of 29 degrees Celsius. The hottest

season of the year occurs from October through December; the highest recorded temperature in Nkhotakota District is 35 degrees Celsius in November of 1996.

Nkhotakota District also experiences "strong Southeasterly winds," or Mwera, between May and September. The occurrence of "gusty stormy winds" coincides with the hottest months of the year, October and November.

In addition to wind and heat, November also marks the start of the rainy season in Nkhotakota District. According to precipitation data from 1992 to 2004, rains can peak any time from December to April, subsiding substantially in May. The chart below describes the precipitation patterns in Nkhotakota District from 1992 to 2004.

Figure 5. Nkhotakota Precipitation 1992-2004



Source: DSOER 2005

The major rivers in Nkhotakota include Bua, Dwangwa, Chirua, Kaombe, Lifuliza, and Dwambadzi. River flow is often erratic as a result of environmental degradation on river banks and erratic rainfall patterns. Flooding is common during the rainy season, which results in loss of human lives, livestock, crops, and other property. Surface runoff

substantially increased in each major river catchment from 1991 to 1999, as can be seen in the table below. This surface runoff has exacerbated fluctuations in river discharges and flood events in Nkhotakota District, and can be attributed to deforestation and marginal land cultivation.

Table 16. Annual Surface Runoff from 1991-1999 (millimeters/catchment)

River	1991	1992	1993	1994	1995	1996	1997	1998	1999
Bua	15.581	30.692	96.366	56.122	14.442	40.763	77.415	74.831	125.988
Dwangwa	53.663	66.612	101.995	52.421	75.621	63.973	62.638	85.851	329.027
Chirua	195.220	81.134	104.347	22.959	27.523	32.087	82.568	295.972	329.027
Kaombe	83.643	54.407	189.708	20.878	7.340	53.378	19.666	70.321	35.748
Lifuliza	175.304	86.780	111.265	85.198	62.609	163.317	120.007	266.552	291.098
Dwambadzi	285.781	240.948	507.588	355.116	1121.078	450.885	297.271	605.937	443.670

Increased surface runoff in Nkhotakota district will reduce aquifer recharging and, ultimately, water table depth. In 2002 and 2003 the Nkhotakota District Water Office measured borehole depth in Traditional Areas within the District to determine the depth at which bore holes can function. Results from this activity are described in the table below.

Table 17. Comparative Bore Hole Depth in Traditional Areas (in meters)

Year	Malengachanzi	Mphonde	Kanyenda	Kafuzira	Mwadzama	Mwansambo
2002	49	35	49	49	42	42
	-	38	52	61	49	43
		54	61			46
2003	43		39	42	36	
	29		41	44		
			31			35

Source: District water office 2004/DSOER

According to the 2005 DSOER:

Although the district is lying along the lakeshore with most of the land having a relatively flat gradient water collection points are deeper. The western side have highlands and abundance of rainfall whose most of the waters end up in runoff and low water seepage to recharge the aquifers. The highly affected areas are Kafuzira, Mwansambo and Kanyenda Traditional areas.

Illovo Sugar also takes groundwater measurements at Dwangwa Estate, which borders Lake Malawi. The average yearly water table depth on the estate is 100.4 centimeters, and has ranged from 53.2 to 121.2 centimeters at different wells in the estate from 2004 to 2007.

I. The availability and effectiveness of other pesticides or non-chemical control methods

Other classes of chemicals apart from pyrethroids may be effective on the typical wall surfaces found in households in Nkhotakota District; however, because this is a pilot program, pyrethroids are the safest class of insecticides available for use, pyrethroids have already been used in IRS in Malawi, and because the vectors are still susceptible to pyrethroids, pyrethroids are the preferred class of insecticides for the pilot IRS program. Environmental management may be difficult to implement in Nkhotakota District due to its adjacency to Lake Malawi; however, during the course of the IRS pilot program, the potential to utilize environmental management and larviciding should be investigated, and ITNs/LLINs are currently being distributed in Nkhotakota District.

J. The requesting country's ability to regulate or control the distribution, storage, use and disposal of the requested pesticide

All facilities used for storage, distribution and transportation of insecticide products should comply with relevant requirements of the Occupational Safety, Health and Welfare Act, Pesticides Act, and relevant Malawi standards on pesticides. To that end, the following sections and the EMP describe the program requirements for storage, distribution and transportation.

Supply Chain and Disposal Options

Malawi has substantial ability to control the distribution, storage and use, but not disposal of, pyrethroids. The supply chain of insecticide will be as follows:

Manufacturer (Pesticide)
▼
Customs (Pesticide)
▼

Distributor Storage (Pesticide)

▼

District Storage (Storekeeper and Supervisor) (Pesticide) ► At the end of the spray round, unused pesticide will be provided to Illovo Sugar for storage and subsequent IRS rounds on Dwangwa Estate.

▼

Spray Operators (spray operators must sign out all pesticide received daily and return empty sachets at the end of the day, see *Distribution*)

▼

District Storage (empties)

▼

There are two options once the empty sachets are returned to the district storage facility. First, the empty sachets may be returned to the manufacturer for disposal. This proposal will be included in tender documents. If manufacturer recapture is not feasible, then USAID will be obligated to store the empty sachets in sealed drums until such time that the Pesticides Control Board can arrange for proper incineration along with obsolete pesticide stocks. Burning or burial of empty sachets are not an acceptable form of disposal according to the Malawi Pesticides Control Board.

Distribution

Currently there are no courses provided to drivers on insecticide transport on a regular basis. Drivers transporting insecticide will be trained according to the guidelines listed in *Pesticide Procedures E* of this document and USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment*, through the auspices of the distributor or Croplife.

Distribution of insecticide sachets within the program must be conducted in the following manner:

- At reception at provincial warehouse lot numbers of insecticide and quantities are registered on shelf inventory card.
- District requisitions are approved at the program (provincial) office where copies are maintained.
- Requisition goes to provincial warehouse where distribution takes place and signed for, based on sachet numbers.
- On reception at district office, all sachets are counted and stamped with the relevant district stamp and registered on stock card.
- 5-6 can refills/day are issued to each spray operator, with their code written on the sachet. Eg M= Matutuine, 49 = no. spray operator João. On the can refills issued to João are written M49. *These sachets are signed for*.
- At the end of the day, empty and full sachets are returned and number checked against what was signed for.

- The next day all previously signed but unused sachets are re-issued and *again signed for by the relevant spray operator*.
- Spray operator performance, number of structures sprayed versus can refills used is calculated to see if there is an over or under application.
- At the end of the spray round, stock remaining = stock at start - no of sachets distributed. No. sachets distributed should be equal to no. can refills used.

Storage

Once the insecticide enters the country, it must first be stored at the distributorship. RTI inspected the storage facilities at two distributorships: (1) Farmers Organization and (2) Chemicals and Marketing Company, Limited. The Farmers Organization representative stated that it can store 30,000 to 100,000 kilograms of lambda-cyhalothrin wettable powder formulation in its warehouses, two of which are located in Blantyre and one of which is located in Lilongwe. The storage facility RTI visited was located in Blantyre; although the space itself was fairly secure and stock quantities well-recorded, it was evident that there was a major warehouse capacity problem. Boxes inside the warehouse were stacked dangerously high, and quantities of pesticide (e.g. paraquat and empty methyl bromide tanks) were even stored outside under the warehouse awning. The interior of the facility required better ventilation. Emergency equipment and some personal protective equipment was not readily available. Food and drink were being eaten inside the warehouse, and the warehouse temperature was not recorded. Sumps are installed in the facility and direct any spillage out into the general environment; this scenario is not ideal, but typical for the developing country situation.

Chemicals and Marketing Company, Limited's storage facility fared better than the facility inspected at Farmers Organization. Fire extinguishers were readily available at several points on the interior and exterior of the facility, and an emergency water supply is readily available through a hose. Pesticide containers were stacked at reasonable heights and on pallets. Fire-fighting and clean-up instructions were posted, as well as signs and symptoms of poisoning and first-aid procedures. However, water from re-packing was on the floor. Bunds should be installed to keep spills (liquid and solid) in their respective repacking/reformulating or storage areas. Like Farmers Organization, sumps are installed in the facility and direct any spillage out into the general environment. Overall, Chemicals and Marketing Company's pesticide warehouse was better managed than that of Farmers Organization. If feasible, insecticide procurements for this round of IRS should be distributed through Chemicals and Marketing Company.

After initial importation, the insecticide must be distributed to temporary storage facilities in Nkhotakota district. Three temporary facilities will be used: one owned by Illovo Sugar (Dwangwa Estate) and two additional temporary storage facilities at Dwambazi Trading centre and at Dwangwa Trading centre near Nkhunga Health Centre for the IRS campaign. Storing pesticides closer to where they will be used will improve efficiency of operation and minimize logistical problems. During research for this report, the team

inspected Illovo Sugar's Dwangwa Estate pesticide storage facility. The store was generally well managed, and the facility included a fire extinguisher, designated places for different commodities, and a separate equipment store, workshop and office. For the benefit of the Dwangwa Estate, Research Triangle Institute, International (RTI) proposes some best practices to improve the storage facility. These include:

- Expand facility to accommodate maximum capacity expected for all pesticide commodities
- Install bottom vents for better ventilation
- Install wire mesh on vents to prevent vermin from entering
- Construct a sump and bunds
- Install exhaust system to remove dust and ash emitted from the plant
- Place insecticide on pallets in case of flooding or spillage
- Keep floor free of dust and dirt
- Record temperature—storage facility temperature should be less than 40 degrees Celsius.

The Dwangwa Estate warehouse as well as the two additional temporary storage facilities must follow the minimum standards:

- Presence of a dedicated and trained storekeeper
- Thermometer installed/temperature recorded
- Insecticide stored separately from food and medicine
- Stock records up-to-date
- First-in, first-out pesticide use established
- Facility double-padlocked and guarded
- Soap and clean water available at all times
- Shower/bathing facilities available for spray operators (designated wash basins at a minimum)

USAID will fund the renovation of storage facilities, training of storekeepers to fulfill not only the minimum standards listed above, but best practices, as well as the commodities required for safety and security required in the facilities (see Appendix 2: EC Budget Items and Procurement List).

Rinse-Water Re-Use and Wash-Water Disposal

Water used to rinse out sprayers at the end of each day must be re-used at the beginning of the next day's work to save water and reduce the potential for pollution from contaminated rinse-water. The best practice for rinse-water re-use is called "progressive rinse." With this rinse method, seven barrels/drums/containers of approximately 200-litres each are placed in a line. Every other container is filled with water (e.g. the first

container is empty, the second is filled with water, the third is empty, and so on; the seventh container is empty).

During the end-of-day cleanup, the remnants of a pump charge from the field are emptied into the first container. This will be a limited volume, which should be much less than half of this container, as most sprayers will be returned empty from the field (the uncommon situations where more insecticide returns is where the distance to the new site makes it difficult for the team to reach to empty their sprayers. Even then, the amount coming back will be less than a full drum, or 220 liters). The spray operator will then fill the sprayer less than half-full with a cup of water from the second container, close and shake the sprayer, and dump the sprayer water in the third container. The spray operator will repeat those steps with the fourth and fifth containers, then with the sixth and seventh containers, making sure to rinse the outside of the sprayer only at the sixth container (although not *in* the sixth container).

The following day, spray pumps are filled with liquid from containers in the same sequential order: container one, then container three, then container five. Any remaining liquid in the fifth and seventh containers are quite dilute and can be disposed in (a) an evaporation tank (b) an ablution block, or (c) a soak pit.

(a) Evaporation Tank. An impervious evaporation tank is repaired or constructed and covered by a locked grate. This can allow the insecticide to settle out and the water to evaporate. This disposal method works well if the tank has the appropriate capacity and if the rains do not cause it to overflow. See the figure below.

Figure 3. Evaporation Tank in Zambia

(b) Ablution Block. Repair or construction of an impervious ablution block that drains to a pit latrine. Although pouring the water directly into a pit latrine can work, this process makes it a little easier and lessens the risk of spillage and human exposure.

(c) Soak Pit. The site for the soak pit may be selected by the environmental authority (soak pits are usually sited at the highest point at the IRS depot/storage site and away from the natural path of run-off water). Depending on the size of the operation, you can construct a small or large pit. Usually an area of three meters by three meters (or nine square meters) is excavated to a depth of one meter. The bottom of the pit is packed with hard coal or charcoal. This is followed by saw dust (where this is feasible) and stone aggregates. The area is then fenced off to keep domestic animals and children out of the

soak pit area. Because there is no loose soil, it serves as a nice area where washing of overalls can be done. The soak pit is also good for drying overalls, laying them either on top of the stones or over the fencing. The figure below shows a soak pit with partially-constructed fencing (the bottom piece of mesh was still being fitted for attachment in this picture).

Figure 4. Soak Pit Surrounded by Wooden and Mesh Fencing.

K. The provisions made for training of users and applicators

Provisions made for training of users and applicators are described under *Pesticide Procedures D*. Training for spray operators and supervisors will be conducted over a 7 to 14 day period. Training will be conducted according to the WHO's "Manual for Indoor Residual Spraying" (WHO 2002).

L. The provisions made for monitoring the use and effectiveness of the pesticide

Monitoring Use

Monitoring appropriate use of the insecticide will be carried out in multiple ways. First, RTI will provide training to district environmental officials or other select authorities such that they are capable of evaluating the quality of spraying activities and associated environmental compliance actions within the program. RTI will work with USAID to determine appropriate reporting mechanisms for these managers. RTI itself will also conduct an inspection to assess compliance with this Environmental Management Plan

and develop a plan of action to achieve complete compliance if deficiencies are found. RTI is already conducting inspections in IRS programs in Zambia, Uganda, Zanzibar, Angola and Senegal. Beyond the capacity building for environmental managers and the RTI inspection, the Chief of Party and other program staff will be responsible for documenting and reporting safety and environmental compliance issues to RTI to acquire technical assistance as needed and address compliance issues in a timely fashion. The objective of these activities is not only to ensure environmental compliance in the short term, but also to integrate safety and environmental standards into the program such that those standards carry forward beyond the timeframe for USAID support of IRS.

Results of environmental compliance monitoring and subsequent mitigation activities from these three sources—district environmental managers, RTI environmental compliance staff, and Malawi program staff—will be summarized in each final project report submitted to USAID. Finally, USAID's Automated Directives System (ADS) 204.5.4 requires that the Strategic Objective (SO) team actively monitor ongoing activities for compliance with the recommendations in this PERSUAP, and modify or end activities that are not in compliance.

Monitoring Effectiveness

The primary function of entomological monitoring associated with vector management is to assure that interventions are effective. Such monitoring is essential for IRS as well as in areas where only ITNs have been deployed. The monitoring program for Malawi will include the following elements:

Determine vector susceptibility to available insecticides. Susceptibility studies detect the presence of individuals in the vector population that are physiologically resistant to the insecticide being tested. For adulticides used in both IRS and on ITNs, susceptibility studies can be carried out using WHO test strips or CDC bottle assays on wild-caught adults or adults reared from immatures. While the CDC bottle assays have the advantage of testing a sample of the same chemical batch being applied, the WHO test strips enable more comparability across countries and time. Furthermore, WHO susceptibility kits have been used in the past by the Malawi NMCP and will be used as part of a nationwide monitoring program funded through the IVCC so Malawi should continue to rely primarily on the WHO susceptibility kits. However, where possible, both should be done as the bottle bioassay tends to be more sensitive to small changes in insecticide susceptibility. In addition to the above "in vivo" resistance information, it is also possible to collect large numbers of the vector species for analysis by polymerase chain reaction (PCR) to determine the frequency of genetic markers coding for pesticide resistance in the local vector population.

Verify that the insecticide was applied properly and had an immediate effect. This involves routine follow-up observations. For IRS, wall bioassays are used to verify there is sufficient residual pesticide on the walls of sampled structures to kill vector mosquitoes, and to monitor the loss of residual efficacy over time. An analogous assay

may be done for ITNs, either with the same type of cone used on the wall, or by forming a "basket" with the treated netting. For houses with mud walls that are sprayed under the IRS program, small punches can be made into the wall and tested for insecticide levels using High Performance Liquid Chromatography (HPLC).

Measure the impact of the intervention on the vector population and/or malaria transmission intensity. Several different techniques are used to monitor the vector population and/or the frequency and infectivity of vector biting. In general, the intention is to determine whether the vector management program has substantially reduced the vector population or survivorship, as indicated either by a reduction in the number of mosquitoes that can be collected, a reduction in mosquito biting, or, as detected through mosquito dissections, the proportion parous (the proportion that have laid at least one batch of eggs). Methods to be used in Malawi will include window exit traps and pyrethrum spray catches (PSCs).

OTHER SECTIONS

The following sections are typically included in a USAID EA, but are not applicable in this circumstance:

- Relationship between short-term uses of the environment and maintenance/enhancement of long-term productivity

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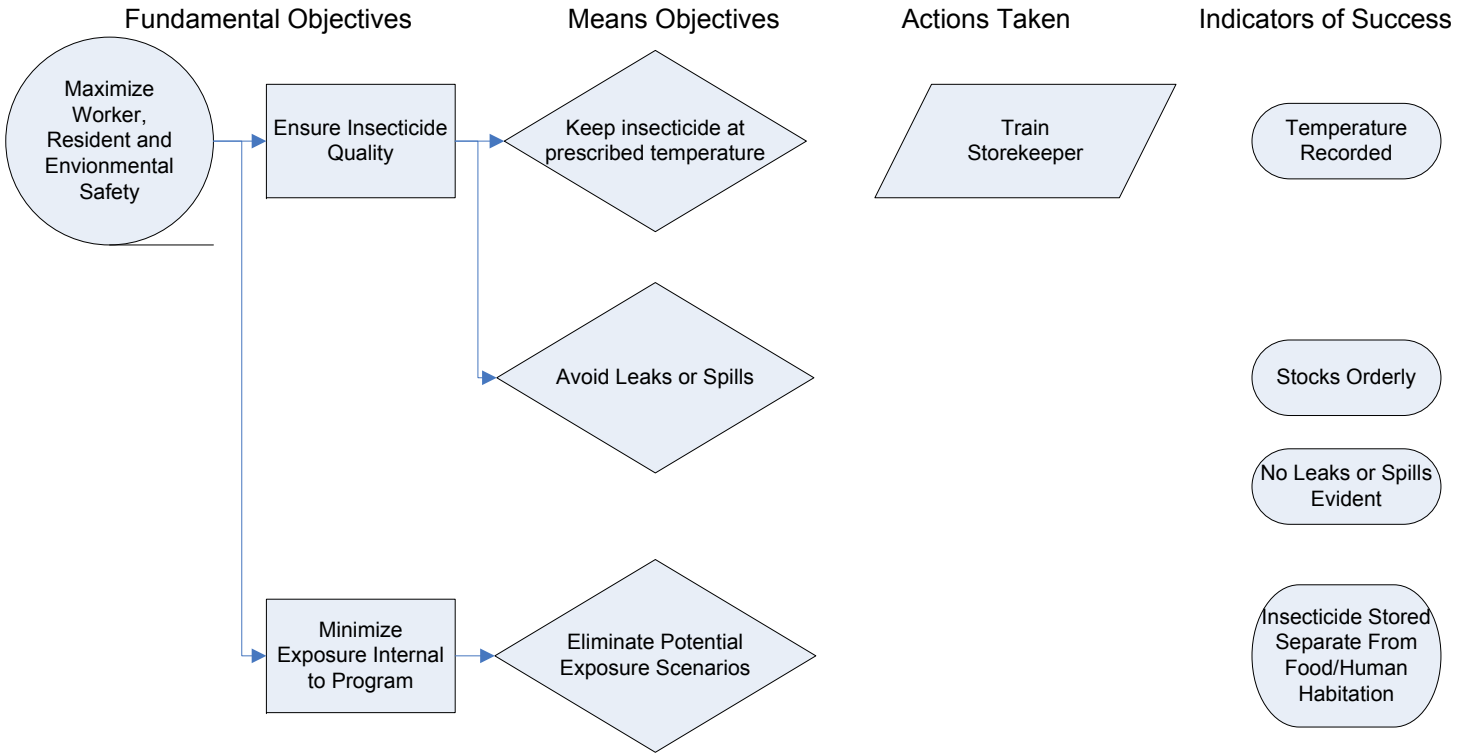
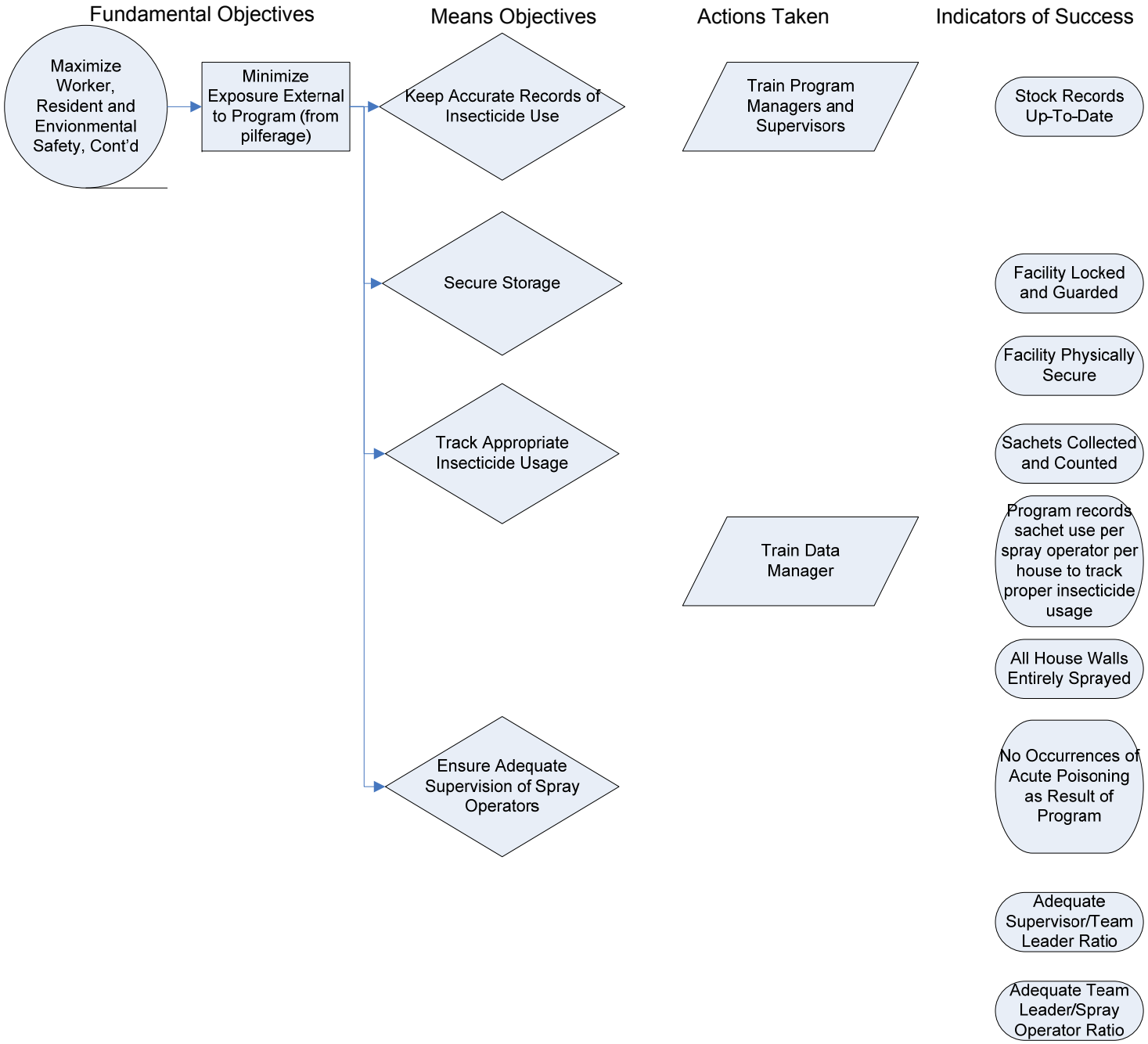
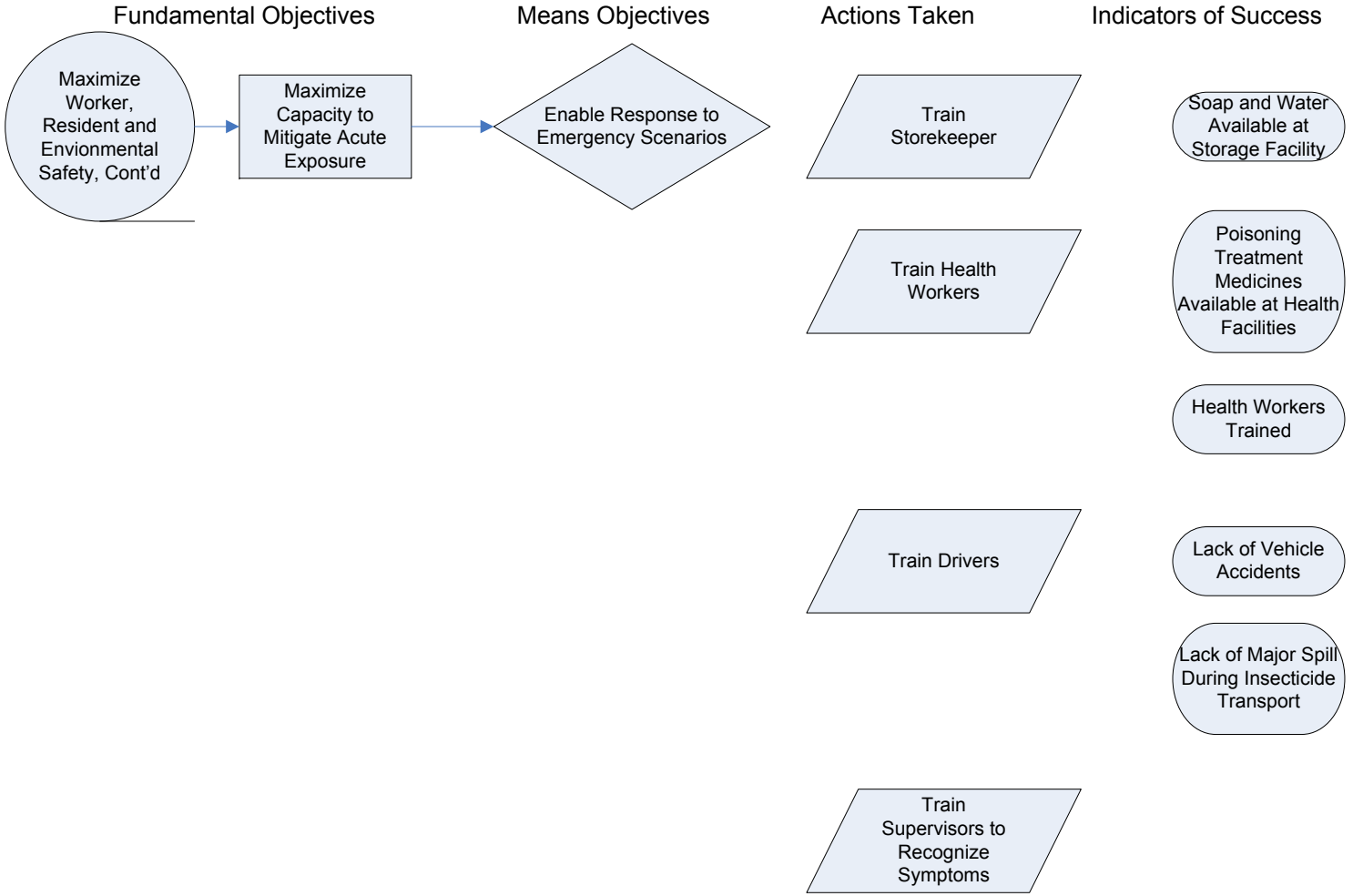
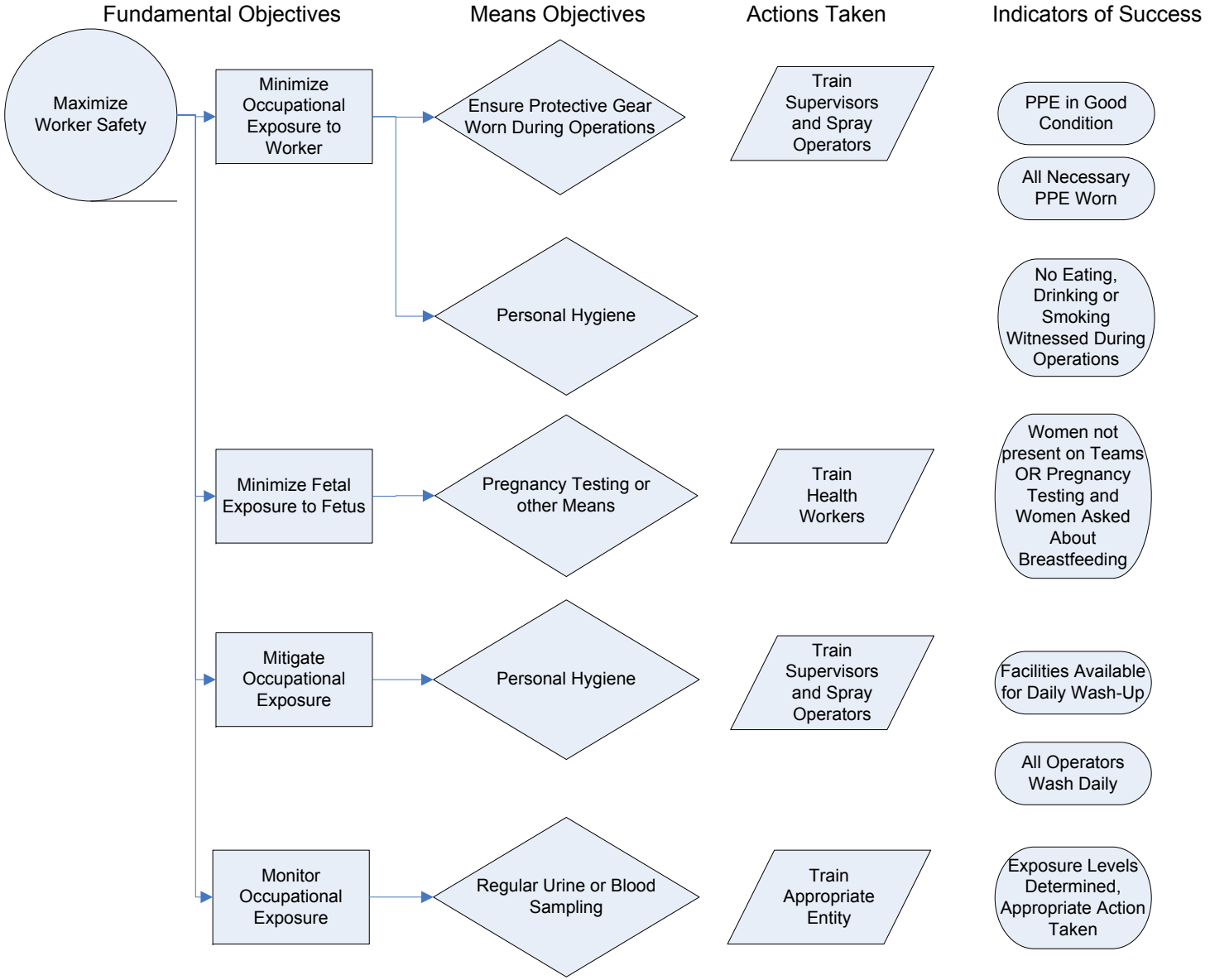
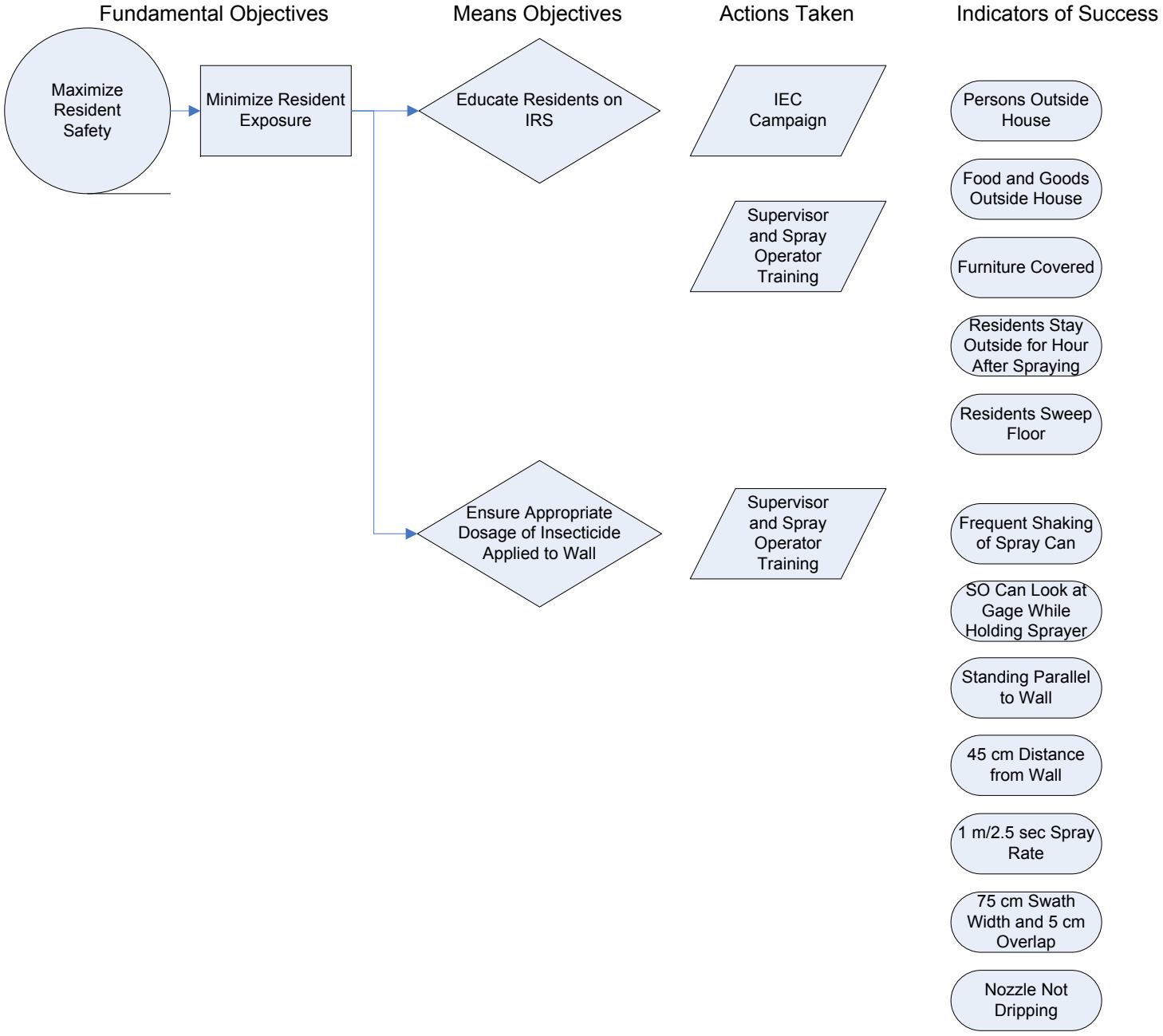
APPENDIX 1 : Minimum Environmental Compliance Requirements for IRS Programs

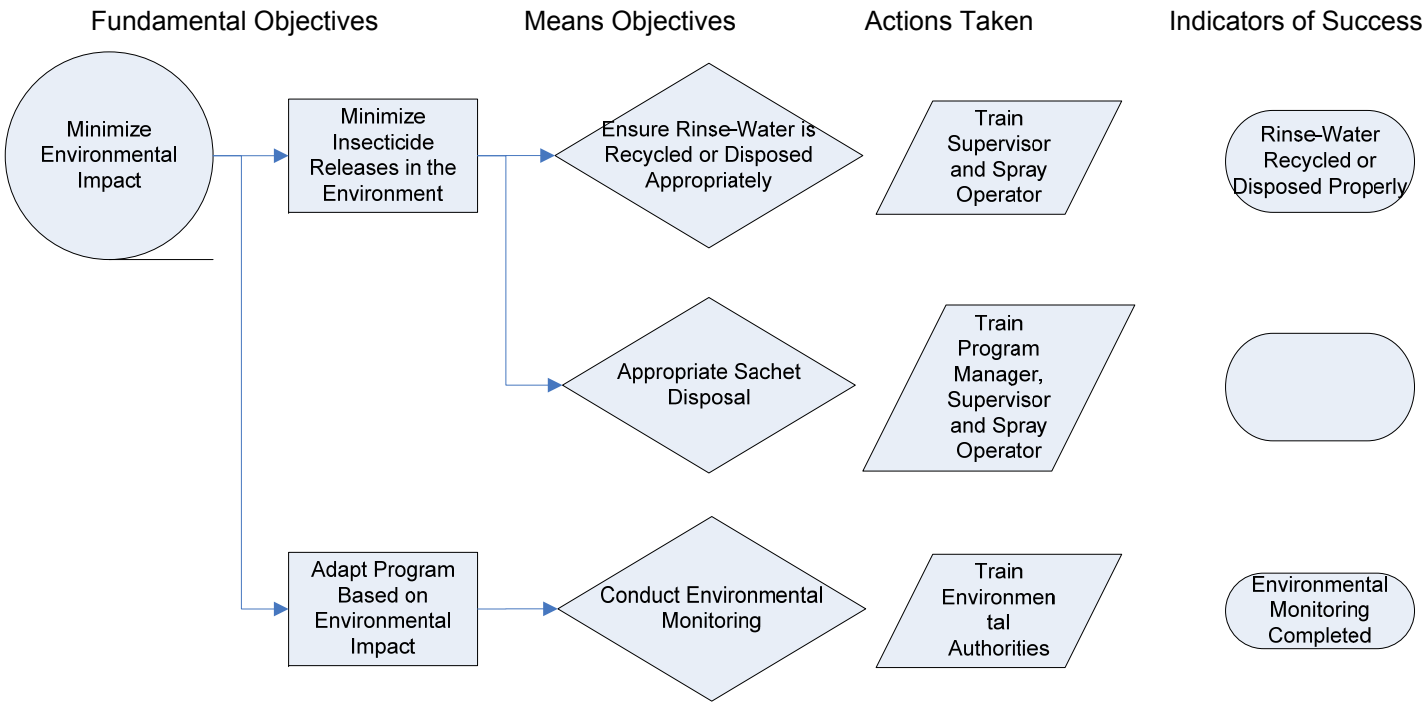



Fundamental Objectives
Means Objectives
Actions Taken
Indicators of Success
Maximize Worker, Resident and Envionmental Safety, Cont'd
Minimize Exposure External to Program (from pilferage)
Keep Accurate Records of Insecticide Use
Secure Storage
Track Appropriate Insecticide Usage
Ensure Adequate Supervision of Spray Operators
Train Program Managers and Supervisors
Train Data Manager
Stock Records Up-To-Date
Facility Locked and Guarded
Facility Physically Secure
Sachets Collected and Counted
Program records sachet use per spray operator per house to track proper insecticide usage
All House Walls Entirely Sprayed
No Occurrences of Acute Poisoning as Result of Program
Adequate Supervisor/Team Leader Ratio
Adequate Team Leader/Spray Operator Ratio


Fundamental Objectives
Means Objectives
Actions Taken
Indicators of Success
Maximize Worker, Resident and Envionmental Safety, Cont'd
Maximize Capacity to Mitigate Acute Exposure
Enable Response to Emergency Scenarios
Train Storekeeper
Train Health Workers
Train Drivers
Train Supervisors to Recognize Symptoms
Soap and Water Available at Storage Facility
Poisoning Treatment Medicines Available at Health Facilities
Health Workers Trained
Lack of Vehicle Accidents
Lack of Major Spill During Insecticide Transport


Fundamental Objectives
Means Objectives
Actions Taken
Indicators of Success
Maximize Worker Safety
Minimize Occupational Exposure to Worker
Ensure Protective Gear Worn During Operations
Train Supervisors and Spray Operators
PPE in Good Condition
All Necessary PPE Worn
Personal Hygiene
No Eating, Drinking or Smoking Witnessed During Operations
Minimize Fetal Exposure to Fetus
Pregnancy Testing or other Means
Train Health Workers
Women not present on Teams OR Pregnancy Testing and Women Asked About Breastfeeding
Mitigate Occupational Exposure
Personal Hygiene
Train Supervisors and Spray Operators
Facilities Available for Daily Wash-Up
All Operators Wash Daily
Monitor Occupational Exposure
Regular Urine or Blood Sampling
Train Appropriate Entity
Exposure Levels Determined, Appropriate Action Taken
Not necessary for pyrethroids


Fundamental Objectives
Means Objectives
Actions Taken
Indicators of Success
Maximize Resident Safety
Minimize Resident Exposure
Educate Residents on IRS
Ensure Appropriate Dosage of Insecticide Applied to Wall
IEC Campaign
Supervisor and Spray Operator Training
Supervisor and Spray Operator Training
Persons Outside House
Food and Goods Outside House
Furniture Covered
Residents Stay Outside for Hour After Spraying
Residents Sweep Floor
Frequent Shaking of Spray Can
SO Can Look at Gage While Holding Sprayer
Standing Parallel to Wall
45 cm Distance from Wall
1 m/2.5 sec Spray Rate
75 cm Swath Width and 5 cm Overlap
Nozzle Not Dripping



To be determined on case-by-case basis

Not applicable for Malawi; generally reserved for DDT use

APPENDIX 2 : EC Budget Items and Procurement List

Storage
Training for storekeepers
Physical Maintenance
- Materials/labor for store-house renovation
- Locks and keys for storage facilities
- Pallets for stacking insecticide and other equipment
- Construction of securable boxes for pesticide if storehouses cannot be properly secured

Emergency Kit
- 2 bags sawdust/sand
- Empty container to contain spillage residues
- Spade
- Brush
- Fire extinguisher

Health Kit
- Container of water or tap (inside)
- Bar of soap
- Eyewash set— *Ensure instructions are in host country language*
- Medical/first-aid kit— *Ensure instructions are in host country language*

Stock Management Kit
- Stock-book
- Bin cards
- Thermometer
- Pens

Storekeeper PPE
- Nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm
- Rubber boots
- Overalls
- Goggles/face-shield
- Vapor masks for half-face respirators with organic vapor cartridges

Health Centers (should be provided by MOH if possible)
Health Worker training in pesticide poisoning
Poisoning treatment meds—*Ensure instructions are in host country language*
Pregnancy test kits — *Ensure instructions are in host country language*

Transport
Training for drivers (see your SEA or PEA for guidance)
For vehicle washing, nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm

Washing
For each central meeting area for spray teams (usually storage facilities, either temporary or permanent):

- Basins for face and hand washing *or* materials to construct temporary bathing facilities *or* materials to renovate existing facilities to accommodate the size and number of spray teams meeting for daily clean-up
- Basins for washing overalls *separate from basins for face/hand washing*
- Materials for wash area demarcation (hard coal/charcoal, saw dust, stone aggregates/gravel, fencing and wire mesh), *or* budget for construction/renovation of ablution block, *or* budget for construction/renovation of evaporation tank with locked grate
- 7 barrels/drums for progressive rinse (this is enough to triple-rinse)—often it is helpful if they are wide enough or deep enough to submerge the entire spray can
- 3 plastic cups to pour rinse-water into spray can
- Detergent for washing overalls
- For each Wash Person, PPE:
    - Chemical apron
    - Nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm
    - Rubber boots
    - Goggles
    - Dust mask

Operations
For each Spray Operator, PPE:

- Broad-rimmed hat/helmet
- Face shield or goggles (face shield preferable)
- Dust mask or filtered mask
- 2 or 3 cotton overalls/spray operator
- Nitrile rubber, neoprene, PVC or butyl rubber gloves, without inside lining, long enough to cover forearm
- Rubber boots (in appropriate sizes that don't cause blisters; keep in mind in several countries the spray teams are composed of 50% women, so smaller boot sizes may be warranted; other shoes/boots will absorb the chemical and is not safe)
- Extra PPE in the event gloves get torn, face shields break, dust masks get contaminated (all this *will* happen)

For each Spray Operator, additional field equipment:

- 1 drop-cloth (can be a bed sheet or something similar) to cover household furniture
- Plastic cover, small handbag or something to prevent spray card from being impregnated with insecticide in the field

Non EC-Related Procurement Suggestions
Funnel with strainer (to easily rid debris out of water used in pump charge) for each spray operator

Identification Cards including name and picture for all program staff (including supervisors, team leaders and spray operators)

APPENDIX 3 : Malawian Pesticides Control Board Functions (from Malawi Pesticides Act, No. 12 of 2000)

11.—(1) The Board shall be responsible for the registration, control and management of all pesticides in Malawi and perform such other functions as assigned to it under this Act.

(2) Without prejudice to the generality of subsection (1), the Board—

(a) shall register pesticides and issue certificates and permits in accordance with this Act ;
(b) shall monitor and control the import, export, manufacture, distribution, sale, storage, use and disposal of pesticides in Malawi ;
(c) may issue guidelines on the environmentally sound handling and use of pesticides after consultation with such persons or bodies as seem to the Board to be broadly representative of the interests concerned ;
(d) may, in consultation with the relevant authorities, conduct public educational campaigns on the safe handling and use of pesticides ;
(e) may advise the Minister on whether or not the Minister should use the power granted under section 23 (3) to exempt a pesticide or class of pesticides from the licensing requirements under the Act, taking into consideration the potential implication for human and animal health and the environment ;
(f) may advise the Minister in connection with all matters relating to pesticides and the performance of functions assigned to the Minister under this Act ;
(g) may propose regulations to be made under this Act by the Minister ; and
(h) may, subject to the approval of the Minister, delegate any of its powers to any government officer.

APPENDIX 4 : Toxicological Profile for Alpha-Cypermethrin (from USAID PEA for IVM)

CAS Registry Number 67375-30-8

Summary of Insecticide

Chemical History

Alpha-cypermethrin is a highly active synthetic pyrethroid insecticide used to control a wide variety of pests in agricultural and public health applications. It is similar to the natural insecticide pyrethrum, which comes from chrysanthemums; however, it is more effective and longer lasting (ATSDR, 2003; IPCS, 1992). Alpha-cypermethrin is available in technical grade formulation, emulsifiable concentrate, ultra-low-volume formulation, suspension concentrate, and in mixtures with other insecticides (HSDB, 2005; IPCS, 1992). For mosquito control, it is used in bed nets and other materials that are dipped in alpha-cypermethrin to protect the user (WHO, 1997, 1998). It is considered one of the best insecticides for impregnation of traps and screens (WHO, 1997). Alpha-cypermethrin is not currently registered for use in the United States (HSDB, 2005), but cypermethrin is.

Alpha-cypermethrin is of low risk to humans when used at levels recommended for its designed purpose (ATSDR, 2003; HSDB, 2005). However, as a synthetic pyrethroid, alpha-cypermethrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the sodium channels of nerve cells (ATSDR, 2003; HSDB, 2005). It has moderate acute toxicity and is a suspected endocrine disruptor but does not inhibit cholinesterase (PAN, 2005). EPA has not classified synthetic pyrethroids, including alpha-cypermethrin, as endocrine disruptors. Typical symptoms of acute exposure are irritation of skin and eyes, headaches, dizziness, nausea, vomiting, diarrhea, and excessive salivation and fatigue. Inhaled alpha-cypermethrin has been shown to cause cutaneous paraesthesia or a burning, tingling, or stinging of the skin. However, these effects are generally reversible and disappear within a day of removal from exposure (ATSDR, 2003; HSDB, 2005; PAN, 2005). Alpha-cypermethrin is harmful if swallowed (MSDS, n.d.). Inhalation and dermal exposure are the most likely human exposure routes (HSDB, 2005). Environmental levels of significance are unlikely if alpha-cypermethrin is applied at recommended rates (IPCS, 1992).

Description of Data Quality and Quantity

Comprehensive reviews on the toxicity of alpha-cypermethrin are not widely available but include the following:

- Toxicological Profile for Pyrethrin and Pyrethroids (ATSDR, 2003)
- Environmental Health Criteria 142: Alpha- Cypermethrin (IPCS, 1992)

EPA and ATSDR have developed quantitative oral human health benchmarks (EPA's chronic RfD and ATSDR's acute oral MRL) for cypermethrin. Alpha-cypermethrin

makes up one quarter of the racemic mixture cypermethrin and has a similar mode of action. Alpha-cypermethrin is also similar to cypermethrin with regard to the signs of intoxication, target organs effects, and metabolic pathways (IPCS, 1992).

Summary Table

• Duration	• Route	• Benchmark Value	• Units	• Endpoint	• Reference
Acute, Intermediate, Chronic	**Inhalation**	**4**	**mg/kg/day**	**Inhalation NOAEL in rats with UF of 100 applied**	
Acute	**Oral**	**0.02**	**mg/kg/day**	**Acute oral MRL for cypermethrin based on neurological effects in rats with UF of 1000 applied**	**ATSDR (2003)**
Intermediate	**Oral**	**0.01**	**mg/kg/day**	**Adopt chronic RfD as intermediate duration**	
Chronic	**Oral**	**0.01**	**mg/kg/day**	**Chronic oral RfD for cypermethrin based on neurological effects in dogs with UF of 100 applied**	**U.S. EPA (2005)**
Acute, Intermediate, Chronic	**Dermal**	**5**	**mg/kg/day**	**Dermal NOAEL in rats with UF of 100 applied**	

For inhalation exposure, a NOAEL of 400 mg/m^3 (447 mg/kg/day)[1] was identified for neurological and respiratory effects in rats exposed to alpha-cypermethrin via inhalation for 4 hours (IPCS, 1992). An uncertainty factor of 100 to account for intra- and interspecies variation was applied, for an inhalation benchmark of 4 mg/kg/day. This value is appropriate for all exposure durations.

Due to limited low-dose oral data for alpha-cypermethrin, health benchmarks for cypermethrin were used and are expected to be protective of human health. The acute oral MRL for cypermethrin of 0.02 mg/kg/day is based on a LOAEL of 20 mg/kg for neurological effects (altered gait and decreased motor activity) in rats with an uncertainty factor of 1,000 applied. Long-Evans rats were given single gavage doses of up to 120 mg/kg cypermethrin. Motor activity and FOB were assessed at 2 and 4 hours post-dosing. A NOAEL was not identified (ATSDR, 2003). The chronic oral RfD for cypermethrin of 0.01 mg/kg/day is based on a NOEL of 1 mg/kg/day for systemic effects with an

[1] *Conversion between mg/m^3 and mg/kg/day assumes, for Fischer-344 rats, an average body weight of 0.152 kg and inhalation rate of 0.17 m^3/day (U.S. EPA, 1988).*

uncertainty factor of 100 applied. Beagle dogs were dosed with up to 15 mg/kg/day cypermethrin in corn oil for 52 weeks. During the first week, increased vomiting was observed in dogs at all dose levels. Additionally, throughout the study all dogs passed liquid feces; however, the incidence was 10- and 30-fold higher in the 5 and 15 mg/kg/day groups, respectively. The NOEL identified for this study was 1 mg/kg/day (U.S. EPA, 2005).

For dermal exposure, a NOAEL of 500 mg/kg/day was identified in rats dermally exposed to alpha-cypermethrin once for 24 hours (IPCS, 1992). An uncertainty factor of 100 to account for intra- and interspecies variation was applied, for a dermal benchmark value of 5 mg/kg/day. This value is appropriate for all exposure durations.

Insecticide Background

CASRN:	67375-30-8
Synonyms:	alfamethrin, alphamethrin, alphacypermethrin, alpha-cypermethrin, alfa-cipermetrina, alfacypermetrin, alfa cipremetrin,[1alpha(S*),3alpha]-(+ -)-Cyano(3-phenoxyphenyl)methyl 3-(2,2-dichloroethenyl)- 2,2-dimethylcyclopropanecarboxylate, (1R cis S) and (1S cis R) Enantiomeric isomer pair of alpha-cyano-3-phenoxybenzyl-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylate, Pesticide Code 209600(S)-alpha-cyano-3-phenoxybenzyl-(1R)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate and (R)-alpha-cyano-3-phenoxybenzyl-(1S)-cis-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate, WL 85871, cyano(3-phenoxyphenyl)methyl 3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (+)-cis isomer, alphametrin, numerous other systematic and non-systematic names (HSDB, 2005; PAN 2005; ATSDR, 2003; MSDS, n.d.)
Chemical Group:	pyrethroid (PAN, 2005)
Registered Trade Names:	Bestox, Fastac, Concord, Dominex, Fendona, Fendona 1.5 SC, Fendona 10 SC, Fendonal WP, Renegade (HSDB, 2005, IPCS, 1992, WHO, 2002), Tenopa SC (alphacypermethrin + flufenoxuron) (HSDB, 2005; PAN 2005; ATSDR, 2003; MSDS, n.d.)

Usage

Alpha-cypermethrin is a pyrethroid insecticide used to combat a wide variety of chewing and sucking insects on field crops, fruits and vegetables, and in forestry uses. It may be applied to crops as either a curative or preventative treatment. Alpha-cypermethrin is also

used in public health applications to control mosquitoes, flies, and other pests. For animal husbandry it is used as an ectoparaciticide and to control flies (HSDB, 2005; IPCS, 1992). Alpha-cypermethrin belongs to the pyrethroid class of insecticides, which have long been used to control mosquitoes, human lice, beetles, and flies (ATSDR, 2003). For mosquito protection, it is used in bed nets and other materials that are dipped into the alpha-cypermethrin to protect the user. Alpha-cypermethrin has been available since 1983 (IPCS, 1992); however, it not currently registered for use in the United States (HSDB, 2005).

Formulations and Concentrations

Alpha-cypermethrin is available in technical grade, emulsifiable concentrates, wettable powder, suspension concentrates, ultra-low-volume liquids, tablets, and in mixtures with other insecticides (HSDB, 2005; IPCS, 1992). Technical grade alpha-cypermethrin is greater than 90 percent pure (HSDB, 2005). Common formulations of alpha-cypermethrin include Fastac, which is available as an emulsifiable concentrate (20–100 g/L), a wettable powder (50 g/kg), a suspension concentrate (15–250 g/L), and an ultra-low-volume liquid (6–15 g/L); and Fendona and Renegade, which are available as an emulsifiable concentrate (50 or 100 g/L), a suspension concentrate (250 g/L), and a wettable powder (50 g/kg). Alpha-cypermethrin is combined with other active ingredients to form other products (IPCS, 1992). WHO has indicated that the content of alpha-cypermethrin in the formulated products must be declared and shall not exceed the listed standards. Technical grade alpha-cypermethrin must have no less than 910 g/kg alphacypermethrin cis 2 ([IR cis] S and [IS cis] R isomers), and the combined content of the cis and trans isomers of alpha-cyano-3-phenoxybenzyl-2,2-dimethyl-3-(2,2-dichlorovinyl-) cyclopropanecarboxylate must be at least 975 g/kg. No more than 1 g/kg of volatile hydrocarbon solvent and 1 mg/kg of triethylamine is permitted. The aqueous suspension concentrate should contain alphacypermethrin cis 2 ([IR cis] S and [IS cis] R isomers) as follows: up to 25 g/kg, ± 15 percent of the declared content; 25 to 100 g/kg, ± 10 percent of the declared content. The alphacypermethrin cis 1:cis 2 isomer ratio must be lower than 5:95 (WHO, 1999).

Shelf Life

Alpha-cypermethrin is stable in acidic and neutral environments. However, it hydrolyzess at pH 12–13 and decomposes at temperatures greater than 220 °C. For practical purposes, field studies have indicated that it is stable to sunlight (IPCS, 1992). It is not compatible with strong oxidizing agents (MSDS, n.d.).

Degradation Products

Based on its structure, alpha-cypermethrin is expected to readily biodegrade in the environment. However, in two tests it did not degrade and therefore cannot be considered readily biodegradable. One of the major transformation products in the microbial

transformation of technical alpha-cypermethrin is 3-phenoxybenzoic acid, which is then transformed to 4-hydroxy-3-phenoxybenzoic acid (IPCS, 1992).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Based on its Koc value, alpha-cypermethrin binds tightly to soil, making it almost immobile in most soil types. In moist soil, volatilization is expected to be the major fate process; however its bond to soil lessens this effect. Volatilization is not a major fate process for dry soil. Biodegradation by environmental organisms in non-sterile soil and by sunlight is expected (HSDB, 2005; IPCS, 1992). Studies have shown that within 2 weeks of treatment with 0.5 kg ai/ha (active ingredient per hectare) of a diluted alpha-cypermethrin emulsifiable concentrate formulation in sandy-clay soil, residues of alpha-cypermethrin were 50 percent less. After 1 year, they were below detection or < 0.01 mg/kg. Similar results were seen after a second and third application to the site indicating that alpha-cypermethrin did not build up in the surface soil. Additionally, no leaching to subsurface soils was observed. Alpha-cypermethrin also does not build up in peat soils (IPCS, 1992).

Fate and Transport in Aquatic Systems

Alpha-cypermethrin binds tightly to suspended solids and sediments in water. It is expected to volatilize from water; however, volatilization is lessened by alpha-cypermethrin's bond with soil. Reported volatilization half-lives are 8 days for a river models and 65 days for a lake model. If adsorption is taken into consideration, the estimated volatilization half-life in a pond model is 125 years. Estimated hydrolysis half-lives are 36 and 4 years at pH 7 and 8 respectively. Alpha-cypermethrin is also expected to undergo photodecomposition. Based on its bioconcentration factor, alpha-cypermethrin has a high potential to bioconcentrate in aquatic organism; however, its potential may actually be lower than this suggests because of the ability of aquatic organisms to rapidly metabolize alpha-cypermethrin (HSDB, 2005).

Human Health Effects

Acute Exposure

Effects/Symptoms

Limited data exist on the acute toxicity of alpha-cypermethrin in humans (IPCS, 1992; HSDB, 2005). Occupationally exposed workers reported only mild skin irritation (IPCS, 1992). The main effects reported from acute exposure to alpha-cypermethrin in humans include skin rashes, eye irritation, itching and burning sensation on exposed skin, and paraesthesia (a result of the direct action of this type of pyrethroid on sensory nerve endings, causing repeated firings in these fibers). Acute inhalation exposures may cause upper and lower respiratory tract irritation. Ingestion of alpha-cypermethrin is also

harmful (HSDB, 2005; MSDS, n.d.). No acute poisonings have been reported (IPCS, 1992).

In rodents, alpha-cypermethrin has moderate to high oral toxicity (HSDB, 2005; IPCS, 1992). Oral LD_{50} values in rats and mice vary greatly and depend on the formulation, concentration, and the vehicle (IPCS, 1992). Acute oral LD_{50} values for technical alpha-cypermethrin range from 79 to 400 mg/kg (in corn oil) in rats (HSDB, 2005; IPCS, 1992; MSDS, n.d.). Although the LD_{50} of 80 mg/kg is considered representative, higher values have been reported. In mice, the reported acute oral LD_{50} of technical alpha-cypermethrin is 35 mg/kg (in corn oil). Oral LD_{50} values for formulated alpha-cypermethrin in rats range from 101 to 174 mg/kg for an emulsifiable concentrate formulation (100 g/L), while 1,804 mg/kg was reported for a suspension concentrate formulation (100 mg/L) and 5,838 mg/kg for an ultra-low-volume liquid formulation (15 g/L) (IPCS, 1992). Clinical signs reported in orally exposed animals are associated with central nervous system activity and included ataxia; gait abnormalities; choreoathetosis; "tip-toe" walk; and increased salivation, lacrimation, piloerection, tremor, and clonic convulsions. Acute dermal exposures are minimally irritating to the skin and eyes of rabbit skin. However, some formulations can cause severe eye irritation that includes corneal opacity and iris damage. Stimulation of the sensory-nerve endings of the skin has been observed in guinea pigs. Reported dermal LD_{50} values of greater than 2,000 mg tech/kg are reported for rats and rabbits (HSDB, 2005; IPCS, 1992). No mortality or signs of toxicity were observed in rats or mice after single dermal applications of up to 500 mg/kg or 4-hour inhalation exposure of mice to 400 mg/m^3. Alpha-cypermethrin is not a dermal sensitizer in guinea pigs (IPCS, 1992).

Treatment

Pyrethroid insecticides and their metabolites can be detected in blood and urine; however, the methods are not practical to use given how quickly these compounds are broken down in the body (ATSDR, 2003). Alpha-cypermethrin poisoning should be treated the same as a pyrethroid poisoning. There are no antidotes for alpha-cypermethrin exposure. Treatment is supportive and depends on the symptoms of the exposed person. Decontamination is all that is necessary for most exposures. If a person exhibits signs of typical pyrethroid toxicity following alpha-cypermethrin exposure (nausea, vomiting, shortness of breath, tremors, hypersensitivity, weakness, burning, or itching), they should immediately remove any contaminated clothing. Any liquid contaminant on the skin should be soaked up and the affected skin areas cleaned with alkaline soap and warm water. The application of topical vitamin E helps to relieve the symptoms of paraesthesia. Eye exposures should be treated by rinsing with copious amounts of saline or room temperature water for at least 15 minutes. Contact lenses should be removed. Medical attention should be sought if irritation, pain, swelling, lacrimation, or photophobia persists. The treatment of ingestion exposures is mostly symptomatic and supportive. Care should be taken to monitor for the development of hypersensitivity reactions with respiratory distress. Gastric decontamination is recommended if large amounts have been

very recently ingested, and oral administration of activated charcoal and cathartic are recommend for ingestion of small amounts or if treatment has been delayed. Vomiting should not be induced following ingestion exposures, but the mouth should be rinsed. The person should be kept calm and medical attention should be sought as quickly as possible. For inhalation exposures, removal to fresh air and monitoring for breathing difficulties, respiratory tract irritation, bronchitis, and pneumonitis are recommended. Oxygen should be administered as necessary (PAN, 2005; HSDB, 2005).

Chronic Exposure

Noncancer Endpoints

Little data are available for humans following chronic exposures to alpha-cypermethrin. Chronic exposure to pyrethrins may cause hypersensitivity pneumonitis characterized by chest pain, cough, dyspnea, and bronchospasm. Because alpha-cypermethrin belongs to this class of chemicals, similar effects may be expected (HSDB, 2005).

Chronic toxicity data are also lacking in animals. No animal data are available for long-term toxicity, reproductive toxicity, teratogenicity, or immunotoxicity (HSDB, 2005; IPCS, 1992). However, chronic toxicity data are available for cypermethrin, including rodent multigenerational reproduction, embryotoxicity, and teratogenicity studies. At doses that produced systemic toxicity, no effects on reproductive parameters or fetal development were observed. Therefore, it is likely that alpha-cypermethrin would also cause no reproductive or developmental effects in rodents because it is a component of cypermethrin. Available data do not indicate that alpha-cypermethrin is mutagenic (IPCS, 1992).

Cancer Endpoints

No data are available on the carcinogenic potential of alpha-cypermethrin (IPCS, 1992).

Toxicokinetics

Like other pyrethroid insecticides, orally administered alpha-cypermethrin, is absorbed via the intestinal tract of mammals, and dermally applied doses are absorbed through intact skin. Little or none is absorbed by inhalation exposures (HSDB, 2005). Most pyrethroids are rapidly broken down by liver enzymes and their metabolites are quickly excreted (HSDB, 2005). The metabolism of synthetic pyrethroids in mammals is generally through hydrolysis, oxidation, and conjugation. Metabolism of alpha-cypermethrin occurs by the cleavage of the ester bond. Studies in rats show that the phenoxybenzyl alcohol and cyclpropan carboxylic ac parts of the molecule are conjugated with sulfate and glucuronide, respectively, before being excreted in urine. Esteric hydrolysis and oxidative pathways occur in rats, rabbits, and humans with esteric hydrolysis being the predominant pathway in humans and rabbits (IPCS, 1992). Within 24 hours of an oral dose of 0.25–0.75 mg in humans, 43 percent was excreted in the urine as free of conjugated cis-cyclprpane carboxlic acid (HSDB, 2005; IPCS, 1992). Orally administered alpha-cypermethrin is eliminated in the urine of rats as the sulfate conjugate

of 3-(4-hydroxyphenoxy) benzoic acid. In the faces it is eliminated partly as unchanged compound. Alpha-cypermethrin levels in tissues are low except for fatty tissues. The reported half-life for elimination from fat is 2.5 days for the first phase of elimination and 17 to 26 days for the second phase (IPCS, 1992).

Ecological Effects

Acute Exposure

Toxicity in Non-Targeted Terrestrial Organisms

Alpha-cypermethrin, like other pyrethroids, is very unlikely to harm terrestrial organisms other than its targets (e.g., mosquitoes and other pests). No toxicity data are available for alpha-cypermethrin in birds. However, cypermethrin has a very low toxicity in birds with acute oral LD_{50} values of greater than 2,000 mg/kg body weight. In feed, the reported LC_{50} values are greater than 10,000 mg/kg diet (IPCS, 1992). As with other pyrethroid insecticides, alpha-cypermethrin is extremely toxic to honey bees. The reported 24-hour oral LD_{50} for alpha-cypermethrin emulsifiable concentrate is 0.13 µg/bee and the 24-hour oral LD_{50} for alpha-cypermethrin in acetone was 0.06 µg/bee. The reported dermal LD_{50}s are 0.03 µg/bee for technical alpha-cypermethrin and 0.11 µg/bee for emulsifiable concentrate (IPCS, 1992). The very high toxicity in bees was not observed in the field, likely as a result of the repellent effect of alpha-cypermethrin, which would limit exposure (IPCS, 1992; HSDB, 2005). Mortality was seen in only 15 percent of honey bees exposed to flowers treated with an emulsifiable concentrate formulation within 48 hours. Other studies using oil-enhanced suspension concentrate formulations showed similarly low toxicity. Additionally, a similar pattern of toxicity was seen in leaf-cutting bees. The toxicity of alpha-cypermethrin to earthworms, Carabid beetles, Syrphid larvae and neuropteran larvae is low while it is relatively high for Linyphiid spiders and Coccinellids (IPCS, 1992).

Toxicity in Non-Targeted Aquatic Systems

Alpha-cypermethrin is very toxic to fish under laboratory conditions, with emulsifiable concentrate formulations being the most toxic (IPCS, 1992); however, these effects are not seen in field studies. Therefore, the hazard to fish from contamination of waterbodies due to overspraying and drift is negligible (IPCS, 1992). Depending on the formulation, the reported 96-hour LC_{50} values range from 0.7 to 350 µg/L (IPCS, 1992). For rainbow trout, the reported 96-hour LC_{50} values range from 2.8 to 350 µg/L (HSDB, 2005; IPCS, 1992). The emulsifiable concentrate formulation is 10 to 70 times more toxic to rainbow trout than the wettable powder or suspension concentrate formulations. However, in field studies, the 14-day LC_{50} for rainbow trout was just 29 g ai/ha for emulsifiable concentrate formulations and greater than 1,000 g ai/ha for suspension concentrate, wettable powder, and micro-encapsulated formulations. For fathead minnows, the reported 96-hour LC_{50} value for technical alpha-cypermethrin was 0.93 µg/L, while the reported 96-hour LC_{50} values for carp range from 0.8 to 11 µg/L depending on the formulation. For fish in the early stages of life, alpha-cypermethrin and cypermethrin toxicity are similar (IPCS,

1992). Alpha-cypermethrin has the potential to accumulate in fish, with a bioconcentration factor of 990 (HSDB, 2005). It has also been shown to be highly toxic to some aquatic invertebrates and aquatic insects (IPCS, 1992).

Chronic Exposure

Due to low rate of application and low persistence of alpha-cypermethrin in both terrestrial and aquatic environments, serious adverse effects are not anticipated from chronic exposures (HSDB, 2005). The hazard of alpha-cypermethrin to fish and aquatic invertebrates is in its acute toxicity. There is no evidence of chronic exposure causing cumulative effects (IPCS, 1992).

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APPENDIX 5 : Toxicological Profile for Bifenthrin (from USAID PEA for IVM)

CAS Registry Number 82657-04-3

Summary of Insecticide

Chemical History

Bifenthrin is a pyrethroid insecticide and acaricide used in agricultural and human health applications (EXTOXNET, 1995; WHO/FAO, 1992). It is primarily available as a wettable powder or an emulsifiable concentrate (EXTOXNET, 1995). Bifenthrin is used to control pests on crops and indoor pests (ATSDR, 2003). For mosquito protection, it is used on bed nets and other materials that are dipped in bifenthrin to protect the user. Bifenthrin is a restricted use pesticide due to its potential toxicity to aquatic organisms, and it may only be purchased and used by certified applicators (ATSDR, 2003; EXTOXNET, 1995).

As a synthetic pyrethroid, bifenthrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the sodium channels of nerve cells (Choi and Soderlund, 2006; EXTOXNET, 1995). Symptoms of acute exposure may include skin and eye irritation, headache, dizziness, nausea, vomiting, diarrhea, excessive salivation, fatigue, irritability, abnormal sensations of the face and skin, and numbness (PAN, 2005). Inhalation of pyrethrins may cause a localized reaction of the upper and lower respiratory tracts (HSDB, 2005). In mammals, pyrethroids are generally of low toxicity due to their rapid biotransformation (HSDB, 2005). EPA has classified bifenthrin as a Class II chemical or moderately toxic. EPA has not classified synthetic pyrethroids, including bifenthrin, as endocrine disruptors. Bifenthrin is highly toxic to fish and other aquatic organisms (EXTOXNET, 1995).

Description of Data Quality and Quantity

Several comprehensive reviews on the toxicity of bifenthrin have been prepared or updated in recent years:

- Toxicological Profile for Pyrethrin and Pyrethroids (ATSDR, 2003)
- Pesticide Residues in Food—1992 Evaluation, Part II: Toxicology—Bifenthrin (WHO/FAO, 1992)
- IRIS summary review (U.S. EPA, 2006)
- Pesticide Information Profile for Bifenthrin (EXTOXNET, 1995).

EPA has developed quantitative human health benchmarks (acute and chronic oral RfDs, intermediate-term oral, and short-, intermediate-, and long-term dermal and inhalation benchmarks) for bifenthrin.

Summary Table

• Duration	• Route	• Benchmark Value	• Units	• Endpoint	• Reference
Acute, Intermediate	Inhalation	0.007	mg/kg/day	Oral NOAEL for neurological effects in dogs at 2.21 mg/kg/day with UF of 300 applied	U.S. EPA (2003)
Chronic	Inhalation	0.004	mg/kg/day	Oral NOAEL for neurological effects in dogs at 1.3 mg/kg/day with UF of 300 applied	U.S. EPA (2003)
Acute	Oral	0.033	mg/kg/day	Acute RfD based on neurotoxicity in rats	U.S. EPA (2003)
Intermediate	Oral	0.007	mg/kg/day	Oral NOAEL for neurological effects in dogs at 2.21 mg/kg/day with UF of 300 applied	U.S. EPA (2003)
Chronic	Oral	0.004	mg/kg/day	Chronic RfD based on neurological effects in dogs	U.S. EPA (2003)
Acute, Intermediate, Chronic	Dermal	0.2	mg/kg/day	Dermal NOAEL for neurological effects in rats at 47 mg/kg/day with UF of 300 applied	U.S. EPA (2003)

For oral exposure, an acute RfD of 0.033 mg/kg/day was derived based on a NOAEL of 32.8 mg/kg/day for neurological effects observed in rats exposed to bifenthrin (study citations not provided), with an uncertainty factor of 1,000 applied to account for the lack of a developmental neurotoxicity study and for interspecies and intrahuman variability (U.S. EPA, 2003). An intermediate NOAEL of 2.21 mg/kg/day was identified for tremors in dogs exposed for 90 days and an uncertainty factor of 300 was applied, resulting in a benchmark of 0.007 mg/kg/day (U.S. EPA, 2003). A chronic oral RfD of 0.004 mg/kg/day was derived based on a NOAEL of 1.3 mg/kg/day for tremors in dogs exposed for 1 year, with an uncertainty factor of 300 applied (U.S. EPA, 2003).

For inhalation exposure, an oral NOAEL of 2.21 mg/kg/day was identified for tremors in dogs exposed for 90 days and an uncertainty factor of 300 was applied (U.S. EPA, 2003). This value (0.007 mg/kg/day) is appropriate to use for short- and intermediate-term inhalation exposures. An oral NOAEL of 1.3 mg/kg/day was identified for tremors in dogs exposed for 1 year and an uncertainty factor of 300 was applied (U.S. EPA, 2003). This value (0.004 mg/kg/day) is appropriate to use for long-term inhalation exposures.

For dermal exposure, a NOAEL of 47 mg/kg/day for neurological effects (staggered gait and exaggerated hind limb flexion) was identified in rats dermally exposed to bifenthrin for 21 days. An uncertainty factor of 300 was applied, for a dermal benchmark value of 0.2 mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 2003).

Insecticide Background

CASRN:	82657-04-3
Synonyms:	(2-methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate, [1alpha, 3alpha(z)]-(+ -)-3-(2-Chloro-3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylic acid (2-methyl[1,1'-biphenyl]-3-yl)methyl ester, 2-Methylbiphenyl-3-ylmethyl (z)-(1RS,3RS)-3-(2-chloro-3,3,3-trifluoroprop-1- enyl)-2,2-dimethylcyclopropanecarboxylate, [1 alpha, 3 alpha(z)]-(+ -)-(2-Methyl[1,1'-biphenyl]-3-yl)methyl 3-(2-chloro- 3,3,3-trifluoro-1-propenyl)-2,2-dimethylcyclopropanecarboxylate (ATSDR, 2003; EXTOXNET, 1995; HSDB, 2005)
Chemical Group:	pyrethroid (PAN, 2005; EXTOXNET, 1995)
Registered Trade Names:	Talstar, Bifenthrine, Biphenate, Brigade, Bifentrina, Biflex, Capture, FMC 54800, FMC 54800 Technical, OMS3024, Torant (with Clofentezine), and Zipak (with Amitraz), Tarstar (HSDB, 2005; EXTOXNET, 1995; ATSDR, 2003; PAN, 2005)

Usage

Bifenthrin is used as a broad spectrum insecticide and acaricide to combat indoor pests and those on a variety of crops (EXTOXNET, 1995; ATSDR, 2003). It is used to control mosquitoes, beetles, weevils, houseflies, lice, bedbugs, aphids, moths, cockroaches, and locusts. Crops on which bifenthrin is used include alfalfa hay, beans, cantaloupes, cereals, corn, cotton, field and grass seed, hops, melons, oilseed rape, potatoes, peas, raspberries, watermelons, and squash. Bifenthrin belongs to the pyrethroid class of insecticides, which have long been used to control mosquitoes, human lice, beetles, and flies. For mosquito protection, it is used on bed nets and other materials that are dipped into the bifenthrin to protect the user. Bifenthrin for agricultural use is restricted by EPA due to its potential toxicity to aquatic organisms, and it may only be purchased and used by certified applicators (ATSDR, 2003).

Formulations and Concentrations

Bifenthrin is available in technical grade, emulsifiable concentrate, suspension concentrate, wettable powder, ultra-low volume (ULV) liquid, and granules (HSDB,

2005; EXTOXNET, 1995; WHO, 2001). Technical grade bifenthrin may be mixed with carriers or solvents, resulting in the commercial formulations. The label of products containing bifenthrin must contain the word "warning" (EXTOXNET, 1995). Technical grade bifenthrin must have no less than 920 g/kg bifenthrin. The wettable powder should contain > 25–100 g/kg +/- 10% of the declared content, 100–250 g/kg +/- 6% of the declared content, or > 250–500 g/kg +/- 5% of the declared content (WHO, 2001). Bifenthrin that is used on bed nets for malaria control comes in a suspension concentrate dose of 25 mg a.i./m^2 (WHO, n.d.).

Shelf Life

Bifenthrin is photostable and stable to hydrolysis. It volatilizes minimally and is generally stable when stored (EXTOXNET, 1995). Bifenthrin is stable for 2 years at 25–50^{o}C. It is most stable in acidic environments and at pHs from 5 to 9, it is stable for 21 days. Pyrethrins, in general, are stable for a long time in water-based aerosols (HSDB, 2005).

Degradation Products

Pyrethroid insecticides are often formulated with synergists that prevent the breakdown of enzymes and thus enhance the activity of the pyrethroid (ATSDR, 2003). The primary metabolic pathway for the breakdown of bifenthrin is ester hydrolysis (HSDB, 2005). The major degradate of bifenthrin metabolism in soil, biota, and water is 4'-hydroxy bifenthrin (Fecko, 1999).

Environmental Behavior

Fate and Transport in Terrestrial Systems

With Koc values ranging from 131,000 to 320,000, the mobility of bifenthrin in soil ranges from low to immobile (HSDB, 2005; EXTOXNET, 1995). Bifenthrin has a low mobility in soils with large amounts of clay, silt, organic matter and in sandy soils without much organic matter (EXTOXNET, 1995). In moist soils, volatilization is a major fate process, although this is lessened by absorption in the soil (HSDB, 2005). Depending on soil type and the amount of air in the soil, the half-life of bifenthrin ranges from 7 days to 8 months (EXTOXNET, 1995). Bifenthrin is expected to biodegrade readily based on its structure and the biodegradation rates of pyrethroids in general (HSDB, 2005). It is not absorbed by plants and dose not translocate in plants (EXTOXNET, 1995).

Fate and Transport in Aquatic Systems

Bifenthrin is fairly insoluble in water, so it is unlikely to leach to groundwater and cause significant contamination (EXTOXNET, 1995). Volatilization is a major fate process from surface water; however, because bifenthrin is expected to adsorb to suspended soils and sediments, volatilization is attenuated. Volatilization half-lives of 50 days for a model river and 555 days for a model lake have been reported, but if adsorption is

considered, the volatilization half-life of a model pond is 3,100 years. Bifenthrin has a high potential to accumulate in aquatic organisms, with an estimated bioconcentration factor of 190. However, bioconcentration is likely to be lower due to the ability of aquatic organisms to readily metabolize bifenthrin (HSDB, 2005).

Human Health Effects

Acute Exposure

Effects/Symptoms

There are limited data on the acute toxicity of bifenthrin in humans. Bifenthrin is classified as having moderate acute toxicity in mammals (EXTOXNET, 1995; WHO/FAO, 1992; PAN, 2005). Incoordination, irritability to sound and touch, tremors, salivation, diarrhea, and vomiting have been caused by high doses. In humans, no skin inflammation or irritation has been observed; however, bifenthrin can cause a reversible tingling sensation (EXTOXNET, 1995).

In animals, the main signs of acute toxicity include clonic convulsions, tremors, and oral discharge (WHO/FAO, 1992). Reported LD_{50} values for bifenthrin include 54–56 mg/kg in female rats, 70 mg/kg in male rats (EXTOXNET, 1995; WHO/FAO, 1992; HSDB, 2005) and 43 mg/kg in mice (WHO/FAO, 1992). Bifenthrin is slightly toxic through dermal contact, with dermal LD_{50}s of over 2,000 mg/kg in rabbits (WHO/FAO, 1992; HSDB, 2005). Neurotoxicity is a key effect of pyrethroids and is caused by interfering with the sodium channels of nerve cells (ATSDR, 2003; Choi and Soderlund, 2006). In mammals, acute exposure to pyrethroids causes tremors, hyperexcitability, salivation, paralysis, and choreoathetosis. However, delayed neurotoxicity has not been observed (HSDB, 2005). Bifenthrin is not a dermal sensitizer in guinea pigs (EXTOXNET, 1995; HSDB, 2005; WHO/FAO, 1992) and did not irritate either abraded or non-abraded skin of rabbits (WHO/FAO, 1992). In rabbits, it is only slightly irritating to the eyes (EXTOXNET, 1995; WHO/FAO, 1992; HSDB, 2005). Bifenthrin is also a suspected endocrine disruptor (ATSDR, 2003; PAN, 2005).

Treatment

Bifenthrin and its metabolites can be detected in blood and urine during the first few days following exposure (but not later, because these compounds are rapidly broken down in the body) (ATSDR, 2003). Treatment depends on the symptoms of the exposed person. Most casual exposures require only decontamination and supportive care (HSDB, 2005). If a person exhibits signs of typical pyrethroid toxicity following bifenthrin exposure, affected skin areas should be washed promptly with soap and warm water. Medical attention should be sought if irritation or paresthesia occurs. Paresthesia may be prevented or stopped with Vitamin E oil preparations. Corn oil and Vaseline® are less effective and less suitable, and zinc oxide should be avoided (PAN, 2005; HSDB, 2005).

Eye exposures should be treated by rinsing with copious amounts of water or saline. Contact lenses should be removed. Medical attention should be sought if irritation

persists (PAN, 2005; HSDB, 2005). Following oral exposures, the person should be kept calm and medical attention should be sought as quickly as possible. Medical personnel will treat severe intoxications with a sedative and anticonvulsant. Ingestion of large amounts of bifenthrin should be treated with gastric lavage, and small ingestions should be treated with activated charcoal and cathartic (PAN, 2005). For sublethal exposures, vomiting may be induced by ipecac and followed by saline cathartic and an activated charcoal slurry, as long as the person is alert and has a gag reflex (HSDB, 2005).

Chronic Exposure

Noncancer Endpoints

No data are available for humans following chronic exposures to bifenthrin (EXTOXNET, 1995). Dietary studies in dogs, rats, and mice indicate that oral exposure to bifenthrin causes neurological effects such as tremors (U.S. EPA, 2006; WHO/FAO, 1992) but not cholinesterase inhibition (PAN, 2005). In a 1-year feeding study in dogs and a lifetime feeding study in mice, intermittent tremors were observed (U.S. EPA, 2006; WHO/FAO, 1992). In subchronic duration exposure studies in dogs and rats, tremors were also seen at higher exposure levels (U.S. EPA, 2006; WHO/FAO, 1992).

Bifenthrin has the potential to be reproductive toxin (PAN, 2005). Reproductive toxicity has been observed in rats and rabbits at doses lower than those that cause tremors (EXTOXNET, 1995). Teratogenicity was not observed in a 2-generation rat study (EXTOXNET, 1995) or a rabbit teratogenicity study (WHO/FAO, 1992; HSDB, 2005).

Additional effects observed in chronic exposure animal studies include increased body weight and organ-to-body ratios (U.S. EPA, 2006). The mutagenicity data are inconclusive for bifenthrin (EXTOXNET, 1995), but it is unlikely to pose a genetic hazard (WHO/FAO, 1992).

Cancer Endpoints

EPA has classified bifenthrin as Class C, possible human carcinogen (EXTOXNET, 1995; PAN 2005). A 2-year, high dose dietary exposure study in rats reported no evidence of cancer. In mice, however, a significant dose-related increase in urinary bladder tumors was observed in male mice. An increased incidence of lung tumors was observed in female mice (U.S. EPA, 2003; EXTOXNET, 1995).

Toxicokinetics

Bifenthrin is readily absorbed through intact skin (EXTOXNET, 1995; HSDB, 2005) and the gastrointestinal tract (WHO/FAO, 1992). It breaks down in the same way as other pyrethroids (EXTOXNET, 1995). Hydrolysis and hydroxylation are the primary steps in the transformation of bifenthrin. In poultry, bifenthrin metabolism begins with hydroxylation of the 2-methyl carbon of the cyclopropane ring, followed by fatty acid conjugation (WHO/FAO, 1992). Oral administration of radioactive pyrethroids have been shown to distribute to every tissue examined (HSDB, 2005). Bifenthrin can accumulate in

fatty tissues such as skin and ovaries (EXTOXNET, 1995). Bifenthrin metabolism and excretion are rapid. In rats given 4–5 mg/kg bifenthrin, 70 percent of the dose was excreted in urine within 7 days, and 20 percent was excreted in feces (EXTOXNET, 1995). However, another study in rats showed that following oral administration of bifenthrin, 70 to 80 percent was eliminated in the feces within 48 hours while only 5 to 10 percent was eliminated in the urine. Biliary excretion raged from 20 to 30 percent (WHO/FAO, 1992).

Ecological Effects

Acute Exposure

Toxicity in Non-Targeted Terrestrial Organisms

Bifenthrin, like other pyrethroids, is unlikely to harm terrestrial organisms other than its targets, such as mosquitoes and other pests, due to its low persistence in the environment (HSDB, 2005). Bifenthrin has a moderate toxicity in birds (EXTOXNET, 1995). The 8-day dietary LC_{50} values range from 1,280 ppm in mallard ducks to 4,450 ppm in bobwhite quail. Oral LD_{50} values range from 1,800 mg/kg in bobwhite quail to 2,150 mg/kg in mallard ducks. Additionally, concerns about bioaccumulation in birds have been reported. As with other pyrethroid insecticides, bifenthrin is extremely toxic to honey bees (EXTOXNET, 1995; HSDB, 2005).

Toxicity in Non-Targeted Aquatic Systems

Bifenthrin is also known to be toxic to a wide variety of aquatic organisms, including fish, crustaceans, aquatic insects, mollusks, nematodes, flatworms, phytoplankton, and zooplankton (PAN, 2005). Bifenthrin is very toxic to fish (EXTOXNET, 1995); however, because it is not very water soluble and has a high affinity for soil, the risk to aquatic systems is not expected to be high (EXTOXNET, 1995). The high toxicity in fish is illustrated by the low exposures that cause lethality. The reported 96-hour LC_{50} is 0.00015 mg/L in rainbow trout and 0.00035 mg/L in bluegill sunfish (EXTOXNET, 1995; HSDB, 2005). Average LC_{50} values are 17.5 µg/L in sheepshead minnow and 0.36 µg/L in gizzard shad (PAN, 2005). In Daphnia, the reported 48-hour LC_{50} is 0.0016 mg/L (HSDB, 2005). The risk of bioaccumulation of the bifenthrin formulation Talstar®100EC in aquatic organisms is reported to be very high (ASTRACHEM, n.d.). The whole-body bioconcentration factor values for fathead minnow in water T a concentration of 0.0037 µg/L were 21,000 (over 127 days) and 28,000 (over 254 days) (CalDFG, 2000).

Chronic Exposure

Toxicity in Non-Targeted Terrestrial Organisms

No data were located on the chronic toxicity to nontarget terrestrial organisms.

Toxicity in Non-Targeted Aquatic Systems

Chronic exposure of fathead minnow to a 95.7 percent bifenthrin formulation for 246 days resulted in a reported LOEC of 0.41 µg/L, NOEC of 0.30 µg/L, and MATC of 0.351

µg/L. Chronic exposure of fathead minnow to a 96.2 percent bifenthrin formulation for 346 days resulted in a reported LOEC of 0.090 µg/L, NOEC of 0.050 µg/L, and MATC of 0.067 µg/L (CalDFG, 2000).

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APPENDIX 6 : Toxicological Profile for Cyfluthrin (from USAID PEA for IVM)

CAS Registry Number 68359-37-5

Summary

Chemical History

Cyfluthrin is a synthetic pyrethroid insecticide first registered by EPA in 1987. It is used in agricultural and human health applications against a wide variety of pests. It is similar to the natural insecticide pyrethrum, which comes from chrysanthemums; however, it is more effective and longer lasting (ATSDR, 2003). Cyfluthrin has both contact and stomach poison action (EXTOXNET, 1998) and it interferes with nervous system transmissions through inhibition of the sodium channel system (Choi and Soderlund, 2006; WHO, 2004). It is available as the technical product, emulsifiable concentrate, wettable powder, aerosol, granule, liquid, oil-in-water emulsion, dust, concentrate, and ultra-light-volume oil spray (EXTOXNET, 1998; IPCS, 1997). For mosquito control, it is used in bed nets and other materials that are treated with cyfluthrin to protect the user (WHO, 1998). Cyfluthrin can be found in both restricted use pesticides and general use pesticides (EXTOXNET, 1998). When used, it is applied by spraying, dusting, fogging, or impregnation (WHO, 2004; IPCS, 1997). It is considered moderately toxic to mammals (EXTOXNET, 1998). EPA has not classified synthetic pyrethroids, including cyfluthrin, as endocrine disruptors. Typical symptoms of acute human exposure are skin and eye irritation. Dermal irritation may include itching, burning, or stinging, which may lead to a numbness that lasts up to 24 hours. Skin irritation may occur immediately following exposure or be delayed for 1 to 2 hours (EXTOXNET, 1998). In animals, very high doses have been shown to cause nervous system effects, including irritability, excessive salivation, uncoordinated gait, tremors, convulsions, and death (EXTOXNET, 1998; ATSDR, 2003).

Description of Data Quality and Quantity

EPA has developed a quantitative human health benchmark for cyfluthrin (EPA's chronic oral RfD). Several reviews on the toxicity of cyfluthrin have been prepared or updated in recent years and recommended resources include the following:

- Toxicological Profile for Pyrethrin and Pyrethroids (ATSDR, 2003)
- IRIS summary review (U.S. EPA, 2005b)
- Pesticide Information Profiles: Cyfluthrin (EXTOXNET, 1998)
- Toxicological Evaluation of Certain Veterinary Drug Residues in Food. WHO Food Additives Series 39: Cyfluthrin (IPCS, 1997)
- Specifications and Evaluations for Public Health Pesticides: Cyfluthrin (WHO, 2004).

Summary Table

• Duration	• Route	• Benchmark Value	• Units	• Endpoint	• Reference
Acute	**Inhalation**	**0.0007**	**mg/kg/day**	**Inhalation NOAEL in rats with UF of 100 applied**	**U.S. EPA (2005a)**
Intermediate, Chronic	**Inhalation**	**0.0002**	**mg/kg/day**	**Inhalation NOAEL in rats with UF of 100 applied**	**U.S. EPA (2005a)**
Acute	**Oral**	**0.02**	**mg/kg/day**	**Acute RfD based on mammalian neurotoxicity**	**U.S. EPA (2005a)**
Intermediate	**Oral**	**0.024**	**mg/kg/day**	**Adopt chronic RfD for intermediate duration**	
Chronic	**Oral**	**0.024**	**mg/kg/day**	**Chronic RfD based on neurological effects in dogs**	**U.S. EPA (2005a)**
Acute, Intermediate, Chronic	**Dermal**	**3**	**mg/kg/day**	**Dermal NOAEL in rabbits with UF of 100 applied**	

For inhalation exposure, a NOAEL of 0.00026 mg/L (0.07 mg/kg/day) was identified for body weight effects in rats exposed to beta-cyfluthrin via inhalation for 28 days. A NOAEL of 0.00009 mg/L (0.02 mg/kg/day) was identified for neurological and body weight effects in rats exposed to cyfluthrin via inhalation for 13 weeks. An uncertainty factor of 100 to account for inter- and intraspecies variation was applied, for a short-term inhalation benchmark of 0.0007 mg/kg/day and an intermediate- and long-term inhalation benchmark of 0.0002 mg/kg/day.

For oral exposure, an acute oral RfD of 0.02 mg/kg/day was derived based on a NOAEL of 2 mg/kg/day for acute mammalian neurotoxicity following exposure to beta-cyfluthrin. An uncertainty factor of 100 was applied for inter- and intraspecies variability (U.S. EPA, 2005a). A chronic oral RfD of 0.024 mg/kg/day was derived based on a NOAEL of 2.4 mg/kg/day for neurological effects in dogs exposed to cyfluthrin for 53 weeks. An uncertainty factor of 100 was applied for inter- and intraspecies variability (U.S. EPA, 2005a). An intermediate oral RfD of 0.024 mg/kg/day was derived based on a NOAEL of 2.4 mg/kg/day for neurological effects in dogs exposed to beta-cyfluthrin for 90 days. An uncertainty factor of 100 was applied for inter- and intraspecies variability (U.S. EPA, 2005a).

For dermal exposure, a NOAEL of 250 mg/kg/day (85 percent purity) was identified in rabbits dermally exposed to cyfluthrin 5 times a week for 6 hr/day for 3 weeks (IPCS, 1997). An uncertainty factor of 100 to account for inter- and intraspecies variation was

applied, for a dermal benchmark value of 3 mg/kg/day. This value is appropriate for all exposure durations.

Insecticide Background

CASRN:	68359-37-5
Synonyms:	Cyano(4-fluoro-3-phenoxyphenyl) methyl 3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate; BAY-FCR 1272; (R,S)-alpha-Cyano-4-fluoro-3-phenoxybenzyl-(1R,S)-cis,trans-3-(2,2- dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate; 3-(2,2-Dichloroethenyl)-2,2-diethylcyclopropanecarboxylic acid cyano(4-fluoro- 3-phenoxyphenyl)methyl ester; Cyfluthrine; FCR 1272; (RS)-alpha-Cyano-4-fluoro-3-phenoxybenzyl (1RS, 3RS: 1RS, 3SR)-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate (ATSDR, 2003; HSDB 2005)
Chemical Group:	pyrethroid (ATSDR, 2003)
Registered Trade Names:	Attotox, Baythroid, Baygon aerosol, Baythroid H, Cyfoxlate, Contur, Laser, Responsar, Solfac, Tempo, Tempo H (ATSDR, 2003; EXTOXNET, 1998)

Usage

Cyfluthrin is effective in combating a broad spectrum of insect pests in agricultural, public health, and structural applications (WHO, 2004; EXTOXNET, 1998). The main agricultural use of cyfluthrin is against chewing and sucking insects on crops (EXTOXNET, 1998; HSDB, 2005; ATSDR 2003). In public health applications, it is used to control mosquitoes, houseflies, and cockroaches (HSDB, 2005). It is primarily a contact insecticide and is applied by residual spraying, fogging, or impregnation (WHO, 2004).

Formulations and Concentrations

Cyfluthrin is available in technical grade, emulsifiable concentrate, wettable powder, aerosol, granules, liquid, oil-in-water emulsion, and ultra-light-volume oil sprays (EXTOXNET, 1998; HSDB 2005). Technical grade cyfluthrin may be mixed with carriers or solvents resulting in the commercial formulations. These commercial formulations may also include ingredients that may potentiate the toxicity compared to technical grade cyfluthrin (EXTOXNET, 2005). WHO indicates that the content of cypermethrin in the formulated products must be declared and shall not exceed the listed standards. Technical grade cyfluthrin must have no less than 920 g/kg cyfluthrin and should contain the four diastereoisomers as follows:

- Diastereoisomer I, (R)-alpha-cyano-4-fluoro-3-phenoxybenzyl-(1R)-cis -3-(2,2-dichlorovinyl)-2,2- dimethylcyclopropanecarboxylate + (S)-alpha, (1S)-cis: 23–27 percent
- Diastereoisomer II, (S)-alpha-cyano-4-fluoro-3-phenoxybenzyl-(1R)-cis -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate + (R)-alpha, (1S)-cis: 17–21 percent
- Diastereoisomer III, (R)-alpha-cyano-4-fluoro-3-phenoxybenzyl-(1R)-trans -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate + (S)-alpha, (1S)-trans: 32–36 percent
- Diastereoisomer IV, (S)-alpha-cyano-4-fluoro-3-phenoxybenzyl-(1R)- trans -3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropanecarboxylate + (R)-alpha, (1S)-trans: 21–25 percent.

The wettable powder should contain 100 g/kg cyfluthrin +/- 10 percent of the declared content. The oil-in-water emulsion shall contain 50 g/kg or g/L cyfluthrin +/- 10 percent of the declared content at 20 +/- 2 ^{o}C (WHO, 2004, ATSDR, 2003). For malaria control, a 10 percent wettable powder formulation has been found to be safe and effective for indoor residual spraying against malaria vectors at target doses of 15 to 50 mg/m^2, while a 5 percent oil in water emulsion is effective and safe for use in impregnation of bed nets at a dose of 50 mg/m^2 (WHO, 1998).

Shelf Life

Cyfluthrin in water-based aerosols is stable for a long time. It is thermally stable at room temperature. Topical cyfluthrin preparations made with piperonyl butoxide should be stored at temperatures below 40 ^{o}C (and optimally at 15 to 30 ^{o}C) and in tightly closed containers (HSDB, 2005). Australian researchers reported that cyfluthrin is stable and does not break down for up to 52 weeks when used on stored wheat (EXTOXNET, 1998).

Degradation Products

Pyrethroid insecticides are often formulated with synergists that act to prevent the breakdown of enzymes and thus enhance the activity of the pyrethroid (ATSDR, 2003). Cyfluthrin's breakdown products include 4-fluoro-3-phenoxybenzoic acid (PAN, 2005). In soil, the primary breakdown products include carbon dioxide and 4-fluoro-3-phenyl-benzaldehyde (a compound of considerably lower toxicity than the parent compound) (EXTOXNET, 1998).

Environmental Behavior

Fate and Transport in Terrestrial Systems

The use of cyfluthrin as an insecticide may result in its release into the environment via a variety of waste streams (HSDB, 2005). Once in the environment, cyfluthrin is expected to be highly immobile in the soil based on its Koc value (HSDB, 2005; EXTOXNET,

1998). Because it is immobile in soil, cyfluthrin does not easily leach into groundwater (EXTOXNET, 1998).

Cyfluthrin is one of the more persistent pyrethroids and as a result, it is used more often in agricultural applications (ATSDR, 2003). It can be broken down by sunlight, and in surface soils, the reported half-life ranges from 48 to 72 hours. Reported half-lives in German loam and sandy loam soils are 51 to 63 days. Persistence under anaerobic conditions is similar. The persistence of cyfluthrin in soil is not significantly affected by soil moisture content (EXTOXNET, 1998; ATSDR, 2003).

The major fate processes for cyfluthrin in soil are biodegradation and photolysis. Under anaerobic conditions, more than 90 percent biodegradation was reported during an incubation period of 140 days. Anaerobic biodegradation of cyfluthrin initially produces 3-(2,2-dichlorovinyl)2,2-dimethylcyclopropancarboxcylic acid and 4-fluoro-3-phenoxybenzoic acid. Photodegradation was observed when cotton fabric was irradiated for 96 hours in simulated natural sunlight, resulting in almost 75 percent photo-degradation (HSDB, 2005). Volatilization is not expected to be a major fate process from either moist or dry soils (HSDB, 2005).

Fate and Transport in Aquatic Systems

Cyfluthrin binds tightly to soil, is practically insoluble in water, and is less dense than water, allowing it to float on the surface film of natural water (EXTOXNET, 1998; HSDB, 2005). It is stable in water under acidic conditions but hydrolyzes rapidly under basic conditions (EXTOXNET, 1998). On surface waters, cyfluthrin breaks down by photolysis and is not expected to volatilize (EXTOXNET, 1998; HSDB, 2005). In aqueous solutions, an experimental half-life of 16 hours was identified when irradiated by environmentally significant wavelengths of light (HSDB, 2005). Aqueous hydrolysis does not play an important role in the environmental fate of cyfluthrin. Hydrolysis half-lives of 231 days and 2 days were identified at pH 7 and 8, respectively (ATSDR, 2003). Cyfluthrin has a high potential to bioconcentrate in aquatic organisms (HSDB, 2005).

Human Health Effects

Acute Exposure

Effects/Symptoms

Limited data are available on the acute toxicity of cyfluthrin in humans, because pyrethroid poisonings are uncommon. Cases of acute occupational or accidental exposure to pyrethroids resulted in burning, itching, and tingling of the skin which resolved after several hours. Reported systemic symptoms included dizziness, headache, anorexia, and fatigue. Vomiting occurred most commonly after ingestion of pyrethroids. Less commonly reported symptoms included tightness of the chest, paresthesia, palpitations, blurred vision, and increased sweating. In serious cases, coarse muscular fasciculations (twitching), convulsions, and coma were reported (IPCS, 1997). Cyfluthrin is of low toxicity to humans largely due to its poor absorption from the bloodstream and rapid

breakdown and excretion. Acute effects of cyfluthrin exposure in humans consist primarily of immediate or delayed skin irritation and immediate eye irritation. Itching, burning, and stinging of exposed skin can progress to cutaneous paresthesias, which can last up to 24 hours. Sweating, heat, and water can make dermal symptoms worse (WHO, 2004; EXTOXNET, 1998; HSDB, 2005; IPCS, 1997).

As a pyrethroid, cyfluthrin inhibits cholinesterase (HSDB, 2005), and symptoms of acute toxicity in animals may include irritability, excessive salivation, uncoordinated gait, tremors, convulsions, and death (HSDB, 2005; EXTOXNET, 1998). Cyfluthrin is a type II pyrethroid, a class which is known to produce a complex poisoning syndrome involving a progressive development of symptoms. In rats, this manifests as burrowing behavior, coarse tremors, clonic seizures, sinuous writhing, and profuse salivation without lacrimation (HSDB, 2005). Nervous system effects have been reported in acute high-dose exposures of animals to cyfluthrin by oral routes (EXTOXNET, 1998). Neurological effects (e.g., disturbed posture, abnormal motor activity, restlessness, and agitated gate) have also been seen following acute inhalation exposures (ATSDR, 2003). Neurological symptoms following daily dermal doses of $\geq$ 1,845 mg/kg in rats for up to 7 days included pawing and whole body tremors (ATSDR, 2003).

The vehicle used in formulating cyfluthrin significantly affects its toxicity (WHO, 2004). Reported LD_{50} values range from 16 to 1,189 mg/kg body weight, depending on the vehicle used (WHO, 2004). The reported oral LD_{50}s range from 500 to 1,271 mg/kg in rats, 1,401 to 609 mg/kg in mice, greater than 100 mg/kg in dogs, greater than 1,000 mg/kg in rabbits, and greater than 1,000 mg/kg in sheep (EXTOXNET, 1998; HSDB, 2005).The oral LD_{50}s for cyfluthrin in polyethylene glycol and xylene are 500 and 270 mg/kg, respectively (HSDB, 2005), while the oral LD_{50} for a 5 percent water emulsion preparation is reported as 2,100 mg/kg body weight in rats (WHO, n.d.). Inhalation exposures in rats have resulted in 4-hour LC_{50}s ranging from 469 to 592 μg/L and a reported 1-hour LC_{50} greater than 1,089 μg/L (EXTOXNET 1998). The 4-hour LC_{50}s for aerosol and dust exposures in rats are reported as 0.1 mg/L and 0.53 mg/L, respectively (HSDB, 2005). Cyfluthrin is not considered highly toxic via the dermal route of exposure, with a dermal LD_{50} of greater than 5,000 mg/kg in rats (EXTOXNET, 1998; HSDB, 2005). Additionally, it is not a dermal sensitizer or irritant in guinea pigs and rabbits (WHO, 2004; EXTOXNET, 1998; HSDB, 2005) but did induce eye irritation in rabbits (WHO, 2004; HSDB, 2005).

Treatment

Cyfluthrin and its metabolites can be detected in blood and urine; however, the methods are not practical given how quickly these compounds are broken down in the body (ATSDR, 2003). There are no antidotes for cyfluthrin exposure. Treatment depends on the symptoms of the exposed person. If a person exhibits signs of typical pyrethroid toxicity following cyfluthrin exposure (nausea, vomiting, shortness of breath, tremors, hypersensitivity, weakness, burning, or itching), they should immediately remove any contaminated clothing. Any liquid contaminant on the skin should be soaked up and the

affected skin areas cleaned with alkaline soap and warm water. Eye exposures should be treated by rinsing with copious amounts of 4 percent sodium bicarbonate or water. Contact lenses should be removed. Vomiting should not be induced following ingestion exposures, but the mouth should be rinsed. The person should be kept calm and medical attention should be sought as quickly as possible. Medical personnel will treat severe intoxications with a sedative and anticonvulsant. Ingestion of large amounts of cyfluthrin should be treated with gastric lavage using a 5 percent bicarbonate solution followed by powdered activated charcoal. Skin irritation may be treated with a soothing agent; exposure to light should be avoided (PAN, 2005; HSDB, 2005).

Chronic Exposure

Noncancer Endpoints

Little data are available for humans following chronic exposures to cyfluthrin, although it is not likely to cause long-term problems when used under normal conditions (ATSDR, 2003). Available animal data suggest that chronic toxicity is highest by inhalation exposure, with lower toxicity by oral exposure. Dermal exposure has the lowest chronic toxicity (WHO, 2004). Cyfluthrin does not appear to be a reproductive or developmental toxin in animals (HSDB, 2005; WHO, 2004; ATSDR, 2003; EXTOXNET, 1998; WHO/FAO, 1997). However, treatment-related reductions in viability, decreased lactation, and deceased birth weight or weight gain were observed in one 3-generation rat study (ATSDR, 2003; EXTOXNET, 1998; U.S. EPA, 2005b). No developmental or teratogenic effects were observed in several animal studies (HSDB, 2005; EXTOXNET 1998; U.S. EPA, 2005b). In a 1-year dog feeding study, high doses of cyfluthrin caused slight ataxia, increased vomiting, and increased pasty or liquid feces. Decreased body weights were seen in males (U.S. EPA, 2005b). Cyfluthrin does not show any mutagenic potential (HSDB, 2005; WHO, 2004; EXTOXNET, 1998; WHO/FAO, 1997). Decreased weight gain and organ weight changes secondary to body weight are the only significant effects observed in long-term feeding studies in rats, mice, and dogs (WHO/FAO, 1997; EXTOXNET, 1998; U.S. EPA, 2005b). Additionally, reversible damage to the sciatic nerve was observed (EXTOXNET, 1998).

Cancer Endpoints

No evidence of carcinogenic potential has been reported in rats and mice exposed to cyfluthrin (WHO, 2004; EXTOXNET, 1998; WHO/FAO, 1997).

Toxicokinetics

Pyrethroids are rapidly absorbed via inhalation as is indicated by the excretion of their metabolites within 30 minutes of exposures. In workers, plasma cyfluthrin levels confirmed absorption. Oral exposure to pyrethroids results in absorption from the gastrointestinal tract. Cyfluthrin metabolites were identified in the urine of an orally exposed volunteer. Minimal oral absorption was estimated based on the recovery of urinary cyfluthrin metabolites (ATSDR, 2003).

As with other synthetic pyrethroids, biotransformation in mammals exposed to cyfluthrin occurs through hydrolysis of the central ester bond, oxidative attacks at several sites, and conjugation reactions that produce water-soluble metabolites that are excreted in urine and feces. For cypermethrin, the rapid hydrolytic cleavage of the ester bond is followed by oxidation, which results in carboxylic acid derivatives and phenoxybenzoic acid derivatives that are then excreted as alcohols; phenols; carboxylic acids; and their glycine, sulfate, glucuronide, or glucoside conjugates (ATSDR, 2003). The metabolism of cyfluthrin is biphasic with a rapid initial phase and a slower second phase. This is demonstrated by the elimination of 60 percent of an intravenous dose within the first 24 hours followed by 6 percent elimination during the second 24 hours. Similarly, in feces 20 percent was eliminated on the first day and 3 to 4 percent was eliminated on the second day. Additionally, a single oral dose of cyfluthrin was shown to be 98 percent eliminated within 48 hours (EXTOXNET, 1998). Inhalation of a single dose of cyfluthrin in humans resulted in urinary metabolites within 30 minutes of exposure (ATSDR, 2003; WHO/FAO, 1997).

Elimination of cyfluthrin following inhalation exposure follows first-order kinetics with 93 percent of the dose being excreted within 24 hours of exposure. The elimination half-times for cis-/trans-3-(2,2-dichlorovinyl)-2,2-dimethylcyclopropane carboxylic acid (DCCA) and, 4-fluoro-3-phenoxybenzoic acid (FPBA) metabolites and their isomers range from 5.3 to 6.9 hours and remain constant over a range of exposure levels (ATSDR, 2003). Based on occupational human exposure studies, the elimination half-time for cyfluthrin is estimated at 0.5 to 2 hours for plasma and 5 hours for urine (ATSDR, 2003). Oral exposures to cyfluthrin resulted in approximately 60 to 70 percent of the dose being eliminated in the urine and the rest eliminated in the feces (WHO/FAO, 1997).

Ecological Effects

Acute Exposure

Toxicity in Non-Targeted Terrestrial Organisms

Cyfluthrin has a very low toxicity in birds (EXTOXNET, 1998; HSDB, 2005). Oral LD_{50} values range from greater than 2,000 mg/kg in acute tests in bobwhite quail to greater than 5,000mg/kg in subacute tests in mallards and bobwhite quail (EXTOXNET, 1998). Other reported oral LD_{50}s are 4,500 to greater than 5,000 mg/kg in hens (depending on the vehicle used), greater than 2,000 mg/kg in Japanese quail, and 250 to 1,000 mg/kg in canaries (EXTOXNET, 1998; HSDB, 2005). As with other pyrethroid insecticides, cyfluthrin is extremely toxic to honey bees in laboratory tests. The reported LD_{50} is 0.037 mg/bee (EXTOXNET, 1998). However, in the field, serious adverse effects have not been seen due to low application rates and low environmental persistence (HSDB, 2005). Cyfluthrin is also highly toxic to other beneficial insects (EXTOXNET, 1998) but of low toxicity to earthworms (WHO, 2004).

Toxicity in Non-Targeted Aquatic Systems

As with other pyrethroids, cyfluthrin is very toxic to marine and freshwater fish and invertebrates (EXTOXNET, 1998; WHO, 2004). The high toxicity in fish is illustrated by the low exposures that cause lethality. The reported 48-hour LC_{50} for rainbow trout is 0.00068 mg/L, while in bluegill, carp, and golden orfe, the reported LC_{50}s are 0.0015, 0.022, and 0.0032 mg/L, respectively. In sheepshead minnow, an LC_{50} of 0.004 mg/L is reported (EXTOXNET, 1998). The 96-hour LC_{50} values range from 28 ng/L in bluegill sunfish to 330.9 ng/L in golden orfe (HSDB, 2005). In marine and estuarine invertebrates, extreme sensitivity to cyfluthrin is also seen. Reported LC_{50}s include 2.42 ng/L for mysid shrimp. An EC_{50} of 3.2 ng/L was seen in eastern oysters (EXTOXNET, 1998). Cyfluthrin has a high potential to bioconcentrate in aquatic organisms based on the measured BCF of the structurally similar insecticide cypermethrin (HSDB, 2005).

Chronic Exposure

Due to low rate of application and low persistence of cyfluthrin in both terrestrial and aquatic environments, serious adverse effects are not anticipated from chronic exposures (HSDB, 2005).

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APPENDIX 7 : Toxicological Profile for Deltamethrin (from USAID PEA for IVM)

CAS Registry Number 52918-63-5

Summary of Insecticide

Chemical History

Deltamethrin is a broad spectrum synthetic pyrethroid insecticide used in agricultural and human health applications. It was first marketed in 1977 (IPCS, 1990; EXTOXNET, 1995; WHO/FAO, 2001) and has been in use longer than any alpha-cyano pyrethroid with an excellent safety record (WHO/FAO, 1999). It is similar to the natural insecticide pyrethrum, which comes from chrysanthemums; however, it is more effective and longer lasting (EXTOXNET, 1995; WHO/FAO, n.d.; IPCS, 1990). Deltamethrin is considered the most powerful synthetic pyrethroid (EXTOXNET, 1995). For mosquito control, it is used on bed nets and other materials that are dipped in deltamethrin to protect the user (Barlow et al., 2001; EXTOXNET, 1995; WHO/FAO, 2001). Deltamethrin is typically formulated as emulsifiable concentrates, wettable powders, ultra-light-volume (ULV) and flowable formulations, and granules either alone or combined with other pesticides (EXTOXNET, 1995; IARC, 1991). A dispersible tablet is also used to treat mosquito nets (Barlow et al., 2001). Deltamethrin is of moderate toxicity to mammals because metabolizes rapidly and does not accumulate (WHO/FAO, n.d.; WHO/FAO, 1999). It is of low risk to humans when used at levels recommended for its designed purpose (ATSDR, 2003; WHO, 2004). General population exposures are expected to be very low and to occur mostly through public health uses and dietary residues. As a synthetic pyrethroid, deltamethrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the sodium channels of nerve cells (Choi and Soderlund, 2006). EPA has not classified synthetic pyrethroids, including deltamethrin, as endocrine disruptors. Typical symptoms of acute exposure are irritation of skin and eyes, severe headaches, dizziness, nausea, anorexia, vomiting, diarrhea, excessive salivation, and fatigue. Tremors and convulsions have been reported in severe poisonings. Inhaled deltamethrin has been shown to cause cutaneous paraesthesia (a burning, tingling, or stinging). However, these effects are generally reversible and disappear within a day of removal of the exposure (Barlow et al., 2001; WHO, 2004; ATSDR, 2003; IPCS, 1989, 1990). In animals, the critical effect is neurotoxicity (WHO, 2004).

Description of Data Quality and Quantity

Adequate dose-response studies on the toxicity of deltamethrin exist for oral, dermal, and inhalation exposures. Most are oral exposure studies (WHO, 2004). Several comprehensive reviews on the toxicity of deltamethrin have been prepared or updated in recent years:

- Environmental Health Criteria 97: Deltamethrin (IPCS, 1990)

- Health and Safety Guide No. 30: Deltamethrin Health and Safety Guide (IPCS, 1989)
- A review article by Barlow et al. (2001)
- Pesticide Information Profiles (PIP) for Deltamethrin (EXTOXNET, 1995)
- Data Sheets on Pesticides No. 50—Deltamethrin (WHO/FAO, n.d.)
- A Generic Risk Assessment Model for Insecticide Treatment and Subsequent Use of Mosquito Nets (WHO, 2004)
- Malaria Vector Control—Insecticides for Indoor Spraying (WHO/FAO, 2001)

EPA has developed quantitative human health benchmarks (acute and chronic oral RfDs, intermediate-term oral, and short-, intermediate-, and long-term dermal and inhalation benchmarks) for deltamethrin.

Summary Table

• Duration	• Route	• Benchmark Value	• Units	• Endpoint	• Reference
Acute, Intermediate, Chronic	**Inhalation**	**0.01**	**mg/kg/day**	**Oral NOAEL for clinical signs in dogs at 1 mg/kg/day with UF of 100 applied**	**U.S. EPA (2004)**
Acute	**Oral**	**0.01**	**mg/kg/day**	**Acute RfD based on neurological effects in rats**	**U.S. EPA (2004)**
Intermediate	**Oral**	**0.01**	**mg/kg/day**	**Oral NOAEL for clinical signs in dogs at 1 mg/kg/day with UF of 100 applied**	**U.S. EPA (2004)**
Chronic	**Oral**	**0.01**	**mg/kg/day**	**Chronic RfD based on clinical signs in dogs**	**U.S. EPA (2004)**
Acute, Intermediate, Chronic	**Dermal**	**10**	**mg/kg/day**	**Dermal NOAEL of 1000 mg/kg/day in rats with a UF of 100 applied**	**Barlow et al. (2001)**

For oral exposure, an acute RfD of 0.01 mg/kg/day was derived based on a NOAEL of 1 mg/kg/day for neurological effects (reduced motor activity) observed in rats exposed to deltamethrin (Crofton et al., 1995), with an uncertainty factor of 100 applied to account for interspecies and intrahuman variability (U.S. EPA, 2004). A chronic oral RfD of 0.01 mg/kg/day was derived based on a NOAEL of 1 mg/kg/day for clinical signs and reduced weight gain in dogs (study citation not provided), with an uncertainty factor of 100

applied (U.S. EPA, 2004). The chronic RfD is appropriate to use for intermediate-term exposures (U.S. EPA, 2004).

For inhalation exposures, the chronic RfD is also appropriate for short-, intermediate-, and long-term exposures (U.S. EPA, 2004).

For dermal exposure, a NOAEL of 1,000 mg/kg/day was identified in rats dermally exposed to deltamethrin for 21 days (study citation not provided). An uncertainty factor of 100 was applied to account for interspecies and intrahuman variability, for a dermal benchmark value of 10 mg/kg/day. This value is appropriate for all dermal exposure durations (Barlow et al., 2001). The large difference between the oral and dermal NOAELs is due to rapid absorption of deltamethrin from the gastrointestinal tract versus low dermal absorption (WHO, 2004; Barlow et al., 2001).

Insecticide Background

CASRN:	52918-63-5
Synonyms:	cyano(3-phenoxy-phenyl)methyl;2-(2,2dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate (CA); alpha-cyano-m-phenoxybenzyl,(1R,3R)-3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropanl-carboxylate, (S)-alpha-cyano-3-phenoxybenzyl (1R)-cis-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane-carboxylate, decamethrine, FMC 45498, NRDC 161, OMS 1998, RU 22974, RUP 987 (EXTOXNET, 1995; IARC, 1991; WHO/FAO, n.d.).
Chemical Group:	pyrethroid (PAN, 2005)
Registered Trade Names:	Products containing deltamethrin (NRDC 161 and RU 22974): Butoflin, Butoss, Butox, Cislin, Cislin 2.5% EC, Cislin 2.5% WP, Cislin RTU, Crackdown, Cresus, Decis, Decis-Prime, K-Othrin, K-Orthine, K-Otek, Kordon, Sadethrin (EXTOXNET, 1995; WHO/FAO, n.d.; ATSDR, 2003; IPCS, 1989; IARC, 1991; FPA, 2002).

Usage

Deltamethrin is used to combat pests on a variety of crops, including cotton, fruit, vegetables, coffee, maize, wheat, rapeseed, hops, and soybeans (ATSDR, 2003; EXTOXNET, 1995; IPCS, 1989, 1990). It is also used to control insects in stored grains, to protect cattle from infestation, and in public health applications. It may be applied to foods, field crops, gardens, orchards, and vineyards (WHO/FAO, n.d.). Public health uses include malaria control in Central America and Africa (IPCS, 1990). Deltamethrin belongs to the pyrethroid class of insecticides, which have long been used to control mosquitoes, human lice, beetles, and flies (ATSDR, 2003). For mosquito protection, it is used on bed nets and other materials that are dipped into the deltamethrin to protect the

user. All concentrated formulations of deltamethrin were restricted by EPA due to its potential toxicity to aquatic organisms, and it may only be purchased and used by certified applicators (ATSDR, 2003).

Formulations and Concentrations

Deltamethrin is available in technical grade (> 98 percent pure), suspension concentrate, emulsifiable concentrate (25–100 g/L), ultra-low-volume (ULV) concentrate (1.5–30 g/L), wettable powder (25–50 g/kg), flowable powder (7.5–50 g/L), dust powder (0.525 g/kg), and granules (0.5 and 1.0 g/kg) alone or combined with other pesticides (IPCS, 1989, 1990; WHO/FAO, n.d.). Deltamethrin that is marketed for use as a bed net treatment comes in a single 400 mg tablet form (WHO, 2004).

Shelf Life

In storage conditions at 40^{o}C, deltamethrin is stable to light, heat, and air for 6 months and to light and air for 2 years. It is most stable in acidic media and unstable in alkaline environments (EXTOXNET, 1995; IPCS, 1989, 1990; WHO/FAO, n.d.).

Degradation Products

Deltamethrin's major metabolites are free and conjugated Br_2CA, *trans*-hydroxymethyl-Br_2CA, and 3-(4-hydroxyphenoxy)benzoic acid formed by ester cleavage, oxidation, and conjugation (IPCS, 1990).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Deltamethrin is not expected to be mobile in soil, with a Koc ranging from 46,000 to 1,630,000 (HSDB, 2005). Additionally, it binds tightly to soil particles, is insoluble in water, and has low application rates (IPCS, 1989, 1990). Volatilization is a major environmental fate process from moist soils but this is lessened by its adsorption to soil. Another major fate process is biodegradation, with a half-life of several weeks to greater than 100 days (HSDB, 2005). As with other synthetic pyrethroids, deltamethrin degrades rapidly in soil and plants (IPCS, 1990). Degradation occurs within 1 to 2 weeks for soil, and no residues remain on plants after 10 days (EXTOXNET, 1995). Deltamethrin does not bioaccumulate in terrestrial systems (IPCS, 1990).

Fate and Transport in Aquatic Systems

Because deltamethrin binds tightly to soil and is practically insoluble in water, very little leaching into groundwater is expected. In pond water, deltamethrin was absorbed rapidly by sediment, uptake by plants, and evaporation (EXTOXNET, 1995). Volatilization is a major environmental fate process in surface waters but is lessened by soil adsorption. Deltamethrin breaks down quickly in water with reported half-lives of 2 to 4 hours. The estimated volatilization half-life in a model river is 30 hours, and in a model lake, 500 hours. In a model pond, the estimated volatilization half-life is 7 years if adsorption is

considered. Deltamethrin has a high potential to bioconcentrate in aquatic organisms. It has an estimated bioconcentration factor of 270. The reported estimated hydrolysis half-life was 36 years at pH 7 and 3.6 years at pH 8 (HSDB, 2005).

Human Health Effects

Acute Exposure

Effects/Symptoms

There are limited data on the acute toxicity of deltamethrin in humans. Acute effects in humans include irritability, headache, salivation, sweating, fever, anxiety, rapid heart beat, diarrhea, dyspnea, tinnitus, runny nose, vomiting, edema, hepatic microsomal enzyme induction, peripheral vascular collapse, serum alkaline phosphatase elevation, tremors, ataxia, convulsions leading to muscle fibrillation and paralysis, and death due to respiratory failure (EXTOXNET, 1995; WHO/FAO, n.d.; IPCS, 1990). Dermatitis is expected after dermal exposures, which often occur as a result of inadequate handling safety precautions during agricultural use (EXTOXNET, 1995; IPCS, 1990). Coma was caused within 15 to 20 minutes at oral exposure levels of 100 to 250 mg/kg (EXTOXNET, 1995). Facial paraesthesia is a common indicator of exposure of humans to high levels (WHO/FAO, n.d.).

In clinical studies in humans, slight irritation but no skin damage was reported in patch tests of deltamethrin put on faces of volunteers (IPCS, 1990). Acute occupational exposures to deltamethrin have resulted mostly in dermal symptoms including itching, burning, and paraesthesia. These are an early, reversible signs of exposure and are due to local, not systemic, exposures (Barlow et al., 2001; IPCS, 1990; EXTOXNET, 1995). Neurological signs such as headaches, dizziness, fatigue, nausea, anorexia, transient EEG changes, muscular fasciculation, and convulsions have also been reported following acute occupational exposures (Barlow et al., 2001; EXTOXNET, 1995). Loss of consciousness, muscle cramps, myosis, and tachycardia were reported in a 13-year-old girl who attempted suicide by ingesting 5 g of deltamethrin (200 mL of a 2.5% EC formulation). After appropriate medical intervention, she recovered completely within 48 hours. Only digestive and hepatic signs were observed in a 23-year-old man who attempted suicide by ingesting 1.75 g of deltamethrin (70 mL of a 2.5% EC formulation) (IPCS, 1990).

Animal studies have indicated that deltamethrin has low acute toxicity; however, this varies greatly depending on the route of administration and the vehicle used (WHO, 2004; Barlow et al., 2001). In acute exposure studies, the mouse is the species most susceptible to deltamethrin toxicity (WHO/FAO, n.d.). Reported oral LD_{50} values range from 19 to 34 mg/kg in mice, 52 to over 5,000 mg/kg in male rats, 30 to 139 mg/kg in female rats, and over 300 mg/kg in dogs (EXTOXNET, 1995; IPCS, 1990; WHO/FAO, n.d.; WHO/FAO, 2001; Barlow et al., 2001). Following acute dermal exposure, the reported LD_{50} is greater than 2,940 mg/kg in rats and dogs and greater than 2,000 mg/kg in rabbits (EXTOXNET, 1995; IPCS, 1990; WHO/FAO, n.d.; WHO/FAO, 2001). The reported inhalation 6-hour LD_{50} in rats is 600 mg/m^3 (IPCS, 1990).

Hyperactivity and hypersensitivity are general characteristics of pyrethroid poisonings. However, the signs of acute deltamethrin poisoning are different from other pyrethroids in that it produces a unique set of effects that occur in a specific sequence in animals. They begin with chewing, pawing, and burrowing behavior; excessive salivation; and coarse tremors advancing to choreoathetosis and sometimes terminal clonic seizures. Rolling convulsions are especially characteristic of deltamethrin poisoning (WHO/FAO, n.d.; EXTOXNET, 1995). In rabbits and guinea pigs, no primary skin irritation or sensitization was observed following acute dermal exposure to 0.5 g/animal, although transitory ocular irritation was seen in rabbits without immediate rinsing (EXTOXNET, 1995; WHO/FAO, n.d.). However, another study reported skin irritation in rats and guinea pigs (EXTOXNET, 1995). Cardiovascular effects include a rapid fall in blood pressure, severe bradycardia, and EKG changes in intravenously exposed dogs (WHO/FAO, n.d.)

Treatment

Deltamethrin and its metabolites can be detected in blood and urine; however, the methods are not practical given how quickly these compounds are broken down in the body (ATSDR, 2003; WHO/FAO, n.d.). Levels of the degradation products bromide, cyanide, and 3-phenoxybenzyl in urine may be useful indicators in cases of severe toxicity (WHO/FAO, n.d.).

There are no antidotes for deltamethrin exposure (IPCS, 1989; WHO/FAO, n.d.). Treatment depends on the symptoms of the exposed person. If a person exhibits signs of typical pyrethroid toxicity following deltamethrin exposure (nausea, vomiting, shortness of breath, tremors, hypersensitivity, weakness, burning, or itching), they should immediately remove any contaminated clothing. Any liquid contaminant on the skin should be soaked up and the affected skin areas cleaned with alkaline soap and warm water. Eye exposures should be treated by rinsing with copious amounts of 4 percent sodium bicarbonate or water. Contact lenses should be removed. Vomiting should not be induced following ingestion exposures, but the mouth should be rinsed. The person should be kept calm and medical attention should be sought as quickly as possible (PAN, 2005; WHO/FAO, n.d.). Medical personnel will treat severe intoxications with a sedative and anticonvulsant (IPCS, 1989). Ingestion of large amounts of deltamethrin should be treated with gastric lavage using a 5 percent bicarbonate solution followed by powdered activated charcoal. Skin irritation may be treated with a soothing agent and exposure to light should be avoided (WHO/FAO, n.d.)

Chronic Exposure

Noncancer Endpoints

Little data are available for humans following chronic exposures to deltamethrin; however, it is not likely to cause long-term problems when used under normal conditions. In humans, suspected chronic effects include choreoathetosis, hypotension, prenatal damage, and shock (EXTOXNET, 1995). Chronic occupational exposure to deltamethrin

caused skin and eye irritation; however, no long-term effects were seen (Barlow et al., 2001; EXTOXNET, 1995). After 1 year of using bednets treated with a target does of 25 mg/m^2 deltamethrin, skin irritation occurred one week after treatment, and runny nose and sneezing in the first days of use were reported for target does of 10–30 mg/m^2. No chronic effects were reported (Barlow et al., 2001). Data in animals indicate that oral exposure to deltamethrin is not highly toxic (Barlow et al., 2001; EXTOXNET, 1995; WHO/FAO, n.d.).

In studies of reproductive toxicity in rats, no effects were seen on male or female fertility; number of implantation sites; litter size at birth; or pre- or postnatal survival in rats, mice, and rabbits (Barlow et al., 2001). No effects on reproduction were observed in a 3-generation rat study, but slight embryotoxicity was seen (EXTOXNET, 1995; Barlow et al., 2001). Dose-related decreases in maternal weight gain were seen in pregnant mice dosed with deltamethrin on gestational days 7 to 16. However, no effect on the number of implants, fetal mortality, fetal weight, or malformations was seen (EXTOXNET, 1995). Deltamethrin is not teratogenic in mice, rats, or rabbits at doses that produced clinical signs of toxicity in pregnant dams (Barlow et al., 2001; EXTOXNET, 1995; WHO/FAO, n.d.). Mutagenicity studies in mice, rats, and rabbits indicate that deltamethrin is not mutagenic (Barlow et al., 2001; EXTOXNET, 1995; WHO/FAO, n.d.)

Cancer Endpoints

IARC (1991) has classified deltamethrin as a Group 3 chemical, "not classifiable as to its carcinogenicity in humans." No human carcinogenicity data are available for deltamethrin (IARC, 1991; EXTOXNET, 1995). Long-term dietary studies in rats, mice, and dogs did not find evidence of carcinogenicity (IPCS, 1990). Microbial, mammalian cell, and *in vivo* mammalian mutagenicity studies support the evidence that deltamethrin is not carcinogenic (WHO/FAO, n.d.).

Toxicokinetics

Deltamethrin metabolism has not been well studied in humans. It is expected to be similar to metabolism in rodents (Barlow et al., 2001). Deltamethrin is readily absorbed via the gastrointestinal tract, inhalation, and less so through intact skin. The rate at which it is absorbed depends on the carrier or solvent used. Once absorbed, deltamethrin is readily metabolized and excreted (Barlow et al., 2001; IPCS, 1989, 1990; WHO/FAO, n.d). Similar metabolism and excretion patterns have been observed in extensive studies in rats, mice, and cows. Deltamethrin is metabolized in the liver by microsomal esterases and oxidases. It is distributed to the gut wall and liver. The parent compound is cleaved into cyclopropanecarboxylic acid and 3-phenoxybenxyl alcohol, which is then oxidized to 3-phenolbezoic acid. 3-Phenoxybenxoic acid is the major excretion compound. Hydroxylation of this moiety can occur before or after hydrolysis (Barlow et al., 2001; WHO/FAO, n.d.; EXTOXNET, 1995; IPCS, 1990). In rats, approximately 13 to 21 percent of deltamethrin is eliminated unchanged in the urine and feces within 2 to 4 days; however, the metabolites of the cyano substituent are eliminated more slowly. The half-

life of deltamethrin in the brains of rats is 1 to 2 days. Levels of the metabolites remain higher, especially in the skin, stomach, and body fat, with a half-life of 5 days in body fat (Barlow et al., 2001; EXTOXNET, 1995). Following oral exposure, deltamethrin is completely eliminated within 6 to 8 days (WHO/FAO, n.d.). In feces, 7 to 15 percent of the oral dose is found as the parent compound and its hydroxylates; the hydrolysis products are mainly excreted in the urine. A smaller amount is found in the skin as thiocyanate (WHO/FAO, n.d.)

Ecological Effects

Acute Exposure

Toxicity in Non-Targeted Terrestrial Organisms

Deltamethrin, like other pyrethroids, is very unlikely to harm terrestrial organisms other than its targets, such as mosquitoes and other pests (EXTOXNET, 1996). It has a very low toxicity in birds (IPCS, 1990; IPCS, 1989). Oral LD_{50} values range from greater than 1,800 mg/kg in grey partridge to greater than 4,000 mg/kg in ducks (IPCS, 1989). An 8-hour LD_{50} of more than 4,640 mg/kg diet was reported in ducks, and the 8-hour LD_{50} in quail was greater than 10,000 mg/kg diet (EXTOXNET, 1995). As with other pyrethroid insecticides, deltamethrin is extremely toxic to honey bees, with a 24-hour LD_{50} of 0.079 for technical deltamethrin and 0.4 µg ai/bee for the EC formulation. The contact LD_{50} for bees is reported to be 0.05 µg ai/bee. However, in real-life applications, serious effects have not been noticed due to low application rates and lack of environmental persistence. Deltamethrin is also very toxic to *Typhodromum pyri*, a predatory mite; *Encarsia Formosa*, a parasitic wasp; and spiders (EXTOXNET, 1995; IPCS, 1990).

Toxicity in Non-Targeted Aquatic Systems

In the laboratory, deltamethrin is very toxic to fish and aquatic arthropods. However, under normal use conditions in the environment, no deleterious effects have been observed due to its low application rates and lack of persistence (EXTOXNET, 1995; IPCS, 1990). The reported 96-hour LC_{50} value for technical deltamethrin ranges from 0.39 µg/L in rainbow trout to 3.5 µg/L in *Sarotherodon mossambicus*. For the emulsifiable concentrate, LC_{50} values range from 0.59 µg/L in *Salmo salar* (96-hour) to 4.7 µg/L in brown trout (48-hour). For ultra-light volume concentrate, LC_{50} value ranges from 82 µg/L in bleak to 210 µg/L in common carp. In Daphnia, the reported 48-hour LC_{50} for technical deltamethrin is 5 µg/L (IPCS, 1990). Deltamethrin can accumulate in fish. Fathead minnows accumulated deltamethrin without any effect on mortality (EXTOXNET, 1995). Deltamethrin is also highly toxic to aquatic macroinvertebrates such as lobster (IPCS, 1989).

Chronic Exposure

Due to low application rates and low persistence of deltamethrin in both terrestrial and aquatic environments, serious adverse effects are not anticipated from chronic exposures (HSDB, 2005)

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APPENDIX 8 : Toxicological Profile for Lambda-Cyhalothrin (from USAID PEA for IVM)

CAS Registry Number 91465-08-6

Summary

Chemical History

The synthetic pyrethroid lambda-cyhalothrin is a relatively new addition to this insecticide group. It was developed in 1977 and consists of one enantiomeric (i.e., nonsuperimposable, mirror image) pair of isomers and is a more biologically active form than cyhalothrin (IPCS, 1990a). It is used in the control of pests, including mosquitoes, in agricultural and public and animal health settings (EXTOXNET, 1996). The risks of occupational exposures and exposures to the general public are expected to be very low if proper precautions are followed. At the recommended application rates, lambda-cyhalothrin is not expected to cause adverse environmental effects. As is typical of synthetic pyrethroids, the typical symptoms for acute exposure are neurological and include tingling, burning, or numbness sensations (particularly at the point of skin contact), tremors, incoordination of movements, paralysis or other disrupted motor functions. These effects are generally reversible because lambda-cyhalothrin beaks down rapidly in the body (IPCS, 1990a; EXTOXNET, 1996). EPA has not classified synthetic pyrethroids, including lambda-cyhalothrin, as endocrine disruptors.

Description of Data Quality and Quantity

Lambda-cyhalothrin and cyhalothrin are basically the same chemical and differ only in their stereo chemistry and the number of isomers in each mixture (U.S. EPA, 2002a). Cyhalothrin consists of four stereo isomers while lambda-cyhalothrin is a mixture of only two isomers. The two lambda-cyhalothrin isomers are contained in cyhalothrin and they represent 40 percent of the cyhalothrin mixture. The majority of toxicity studies available were conducted using cyhalothrin as the test chemical. Evidence based on subchronic studies in rats suggests that the two mixtures are not biologically different with respect to their mammalian toxicity (U.S. EPA, 2002a).

EPA and ATSDR have developed quantitative human health benchmarks for cyhalothrin (EPA's acute and chronic oral RfDs and short-, intermediate-, and long-term dermal and inhalation benchmarks, and ATSDR's acute and intermediate oral MRLs).

Recommended resources include:

- Environmental Health Criteria 99: Cyhalothrin (IPCS, 1990a)
- Toxicological Profile for Pyrethrin and Pyrethroids (ATSDR, 2003a)
- Pesticide Information Profiles (PIP) for Lambda-cyhalothrin (EXTOXNET, 1996)
- Specifications and Evaluations for Public Health Pesticides for Lambda-cyhalothrin (WHO, 2003)

– Integrated Risk Information System (IRIS) summary review for cyhalothrin (U.S. EPA, 2005b).

Summary Table

• Duration	• Route	• Benchmark Value	• Units	• Endpoint	• Reference
Acute, Intermediate, Chronic	Inhalation	0.0008	mg/kg/day	Inhalation NOAEL for neurotoxicity in rats at 0.08 mg/kg/day (0.3 µg/L) with uncertainty factor (UF) of 100 applied	U.S. EPA (2002b)
Acute	Oral	0.005	mg/kg/day	Acute RfD based on neurotoxicity in dogs	U.S. EPA (2002b)
Intermediate	Oral	0.001	mg/kg/day	Adopt chronic RfD for intermediate duration	
Chronic	Oral	0.001	mg/kg/day	Chronic RfD based on neurological effects in dogs	U.S. EPA (2002b)
Acute, Intermediate, Chronic	Dermal	0.1	mg/kg/day	Dermal NOAEL in rats with UF of 100 applied	U.S. EPA (2002b)

For inhalation exposure, a NOAEL of 0.3 µg/L (0.08 mg/kg/day) was identified for neurotoxicity, decreased body weight, and slight changes in urinalysis parameters in rats exposed to lambda-cyhalothrin via inhalation for 21 days. An uncertainty factor of 100 was applied, for an inhalation benchmark value of 0.0008 mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 2002a).

For oral exposure, an acute RfD of 0.005 mg/kg/day was derived based on a NOAEL of 0.5 mg/kg/day for neurotoxicity (ataxia) observed in dogs exposed to lambda-cyhalothrin, with an uncertainty factor of 100 applied (U.S. EPA, 2002a). A chronic oral RfD of 0.001 mg/kg/day was derived based on a NOAEL of 0.1 mg/kg/day for gait abnormalities in dogs exposed to lambda-cyhalothrin, with an uncertainty factor of 100 applied (U.S. EPA, 2002a). The chronic RfD was adopted to represent intermediate exposures.

For dermal exposure, a NOAEL of 10 mg/kg/day was identified in rats dermally exposed to lambda-cyhalothrin for 21 days. An uncertainty factor of 100 was applied, for a dermal benchmark value of 0.1 mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 2002a).

Background

CAS #:	91465-08-6
Synonyms:	none (WHO, 2003)
Chemical Group:	synthetic pyrethroid
Registered Trade Names:	Charge, Excaliber, Grenade, Karate, Hallmark, Icon, OMS 0321, PP321, Saber, Samurai, Sentinel, and Matador (EXTOXNET, 1996)

Usage

Lambda-cyhalothrin is a synthetic pyrethroid (IPCS, 1990a) most commonly used for pest control, especially mosquitoes; the insecticide is usually sprayed on interior walls or used to impregnate bed nets (EXTOXNET, 1996). This insecticide is a restricted use pesticide, so it can be purchased and used only by certified applicators (EXTOXNET, 1996). Lambda-cyhalothrin has adulticidal, ovicidal, and larvicidal activity (IPCS, 1990a). In addition to mosquitoes, it is effectively used to control: cockroaches, ticks, fleas, aphids, Colorado beetles, cutworms and butterfly larvae (EXTOXNET, 1996; IPCS, 1990a).

Formulations and Concentrations

There are several formulations for lambda-cyhalothrin, each containing varying amounts of the active ingredient. The typical formulations for lambda-cyhalothrin are

- Technical grade (not less than 810 g/kg lambda-cyhalothrin)
- Emulsifiable concentrate (at 20 +/- 2^{o}C: up to 25 g/l +/- 15% declared content; > 25 g/l to 100 g/l +/- 10% of declared content)
- Wettable powder (up to 25 +/- 15% of declared content: > 25-100 +/- 10 % of declared content)
- Slow release capsule suspension (at 20 +/- 2^{o}C: up to 25 g/l +/- 15% declared content).

The main formulation used for agricultural purposes is the emulsifiable concentrate. The wettable powder formulation is mainly used for public health reasons (WHO, 2003). Lambda-cyhalothrin is commonly mixed with buprofezin, pirimicarb, dimethoate, or tetramethrin, resulting in the usual product (WHO, 2003; EXTOXNET, 1996).

Shelf-Life

This insecticide, like many others, needs to be stored in a cool, dry, and well-ventilated facility (IPCS, 1990a). Lambda-cyhalothrin should not be stored or transported with foodstuffs and household supplies to the limit the potential for cross contamination and human exposure (IPCS, 1990a).

Degradation Products

In the environment, lambda-cyhalothrin degrades through biological and photochemical reactions (IPCS, 1990a). Biological reactions are thought to be more important. Lambda-cyhalothrin will degrade rapidly in soils, remain relatively stable in water, and is usually not found in air due to its low vapor pressure. The main degradation products are 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimenthyl-cyclopropanecorboxylic acid, the amide derivative of cyhalothrin, and 3-phenoxybenzoic acid. The degradation is a result of the cleavage of the ester linkage to give two main degradation products, which are further degraded to carbon dioxide. Lambda-cyhalothrin degrades fairly quickly in alkaline conditions, in comparison to neutral or acidic media. It is strongly absorbed in soils and sediments with little tendency for bioaccumulation (IPCS, 1990a).

In water, lambda-cyhalothrin is stable at pH 5. Racemization at the alpha-cyano carbon occurs at pH 7 to pH 9, creating a one to one mixture of enantiomer pairs A and B. The ester bond is hydrolyzesd at pH 9. Additionally, a moderately high rate of photolysis is seen in dilute aqueous solutions (IPCS, 1990a).

Environmental Behavior

Fate and Transport in Terrestrial Systems

In most soil types, lambda-cyhalothrin is not very mobile. Its high reported organic carbon partitioning coefficient (Koc) value reflects its strong affinity for soil. It is retained more in soil with low sand content or high organic matter content (EXTOXNET, 1996). Studies have shown that lambda-cyhalothrin and its degradation products do not leach through soils into groundwater nor are they transported to other compartments of the environment following agricultural uses (IPCS, 1990a).

Lambda-cyhalothrin is moderately persistent in soil with a soil half-life ranging from 4 to 12 weeks. A longer in-field half-life of approximately 30 days is reported for most soils (EXTOXNET, 1996). The half-life is variable because it is dependent on the availability of sunlight, which speeds degradation (IPCS, 1990a).

Fate and Transport in Aquatic Systems

Lambda-cyhalothrin is not expected to be prevalent in surface or groundwater because it has extremely low water solubility and binds tightly to soil. Lambda-cyhalothrin enters surface water largely through surface runoff. Even so, lambda-cyhalothrin is most likely to stay bound to sediment and settle to the bottom. Studies have shown that hydrolysis of lambda-cyhalothrin occurs rapidly at a pH of 9 but not at a pH of 7, though isomerization was observed at a pH of 7. No hydrolysis or isomerization was seen at a pH of 5.

Human Health Effects

Acute Exposure

Effects/Symptoms

No data on accidental human poisonings have been reported. Additionally, no quantitative epidemiological studies are available (IPCS, 1990a). However, under normal use conditions, acute exposure to lambda-cyhalothrin is not expected to represent a hazard in humans. Transient skin sensations such as periorbital facial tingling and burning have been reported following direct skin exposure in laboratory workers and manufacturing workers handling synthetic pyrethroids. This sensation is possibly due to repetitive firing of sensory nerve terminals and usually lasts for a few hours up to 72 hours post-exposure. No neurological abnormalities have been observed upon medical examination (IPCS, 1990a). Lambda-cyhalothrin can irritate the eyes, skin, and upper respiratory tract. Additionally, oral exposure can cause neurological effects, including tremors and convulsions. Ingestion of liquid formulations may result in aspiration of the solvent into the lungs, resulting in chemical pneumonitis. Based on the acute oral toxicity data, lambda-cyhalothrin has been classified as "Moderately Hazardous" (Class II) (WHO, 2003).

In animals, the technical form of lambda-cyhalothrin is moderately toxic; however, toxicity depends on both the formulation (concentration of active ingredient and solvent vehicle) and the route of exposure (EXTOXNET, 1996). Laboratory data indicate that acute oral exposure to lambda-cyhalothrin is moderately to highly toxic in rats and mice and that mice are more susceptible to the toxic effects than rats (WHO, 2003). The oral LD_{50} for lambda-cyhalothrin in corn oil has been reported to range from 56 mg/kg in female rats up to 79 mg/kg in males. A similar LD_{50} is reported for technical grade lambda-cyhalothrin in rats at 64 mg/kg (EXTOXNET, 1996). The oral LD_{50} in mice is reported as 20 mg/kg (IPCS, 1990a). The effects of acute oral exposure are typical of pyrethroid toxicity, including abnormal motor function (WHO, 2003).

Acute inhalation exposures are also highly toxic to animals (WHO, 2003). In the formulated product Karate, the 4-hour LC_{50} in rats is reported as 0.175 mg/L in females and 0.315 mg/L in males (EXTOXNET, 1996).

Lambda-cyhalothrin is less toxic in animals via acute dermal exposure (WHO, 2003). In rats, dermal LD_{50}s of 632 mg/kg for males and 696 mg/kg for females have been reported for the technical product. Studies have also shown the technical product produced no skin irritation to rabbits and is nonsensitizing in guinea pigs. Mild eye irritation was observed in rabbits. However, dermal exposure to the formulated product Karate causes severe primary skin irritation in rabbits and mild skin sensitization in guinea pigs. Other acute dermal effects are related to the nervous system and include tingling, burning sensations, or numbness (EXTOXNET, 1996).

Treatment

Lambda-cyhalothrin and its breakdown products can be detected in blood and urine, but only within a few days of the last exposure (ATSDR, 2003a). Dermal exposure to lambda-cyhalothrin exposure should be treated by removing contaminated clothing and washing the exposed areas with soap and water. If lambda-cyhalothrin gets into the eyes, they should be rinsed with water for several minutes. Contact lenses should be removed if possible and medical attention should be sought. Vomiting should not be induced following ingestion of lambda-cyhalothrin, and medical attention sought. Inhalation exposures require removal to fresh air and rest (IPCS, 1990b)

Chronic Exposure

Noncancer Endpoints

Based on the available data, it is unlikely that lambda-cyhalothrin would cause chronic effects in humans under normal conditions. No specific target organs have been identified in the available chronic studies (EXTOXNET, 1996). Decreased body weight gain and mild neurological effects have been observed in some animal studies (EXTOXNET, 1996; IPCS, 1990a).

Lambda-cyhalothrin is not expected to be teratogenic, mutagenic, or genotoxic in humans. Studies in animals have found no teratogenic or fetotoxic effects in rats or rabbits. Additionally, it was negative in five test strains in the Ames mutagenicity assay (IPCS, 1990a). No mutagenic or genotoxic effects were seen in other in vitro cytogenic assays or chromosomal aberration tests (EXTOXNET, 1996).

Cancer Endpoints

Data on the carcinogenic potential suggest that lambda-cyhalothrin is not carcinogenic in humans. In rats and mice exposed to cyhalothrin, no carcinogenic effects were observed. EPA has classified lambda-cyhalothrin as a Group D chemical, “not classifiable as to human carcinogenicity” (U.S. EPA, 2002a).

Toxicokinetics

Animal studies have been have been conducted in various species to investigate the toxicokinetics of cyhalothrin and lambda-cyhalothrin. Oral cyhalothrin is readily absorbed, metabolized thoroughly, and eliminated as polar conjugates in the urine (IPCS, 1990a). Studies with lambda-cyhalothrin have shown that it also is rapidly metabolized into less toxic water-soluble compounds and excreted in the urine and feces (EXTOXNET, 1996). In mammals, cyhalothrin is metabolized as a result of ester cleavage to cyclopropanecarboxylic acid and 3-phenoxybenzoic acid, and eliminated as conjugates. Tissue levels decline after exposure stops and residues in the body are low (IPCS, 1990a).

Ecological Effects

Acute Exposure

Toxicity to Non-Target Terrestrial Organisms

Like other synthetic pyrethroids, lambda-cyhalothrin has been shown to be toxic to honey bees but has little effect on birds and domestic animals (EXTOXNET, 1996). In birds, the toxicity of lambda-cyhalothrin ranges from nontoxic to slightly toxic. Oral LD_{50} values in mallard duck are reported as greater than 3,950 mg/kg. Dietary LC_{50} values of 5,300 ppm are reported in bobwhite quail. Additionally, there is no evidence of lambda-cyhalothrin accumulation in bird tissues or in eggs (EXTOXNET, 1996). Lambda-cyhalothrin has shown mixed toxicity to other non-target terrestrial organisms. It is extremely toxic to honey bees, with a contact LD_{50} of 0.9 µg/bee and an oral LD_{50} of 38 ng/bee (EXTOXNET, 1996), but has no adverse effect on earthworms (IPCS, 1990a).

Toxicity to Aquatic Organisms

Like other synthetic pyrethroids, lambda-cyhalothrin has been shown to be quite toxic under laboratory conditions to both cold and warm water fish. Acute 96-hr LC_{50} values range from 0.2 to 1.3 µg/L. It is also highly toxic to aquatic arthropods with 48-hr LC_{50} ranging from 0.008 to 0.4 µg/L (IPCS, 1990a; WHO, 2003). In the field, however, these effects are not likely to occur under the recommended use scenarios (WHO, 2003). No serious adverse effects have been observed due to the low rates of application and the lack of persistence in the environments (IPCS, 1990a). Accumulation studies have shown that although bioaccumulation is possible in fish, it is unlikely due to the rapid metabolism of lambda-cyhalothrin (EXTOXNET, 1996).

Chronic Exposure

Toxicity to Non-Target Terrestrial Organisms

No data were located on the chronic toxicity to non-target terrestrial organisms.

Toxicity to Aquatic Organisms

No data for chronic duration exposures of aquatic organisms were located; however, a subchronic study in Sheepshead minnow embryos and larvae showed no effect on hatchability or larval survival when exposed to up to 0.25 µg/L through 28 days post hatching. A significant effect on larval weight was observed at 0.38 µg/L. In an additional subchronic exposure study, survival, growth, and reproduction of *Daphnia magna* were seen at 40 ng/L but not at 2.5 ng/L (IPCS, 1990a).

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APPENDIX 9 : Pyrethroids and Pyrethroid Poisoning Treatment (from USAID PEA for IVM)

These modern synthetic insecticides are similar chemically to natural pyrethrins, but modified to increase stability in the natural environment. They are now widely used in agriculture, in homes and gardens, and to treat ectoparasitic disease.

Pyrethroids are formulated as emulsifiable concentrates, wettable powders, granules, and concentrates for ultra low volume application. They may be combined with additional pesticides (sometimes highly toxic) in the technical product or tank-mixed with other pesticides at the time of application.

Toxicology

Certain pyrethroids exhibit striking neurotoxicity in laboratory animals when administered by intravenous injection, and some are toxic when ingested orally. However, systemic toxicity by inhalation and dermal absorption is low. Although limited absorption may account for the low toxicity of some pyrethroids, rapid biodegradation by mammalian liver enzymes (ester hydrolysis and oxidation) is probably the major factor responsible for this phenomenon. Most pyrethroid metabolites are promptly excreted (at least in part) by the kidney. Fatalities have occurred rarely after pyrethroid exposure, usually following ingestion (He et al., 1989).

The most severe toxicity is to the central nervous system, although more uncommon. Seizures have been reported in severe cases of pyrethroid intoxication. Seizures are more common with exposure to the more toxic cyano-pyrethroids, which include fenvalerate, flucythrinate, cypermethrin, deltapermethrin, and fluvalinate. There are no reports in the literature of seizures in humans from exposure to permethrin.

Apart from central nervous system toxicity, some pyrethroids do cause distressing paresthesia when liquid or volatilized materials contact human skin. Again, these symptoms are more common with exposure to the pyrethroids whose structures include cyano-groups. Sensations are described as stinging, burning, itching, and tingling, progressing to numbness. The skin of the face seems to be most commonly affected, but the hands, forearms, and neck are sometimes involved. Sweating, exposure to sun or heat, and applying water increase the disagreeable sensations. Sometimes the effect is noted within minutes of exposure, but a 1-2 hour delay in the appearance of symptoms is more common. Sensations rarely persist more than 24 hours. Little or no inflammatory reaction is apparent where the paresthesia is reported; the effect is presumed to result from pyrethroid contact with sensory nerve endings in the skin. The paraesthesia is not allergic in nature, although sensitization and allergic responses have been reported as an independent phenomenon with pyrethroid exposure. Race, skin type, or disposition to allergic disease does not affect the likelihood or severity of the reaction.

Persons treated with permethrin for lice or flea infestations sometimes experience itching and burning at the site of application, but this is chiefly an exacerbation of sensations caused by the parasites themselves, and is not typical of the paraesthesia described above.

Other signs and symptoms of toxicity include abnormal facial sensations, dizziness, salivation, headache, fatigue, vomiting, diarrhea, and irritability to sound and touch. In more severe cases, pulmonary edema and muscle fasciculations can develop. Due to the inclusion of unique solvent ingredients, certain formulations of fluvalinate are corrosive to the eyes. Pyrethroids are not cholinesterase inhibitors. However, there have been some cases in which pyrethroid poisoning has been misdiagnosed as organophosphate poisoning, due to some of the similar presenting signs, and some patients have died from atropine toxicity.

Specific toxicology for the 5 recommended pyrethroids is described below.

Alpha-cypermethrin

Alpha-cypermethrin is a synthetic pyrethroid.

Toxicology

Absorption may occur to some extent after inhalation or dermal exposure but, as with other pyrethroids, alpha-cypermethrin is rapidly metabolized and excreted from the body.

Mode of action: Neurotoxicity through disruption of nerve fiber impulse transmission.

Cyfluthrin

Cyfluthrin is a synthetic pyrethroid with very low vapor pressure. It is readily hydrolyzesd under alkaline conditions, but quite stable at pH 7 or below. Cyfluthrin is very strongly adsorbed to organic matter and can be classified as immobile in soil.

Toxicology

The acute toxicity of cyfluthrin varies depending on the vehicle. Toxicity is high by ingestion but cyfluthrin has poor skin penetration. Although as other α-cyano-pyrethroids, it may irritate the eye and skin, 10 percent WP cyfluthrin is not irritating to the skin and only slightly irritating to mucous membranes.

Absorption route: After oral administration, about 90 percent was absorbed in the intestine. Absorption after inhalation is also possible. Dermal absorption is very low.

Mode of action: Cyfluthrin acts upon the peripheral nervous system as well as on regions of the central nervous system (e.g., certain binding sites—GABA-receptors—in the brain).

Deltamethrin

Deltamethrin is a synthetic pyrethroid of the alpha-cyano group. It is related to cypermethrin and lambda-cyhalothrin, and is a single isomer pyrethroid. Deltamethrin

has been used in malaria control since the late 1970s, and has been impregnated in bednets or curtains and used for indoor residual spraying in spite of its marked excito-repellency, which in some situations may be an advantage as it reduces human-vector contact.

Deltamethrin is used at dosages of 10-25 mg/m^2 giving a residual effect of 3-6 months. Protective clothing for spraymen should consist of overalls (washed daily), canvas or rubber boots, and hats.

Toxicology

Deltamethrin is primarily absorbed from the gastrointestinal tract, but also by inhalation of spray mist.

Mode of action: A neurotoxin, acting primarily on the basal ganglia of the central nervous system, causing repetitive nerve action.

Etofenprox

Etofenprox is a synthetic non-ester pyrethroid with high vapor pressure and low water solubility. Etofenprox is the insecticide with lowest acute toxicity to mammals of those recommended for indoor residual spraying. It is used as a WP 20 percent formulation, at a dosage of 100-300 mg/m^2 giving a residual effect of 3-6 months.

Toxicology

Absorption route: Etofenprox may be absorbed from the gastrointestinal tract or through the intact skin.

Mode of action: Etofenprox disturbs nerve impulses in insect nerve axons.

Lambda-cyhalothrin

Lambda-cyhalothrin is a synthetic pyrethroid, of the alpha-cyano group, with a core (-CCOOCHCN-), as in alpha-cypermethrin and deltamethrin. Lambda-cyhalothrin has low vapor pressure, is essentially insoluble in water, and has low volatility. It is available in WP formulation and is used at a dosage of 20-30 mg/m^2 giving a residual effect of 3-6 months.

Toxicology

Absorption route: Lambda-cyhalothrin may be absorbed through the gastrointestinal tract, by inhalation, or through the skin. Skin absorption of lambda-cyhalothrin is very low and no systemic effects from skin absorption have been described. Dermal and inhalational exposures usually have mild or no adverse effects. Following substantial ingestion, patients may develop coma, convulsions, and severe muscle fasciculations, and may take several days and occasionally weeks to recover. No known fatalities have been reported after lambda-cyhalothrin exposure.

Mode of action: Lambda-cyhalothrin's mode of action is the same as that of other alpha-cyano pyrethroids, primarily affecting the sodium channels in the nerve membrane and causing a long-lasting prolongation of the transient increase in sodium permeability of the membrane during excitation.

Symptoms of poisoning

In normal use, only local skin reactions have been reported. Any pyrethroid reaching the systemic circulation will be metabolized rapidly to much less toxic metabolites. The risk of toxicity of any kind to humans exposed by the usual routes is extremely remote, even with frequent exposure to the low concentrations used for malaria control. Systemic toxicity has not been seen in users, except on very rare occasions when few precautions were taken during packaging of pyrethroids and the victim's whole body was subjected to repeated and often prolonged exposure through soaked clothing.

Nevertheless, if ingested, these products may produce nausea, vomiting, cough, respiratory distress, and convulsions.

The field use of pyrethroids in the recommended concentrations, accompanied by the normal precautions for insecticide use, poses little or no hazard to applicators. Skin reactions such as pruritus, tautness and reddening of the facial skin, partial facial paraesthesia, and signs of irritation in the oropharyngeal cavity or coughing, especially when combined with increased sensitivity to touch stimuli, may be signs of dermal contact or inhalative exposure. These dermal sensations are direct and transitory effects on sensory nerve endings and are not the result of a primary skin irritation. Toxicologically, these are useful characteristics, as they provide an early indication of exposure.

After breathing in the insecticide spray mist, there may be irritation of respiratory mucous membranes with coughing and sneezing.

Treatment by Medical Professional

- 1. **Skin decontamination.** Wash skin promptly with soap and water. If irritant or paresthesia occurs, obtain treatment by a physician. Because volatilization of pyrethroids apparently accounts for paresthesia affecting the face, strenuous measures should be taken (ventilation, protective face mask and hood) to avoid vapor contact with the face and eyes. Vitamin E oil preparations (dL-alpha tocopheryl acetate) are uniquely effective in preventing and stopping the paresthesia. They are safe to apply to the skin under field conditions. Corn oil is somewhat effective, but possible side effects with continuing use make it less suitable. Vaseline is less effective than corn oil. Zinc oxide actually makes the reaction worse.
- 2. **Eye contamination.** Some pyrethroid compounds can be very corrosive to the eyes. Extraordinary measures should be taken to avoid eye contamination. The eye should be treated immediately by prolonged flushing of the eye with copious amounts of clean water or saline. If irritation persists, obtain professional ophthalmologic care.

- 3. **Gastrointestinal decontamination.** If large amounts of pyrethroids, especially the cyano-pyrethroids, have been ingested and the patient is seen soon after exposure, consider gastrointestinal decontamination. Based on observations in laboratory animals and humans, large ingestions of allethrin, cismethrin, fluvalinate, fenvalerate, or deltamethrin would be the most likely to generate neurotoxic manifestations.
- If only small amounts of pyrethroid have been ingested, or if treatment has been delayed, oral administration of activated charcoal and cathartic probably represents optimal management. Do not give cathartic if patient has diarrhea or an ileus.
- 4. **Other treatments.** Several drugs are effective in relieving the pyrethroid neurotoxic manifestations observed in deliberately poisoned laboratory animals, but none has been tested in human poisonings. Therefore, neither efficacy nor safety under these circumstances is known. Furthermore, moderate neurotoxic symptoms and signs are likely to resolve spontaneously if they do occur.
- 5. **Seizures.** Any seizures should be treated as outlined in the general principles for management of acute poisoning.

Section 2: General Principles in the Management of Acute Pesticide Poisonings

Skin Decontamination

Decontamination must proceed concurrently with whatever resuscitative and antidotal measures are necessary to preserve life. Shower patient with soap and water, and shampoo hair to remove chemicals from skin and hair. If there are any indications of weakness, ataxia, or other neurologic impairment, remove the victim's clothing, have the victim lie down, and give the victim a complete bath and shampoo using copious amounts of soap and water. Check for pesticide sequestered under fingernails or in skin folds and wash these areas.

Flush contaminating chemicals from eyes with copious amounts of clean water for 10-15 minutes. If eye irritation is present after decontamination, ophthalmologic consultation is appropriate.

Persons attending the victim should avoid direct contact with heavily contaminated clothing and vomitus. Contaminated clothing should be promptly removed, bagged, and laundered before returning to the patient. Shoes and other leather items cannot usually be decontaminated and should be discarded. Note that pesticides can contaminate the inside surfaces of gloves, boots, and headgear. Decontamination should especially be considered for emergency personnel (such as ambulance drivers) at the site of a spill or contamination. Wear rubber gloves while washing pesticide from skin and hair of patient. Latex and other surgical or precautionary gloves usually do not provide adequate protection from pesticide contamination.

Airway Protection

Ensure that a clear airway exists. Suction any oral secretions using a large bore suction device if necessary. Intubate the trachea if the patient has respiratory depression or if the patient appears obtunded or otherwise neurologically impaired. Administer oxygen as necessary to maintain adequate tissue oxygenation. In severe poisonings, mechanically supporting pulmonary ventilation for several days may be necessary.

Note on Specific Pesticides: There are several special considerations with regard to certain pesticides. In **organophosphate** and **carbamate** poisoning, adequate tissue oxygenation is essential prior to administering atropine.

Gastrointestinal Decontamination

A joint position statement has recently been released by the American Academy of Clinical Toxicology and the European Association of Poisons Centres and Clinical Toxicologists on various methods of gastrointestinal decontamination. A summary of the position statement accompanies the description of each procedure.

- 1. **Gastric Lavage.** If the patient presents within 60 minutes of ingestion, lavage may be **considered**. Insert an orogastric tube and follow with fluid, usually normal saline. Aspirate back the fluid in an attempt to remove any toxicant. If the patient is neurologically impaired, airway protection with a cuffed endotracheal tube is indicated prior to gastric lavage. Lavage performed more than 60 minutes after ingestion has not proven to be beneficial and runs the risk of inducing bleeding, perforation, or scarring due to additional trauma to already traumatized tissues. It is almost always necessary first to control seizures before attempting gastric lavage or any other method of GI decontamination. Studies of poison recovery have been performed mainly with solid material such as pills. There are no controlled studies of pesticide recovery by these methods. Reported recovery of material at 60 minutes in several studies was 8 percent to 32 percent. There is further evidence that lavage may propel the material into the small bowel, thus increasing absorption.

  Note on Specific Pesticides: Lavage is contraindicated in hydrocarbon ingestion, a common vehicle in many pesticide formulations.

  Position Statement: Gastric lavage should not be routinely used in the management of poisons. Lavage is indicated only when a patient has ingested a potentially life-threatening amount of poison and the procedure can be done within 60 minutes of ingestion. Even then, clinical benefit has not been confirmed in controlled studies.

- 2. **Activated Charcoal Adsorption**. Activated charcoal is an effective absorbent for many poisonings. Volunteer studies suggest that it will reduce the amount of poison absorbed if given within 60 minutes. There are insufficient data to support or exclude its use if time from ingestion is prolonged, although some poisons that are less soluble may be adsorbed beyond 60 minutes. Clinical trials with charcoal have been done with poisons other than pesticides. There is some evidence that paraquat is well adsorbed by activated charcoal. Charcoal has been anecdotally successful with other pesticides.

Dosage of Activated Charcoal:

- *Adults and children over 12 years:* 25-100 g in 300-800 mL water.
- *Children under 12 years:* 25-50 g per dose.
- *Infants and toddlers under 20 kg*: 1 g per kg body weight.

Many activated charcoal formulations come premixed with sorbitol. Avoid giving more than one dose of sorbitol as a cathartic in infants and children due to the risk of rapid shifts of intravascular fluid. Encourage the victim to swallow the adsorbent even though spontaneous vomiting continues. Antiemetic therapy may help control vomiting in adults or older children. As an alternative, activated charcoal may be administered through an orogastric tube or diluted with water and administered slowly through a nasogastric tube. Repeated administration of charcoal or other absorbent every 2-4 hours may be beneficial in both children and adults, but use of a cathartic such as sorbitol should be avoided after

the first dose. Repeated doses of activated charcoal should not be administered if the gut is atonic. The use of charcoal without airway protection is contraindicated in the neurologically impaired patient.

Note on Specific Pesticides: The use of charcoal without airway protection should be used with caution in poisons such as organophosphates, carbamates, and organochlorines if they are prepared in a hydrocarbon solution.

Position Statement: Single-dose activated charcoal should not be used routinely in the management of poisoned patients. Charcoal appears to be most effective within 60 minutes of ingestion and may be considered for use for this time period. Although it may be considered 60 minutes after ingestion, there is insufficient evidence to support or deny its use for this time period. Despite improved binding of poisons within 60 minutes, only one study suggests that there is improved clinical outcome. Activated charcoal is contraindicated in an unprotected airway, a GI tract not anatomically intact, and when charcoal therapy may increase the risk of **aspiration** of a hydrocarbon-based pesticide.

Seizures: Lorazepam is increasingly being recognized as the drug of choice for status epilepticus, although there are few reports of its use with certain pesticides. Emergency personnel must be prepared to assist ventilation with lorazepam and any other medication used to control seizures. See dosage table below. For organochlorine compounds, use of lorazepam has not been reported in the literature. Diazepam is often used for this, and is still used in other pesticide poisonings.

Dosage of Diazepam:

- *Adults*: 5-10 mg IV and repeat every 5-10 minutes to maximum of 30 mg.
- *Children*: 0.2 to 0.5 mg/kg every 5 minutes to maximum of 10 mg in children over 5 years, and maximum of 5 mg in children under 5 years.

Dosage of Lorazepam:

- Adults: 2-4 mg/dose given IV over 2-5 minutes. Repeat if necessary to a maximum of 8 mg in a 12 hour period.
- Adolescents: Same as adult dose, except maximum dose is 4 mg.
- Children under 12 years: 0.05-0.10 mg/kg IV over 2-5 minutes. Repeat if necessary .05 mg/kg 10-15 minutes after first dose, with a maximum dose of 4 mg.

Caution: Be prepared to assist pulmonary ventilation mechanically if respiration is depressed, to intubate the trachea if laryngospasm occurs, and to counteract hypotensive reactions.

Phenobarbital is an additional treatment option for seizure control. Dosage for **infants, children, and adults** is 15-20 mg/kg as an IV loading dose. An additional 5 mg/kg IV

may be given every 15-30 minutes to a maximum of 30 mg/kg. The drug should be pushed no faster than 1 mg/kg/minute.

For seizure management, most patients respond well to usual management consisting of benzodiazepines, or phenytoin and phenobarbital.

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