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INTEGRATED VECTOR MANAGEMENT PROGRAMS FOR MALARIA VECTOR CONTROL (2012 UPDATE)

PROGRAMMATIC ENVIRONMENTAL ASSESSMENT

VOLUME 1 OF 2: MAIN DOCUMENT

September 2011/Revised September 2012

This report was produced for review by the United States Agency for International Development (USAID). It was prepared by International Resources Group (IRG) and revised by The Cadmus Group, Inc.

Programmatic Environmental Assessment

INTEGRATED VECTOR MANAGEMENT PROGRAMS FOR MALARIA VECTOR CONTROL (2012 Update)

PROGRAM/ACTIVITY DATA:

This PEA applies to all USAID malaria vector control activities—including but not limited to those under the umbrella of the Presidential Malaria Initiative--involving indoor residual spraying (IRS), insecticide treated nets, wall lining, and control of mosquito larvae, whether via larvicidal agents or environmental management methods.

Program Area 3.1 (health)
Program Element 3.1.3 (Malaria)
Sub-element 3.1.3.2 Insecticide-Treated Nets to Prevent Malaria
Sub-element 3.1.3.3 Indoor Residual Spraying to Prevent Malaria
And other 3.1.3 sub-elements

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Current Date: 19 March 2013 **Expiration Date:** 30 March 2018

Submitted By (Project Point-of-Contact): Cadmus Group and the Global Environmental Management and Support Contract

PEA Amendment (Y/N): No ; supersedes previous PEAs. See "scope" , below

ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion: _____ Negative Determination: X

Positive Determination: X Deferral: _____

ADDITIONAL ELEMENTS: (Place X where applicable)

CONDITIONS X PVO/NGO: _____

SUMMARY OF FINDINGS

Scope. This PEA applies to all USAID malaria vector control activities—including but not limited to those under the umbrella of the Presidential Malaria Initiative--involving Indoor Residual Spraying (IRS), Insecticide Treated Nets, and control of mosquito larvae, whether via larvicidal agents or environmental management methods.

This is a comprehensive document, superseding the 2002 *PEA for Insecticide-Treated Materials in USAID Activities in Sub-Saharan Africa* and the 2007 *Integrated Vector Management Programs for Malaria Vector Control PEA*.

Objective. The objective of this PEA is to (1) provide an umbrella evaluation of environmental and human health issues related to USAID malaria vector control (MVC) activities, satisfying the requirements of 22 CFR 216 and,

on this basis, (2) provide project managers with a technical, policy, and procedural guide for the preparation of Supplemental Environmental Assessment (SEAs) and Initial Environmental Examinations (IEEs) for individual (country-level) malaria vector control programs. (SEAs are required except where country MVC activities are limited to distribution/support for LLINs; in which case treatment in an IEE is acceptable.)

Together, this PEA and the SEAs/IEEs that are prepared in conformity with it are intended to provide a clear basis for deciding, for each country MVC program, which malaria vector control technique USAID can promote and the environmental and occupational health and safety requirements that must be met during implementation. As such, this PEA is a tool for designing and implementing safe, environmentally and socially sound malaria vector control activities.

The intended audience and users of this PEA are USAID/Washington Program Officers; USAID Mission Health and Environment Officers; cooperating country health and environment officials; USAID partners implementing malaria vector control programs; Office of Foreign Disaster Assistance (OFDA) Officers; consultants preparing Initial Environmental Examinations (IEEs), SEAs, and other required approval documents; and the general public.

Findings. This PEA provides findings, including recommended mitigations, in each of the following intervention areas:

- Indoor Residual Spraying
- Insecticide Treated Nets
- Larviciding/Environmental Management Methods for Larvae Control
- Wall Lining

Upon approval of this PEA, as documented by the signatures to this facesheet, the recommended mitigations (6.1.2) become operational requirements for activities in each of these areas, and must be reproduced or referenced in SEAs and IEEs addressing MVC activities at the country or project-level; the PEA provides guidance for SEA development. The specific findings/mitigation requirements are too detailed to reproduce here; however, the following should be particularly noted.

- The IRS Best Management Practices (BMPs) developed by PMI are required by this PEA as mitigation measures in the implementation of IRS activities.
- In addition, PMI will evaluate various approaches for monitoring sprayer exposure to OPs, and will develop protocols based on these evaluations. PMI will use these protocols to guide the implementation of an OP monitoring program.
- Special, additional requirements apply to the use of DDT, including support to Stockholm Convention Reporting.
- PMI will work with international organizations to develop a strategy/system to manage long-life insecticide-treated net waste. In addition, information to net users will address unintended uses of nets and should be tailored to reflect the local environment.
- Annex L of the PEA provides a comprehensive template environmental mitigation and monitoring plan (EMMP) covering all intervention areas listed above. Country- and project-level SEAs and IEEs must require development and implementation of an EMMP fully reflecting the mitigation measures set out by this PEA.

APPROVAL OF THE RECOMMENDED ENVIRONMENTAL ACTION
***(Integrated Vector Management Programs for Malaria Vector Control (2012 Update))*:**

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INTEGRATED VECTOR MANAGEMENT PROGRAMS FOR MALARIA VECTOR CONTROL (2012 UPDATE)

PROGRAMMATIC ENVIRONMENTAL ASSESSMENT

VOLUME 1 OF 2: MAIN DOCUMENT

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DISCLAIMER

Until and unless this document is approved by USAID as a 22 CFR 216 Programmatic Environmental Assessment, the findings and analysis presented herein do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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ACRONYMS

ACTs	artemisinin-based combination therapies
ADD	average daily dose
ATSDR	Agency for Toxic Substances and Disease Registry
BEO	Bureau Environmental Officer
Bti	*Bacillus thuringiensis israelensis*
Bs	*Bacillus sphaericus*
CAS	Chemical Abstracts Service
CFR	U.S. Code of Federal Regulations
CGIAR	Consultative Group on International Agricultural Research
CS	capsule suspension
CSF	cancer slope factor
DAF	dilution and attenuation factor
DDT	dichloro-diphenyl-trichloroethane
EA	environmental assessment
EC	emulsifiable concentrate
EC50	median effective concentration
EIR	entomological inoculation rate
EPA	U.S. Environmental Protection Agency
ESLs	ecological screening levels
EXTOXNET	EXtension TOXicology NETwork
GDP	gross domestic product
GEF	Global Environment Fund
GFATM	Global Fund for AIDS, Malaria and Tuberculosis
GIS	geographic information systems
GUP	general use pesticide
HEAST	health effects assessment summary tables
HI	hazard index
HQ	hazard quotient
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
ICIPE	The International Center for Insect Physiology and Ecology

IEC	Information, Education, and Communication
IEE	Initial Environmental Examination
IPCS	International Program on Chemical Safety
IPM	integrated pest management
IPTp	Intermittent preventive treatment for pregnant women
IRIS	integrated risk information system
IRS	indoor residual spraying
ITM	insecticide-treated material
ITN	insecticide-treated net
IUCN	International Union for Conservation of Nature
IVM	integrated vector management
KAP	knowledge, attitudes, and practices
LADD	lifetime average daily dose
LC50	median lethal concentration
LD50	lethal dose, 50 percent of the test population
LLIN	long-lasting insecticidal net
LOAEL	lowest observed adverse effect level
LSM	Larval source management
MEO	Mission Environmental Officer
MHO	Mission Health Officer
MOA	Ministry of Agriculture
MOE	margin of exposure
MOH	Ministry of Health
MOS	Margin of Safety
MPW	Ministry of Public Works
MRL	minimal risk level
MRLs	maximum residue limits
NC	noncancer
NGO	nongovernmental organization
NOAEL	no observed adverse effect level
NOEL	no observed effect level
OFDA	Office of Foreign Disaster Assistance
PAN	Pesticide Action Network
PBO	piperonyl butoxide
PEA	Programmatic Environmental Assessment

PERSUAP	Pesticide Evaluation Report and Safer Use Action Plan
PMI	President's Malaria Initiative
POPs	persistent organic pollutants
PPE	personal protective equipment
PSCs	pyrethrum spray catches
PVO	private voluntary organization
RAGS	Risk Assessment Guidance for Superfund
RBM	Roll Back Malaria
RED	Re-registration eligibility decision
REO	regional environmental officer
RfD	reference dose
RTI	Research Triangle Institute
RUP	restricted use pesticide
SEA	Supplemental Environmental Assessment
SF	safety factor
SIMA	System Wide Initiative On Malaria And Agriculture
SOP	standard operating procedure
UF	uncertainty factor
ULV	ultra-low volume
UNDP	United Nations Development Program
UNEP	United Nations Environment Program
UNFAO	United Nations Food and Agriculture Organization
UNICEF	United Nations International Children's Emergency Fund
USAID	U.S. Agency for International Development
USDA/FAS	U.S. Department of Agriculture/Foreign Agricultural Service
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WHOPES	WHO Pesticide Evaluation Scheme
WP	wettable powder

EXECUTIVE SUMMARY

1. INTRODUCTION

Malaria is a preventable and treatable disease. About 3.3 billion people, half of the world's population, are at risk of malaria. One in five (20 percent) of all childhood deaths in Africa are due to malaria (World Health Organization – WHO). On June 30, 2005, President Bush pledged to increase funding for malaria prevention and treatment by more than $1.2 billion over five years, specifically in sub-Saharan Africa. This effort is expected to eventually cover more than 175 million people in 15 or more of the most affected African countries. In 2008, the Lantos-Hyde Act authorized an expanded President's Malaria Program (PMI) program for 2009-2013 by authorizing up to $5 billion in U.S. Government (USG) funding for malaria prevention and control globally. PMI is also a key component of the USG's Global Health Initiative (GHI), which was announced by President Obama in May 2009. As a result, the PMI strategy was revised to achieve a goal of having Africa-wide impact by halving the burden of malaria in 70 percent of at-risk population in sub-Sahara Africa, or approximately 450 million people. The PMI program now targets 19 high malaria burden focus and two non-focus countries and two regional programs: (focus) Angola, Tanzania, Uganda, Malawi, Mozambique, Rwanda, Senegal, Benin, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Mali, Zambia, Nigeria, Democratic Republic of the Congo (DRC), Guinea, Zimbabwe; (non-focus) Burkina Faso and Burundi: (regional program) Mekong and Amazon; and up to five additional endemic countries.

As a federal government agency, USAID is subject to Title 22, Code of Federal Regulations, Part 216 (22 CFR 216), or more often called Regulation 216, to define USAID's environmental impact assessment procedures. Based on the nature of the proposed activities and geographic coverage, a Programmatic Environment Assessment (PEA) approach is warranted for meeting Regulation 216 requirements and provides the protocols that assure the environmental soundness of project implementation.

During the course of USAID involvement in the Malaria Vector Control Programs, two PEAs have been prepared to evaluate potential environmental and human health effects from the implementation of the malaria control interventions. In 2002, USAID identified the need for insecticide-treated materials as an important tool in the integrated malaria control program, and prepared the *Programmatic Environmental Assessment for Insecticide-Treated Materials in USAID Activities in Sub-Saharan Africa*, which addressed the risks associated with the use of insecticide-treated materials. In 2007, a second PEA was prepared to address the expansion of the USAID malaria control programs and the Agency's prominent role as a key member of the Roll Back Malaria (RBM) Partnership. *The Integrated Vector Management Programs for Malaria Vector Control Programmatic Environmental Assessment* addressed the human and environmental risks associated with indoor residual spraying (IRS), insecticide-treated nets (ITNs), larviciding, and environmental management activities.

Recently, it was acknowledged that an updated PEA was warranted to assess new pesticides, program changes, and lessons learned during the course of the program. This PEA evaluates the existing program interventions and new interventions and pesticides that were identified during the scoping process, and provides an assessment of the potential inadvertent human health and environmental impacts related to the malaria vector control actions. The objective of the 2012 PEA is to evaluate the potential impacts of the program at large. The PEA's intent is to serve as an umbrella evaluation of environmental and human health issues related to the Malaria Vector Control Program implementation and to provide project managers with a technical, policy, and procedural guide for the preparation of country- and

activity-specific Supplemental Environmental Assessments (SEAs) for individual malaria vector control programs.

Scoping was carried out to facilitate a more efficient PEA preparation process and to define the issues and alternatives that would be examined in detail in the environmental assessment. The significant issues that were identified during the scoping process include the following:

- Issues not addressed in past PEAs
- Issues identified in past PEAs that should be further assessed
- Issues identified during past five years of program implementation
- New technologies or pesticides
- IRS Best Management Practices contribution to minimizing impacts

This PEA was prepared using the numerous secondary sources found in professional journals and in publications by environmental and public health organizations, and through consultations with USAID Malaria Advisors and Environmental Officers.

2. BACKGROUND INFORMATION

Malaria is transmitted exclusively through the bites of *Anopheles* mosquitoes. The intensity of transmission depends on factors related to the parasite, the vector, (i.e. the mosquito), the human host, and the environment. Malaria remains the most important vector-borne disease in public health and the current intensification of malaria-control efforts includes the delivery of a package of vector-control interventions aimed at controlling transmission. Integrated vector management (IVM) is a rational decision-making process for the optimal use of resources for vector control. The aim of IVM is to improve the efficiency, effectiveness and ecological soundness of vector control interventions, and to contribute to achieving national and global targets set for vector-borne disease control. To achieve this, vector control needs to be increasingly based on local evidence, integrating interventions where appropriate, collaborating with the health sector and with other sectors, and actively engaging communities.

The recent progress in malaria vector control has been largely accomplished through a massive increase in vector control through long-lasting insecticidal nets (LLINs) and IRS. Since both of these prevention measures depend on the ability of insecticides to kill or reduce the lifespan of female mosquitoes, understanding and monitoring insecticide resistance is critical to their continued effectiveness.

In the past year, the President's Malaria Program has scaled up the coverage of control measures and has increased activities using four proven malaria prevention and treatment measures: ITNs, the majority of which are LLINs; IRS; intermittent preventive treatment for pregnant women (IPTp); and improved laboratory diagnosis and appropriate treatment, including artemisinin-based combination therapies (ACTs). PMI has focused a large proportion of its resources on procuring and distributing nets, educating people on the dangers of malaria, and encouraging them to sleep under a net every night. During the past two years a consortium of partners, including PMI, Global Fund, UNICEF, and others have made strides to increase net distribution, with the goal to provide one net per every two persons at risk. IRS has also grown substantially, both within PMI focus countries, and in other countries. PMI's goal is for 85 percent of all houses in a target geographic area to be sprayed. IRS standardized Best Management Practices have been developed to ensure that all workers handle the pesticides in an appropriate manner – from transportation, storage, and stock control, to spraying and waste management – and that all residents are protected from unnecessary exposure to the pesticides.

3. PROPOSED ALTERNATIVES AND INTERVENTIONS

The purpose of the PEA is to analyze alternative design options and strategies in terms of environmental costs and benefits. There are only two alternatives for the USAID Malaria Control Program, either no action, where no interventions would be implemented to control the progress of malaria, or the continuation of the USAID Malaria IVM program with existing interventions and pesticides. During the scoping process one additional intervention, wall lining, and several new pesticides for IRS, larviciding, and LLINs were identified as potential options for controlling malaria vectors.

The existing program alternative includes the two principle malaria vector control interventions – IRS and LLINs – which are currently the mainstream of the USAID Malaria Control program, and two interventions that have potential for contributing to malaria control by targeting mosquitoes at the larval stage – larviciding and environmental management methods. The re-treating of insecticide treated nets is also included in the program. Wall lining is a new intervention which is currently being evaluated in field trials in several sub-Saharan African countries.

New pesticides are continuously being developed and researched for malaria vector control. Several new products under the WHO Pesticide Evaluation Scheme (WHOPES) laboratory and/or field-testing and evaluation have been included in this PEA as new options for controlling the malaria vector. They include spinosad for larviciding, chlorfenapyr, and a new capsule suspension (CS) formulation of pirimiphos-methyl for IRS, and pyriproxyfen and piperonyl butoxide (a synergist) for incorporation into other vector control interventions.

IRS

Indoor residual spraying (IRS) is a commonly used malaria vector control method that has been particularly effective in seasonal transmission settings. It is implemented by applying residual insecticides (to which female *Anopheles* 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. The residual effect of the insecticide is sufficient to kill resting mosquitoes for a period ranging from 3 to 12 months. WHO has recommended 12 pesticides for use for IRS, including alpha-cypermethrin, bendiocarb, bifenthrin, cyfluthrin, DDT, deltamethrin, etofenprox, fenitrothion, lambda-cyhalothrin, malathion, pirimiphos-methyl, and propoxur.

LLINS

Untreated bed nets provide a protective barrier around the people that are sleeping underneath, but mosquitoes are still able to feed through the nets. Nets that are treated with pesticides repel and kill the mosquitoes, thus providing an additional level of protection. Long lasting insecticidal-treated nets (LLINs) maintain effective levels of insecticide for at least three years of use. The pesticides are applied to the material by the manufacturer and are either coated or impregnated into the net fibers. There are currently 10 LLINs recommended by the World Health Organization. The PMI program also considers the use of LLIN products that receive WHO interim or full recommendation status.

Several programs continue to distribute ITNs that require re-treatment, though most nets procured by national malaria control programmes currently are LLINs. However, it will take a few more years before LLINs fully replace the current generation of conventionally treated nets. These nets will continue to require re-treatment with insecticide one to two times a year or after every three washes to ensure their effectiveness.

LARVICIDING

Larviciding is the general term for killing mosquitoes by applying agents to control mosquito larvae and/or pupae. Larvicide agents considered for the Malaria Vector Control Program include bacterial larvicides, methoprene, temephos, and molecular films and oils.

ENVIRONMENTAL MANAGEMENT METHODS

Environmental management approaches to vector control aim at modifying the environment to deprive the target vector population of its requirements for development and survival. Environmental management methods considered for the Malaria Vector Control Program include filling breeding sites, lining water sources and canals, physical wetland drainage, biological wetland drainage, impoundment planning, deepening and narrowing of old drains, vegetation manipulation, synchronized cropping and intermittent irrigation, larvivorous fish introduction, and saltwater flooding.

WALL LININGS

Wall linings are sheets of polyethylene fabric incorporated with pyrethroids which are attached to the wall of a home. They are expected to have a similar impact on the vector as IRS, but last at least 3 years longer than IRS.

NEW PESTICIDES FOR THE EXISTING PMI PROGRAM

The following pesticides have recently been added to the PMI program, or are under consideration:

New Larvicide Pesticide – Spinosad:

Spinosad is derived through the fermentation of a naturally occurring soil dwelling bacterium, traditionally used in commercial agriculture and home gardens to control a variety of insects.

New IRS Pesticide – Chlorfenapyr (pyrroles class):

Chlorfenapyr is the first commercial pesticide to be derived from a class of compounds known as halogenated pyrroles.

New IRS Pesticide formulation – Pirimiphos-methyl CS:

The new CS formulation of Pirimiphos has been specifically designed for use in the IRS program to provide long-lasting residual control on a range of surfaces.

New Larvicide Pesticide – Pyriproxyfen

Pyriproxyfen is a pyridine-based larvicide, which is being proposed for use on other vector control interventions.

New Synergist– Piperonyl butoxide

Piperonyl butoxide (PBO) is a synergist used in a wide variety of pesticides. Synergists are chemicals that lack pesticidal effects at typical field use rates, but enhance the pesticidal properties of other chemicals.

4. AFFECTED ENVIRONMENT

This PEA is broad by nature and, as such, cannot provide adequate descriptions of the diverse environments where USAID will support malaria control interventions. Thus, SEAs or other required approval documents, that are the next tier of the environmental assessment process, must address the affected environment on a country-by-country basis.

5. PESTICIDE PROCEDURES AND HUMAN HEALTH AND ENVIRONMENTAL CONSEQUENCES

The Pesticide Procedures portion of Regulation 216 states that "all proposed projects involving assistance for the procurement or use, or both, of pesticides shall be subject to the procedures prescribed in §216.3(b)(i)". Included in the PEA are the following factors that are to be considered in such an evaluation and where they are discussed within this document.

a) The U. S. Environmental Protection Agency (USEPA) registration status of the requested pesticide

b) The basis for selection of the requested pesticide

c) The extent to which the proposed pesticide use is part of an integrated pest management program

d) The proposed method or methods of application, including availability of appropriate application and safety equipment

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

f) The effectiveness of the requested pesticide for the proposed use

g) Compatibility of the proposed pesticide with target and non-target ecosystems

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

i) The availability and effectiveness of other pesticides or non-chemical control methods

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

k) The provisions made for training of users and applicators

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

HUMAN HEALTH RISK ASSESSMENT

This PEA provides an assessment of the potential inadvertent human health impacts related to the malaria vector control actions described above. The human health risk assessment focuses on the risks to workers and residents from IRS, the use of LLINs/ITNs and wall linings, re-treatment of ITNs, and larviciding. The 2012 assessment set out to update and refine the human health risk assessment that was presented in the 2007 PEA for the Malaria Vector Control Program.

Objectives

The human health assessment is an update and refinement of the assessment presented in the 2007 PEA (USAID, 2007). The 2007 PEA did not include risk assessments for larviciding, long-lasting insectide-treated nets, or wall linings. The 2007 PEA implemented screening-level methods that were "based on several assumptions and simplifications that are intended to produce conservative estimates of risk" (USAID, 2007; Section 5.1.3.3). Recommendations from the human health assessment in the 2007 PEA that are implemented in this report include:

1) Conduct simple follow-on modeling related to scenarios where remedial steps are recommended;

2) Apply an environmental modeling approach to predict the environmental fate of persistent, bioaccumulative pesticides (such as DDT); and,

3) Refine the exposure models for IRS worker and resident receptors.

Methodology

The human health risk assessment is structured according to four steps. These steps are:

- **Problem Formulation:** Describes the IVM actions and pesticides covered and presents the conceptual models of potentially complete exposure pathways used in the exposure assessment.
- **Exposure Assessment:** Focuses on identifying how much of a chemical a receptor may be exposed to, and quantifying the rate of exposure, for each exposure pathway.
- **Toxicity Assessment:** Identifies the different types of potential adverse health effects for pesticide exposures and documents the toxicity criteria for cancer risk and noncancerous hazard.
- **Risk Characterization:** Presents the results for each exposure scenario identified in the problem formulation, including key uncertainties and recommendations.

A range of potential exposure intensities was evaluated in order to provide risk managers with information on the degree of uncertainty related to certain exposure parameters. Inputs for the exposure assessment can be organized into two groups, with major sources of parameter values cited:

- Exposure concentrations were derived from information in various sources including the Environmental Protection Agency report *Standard Operating Procedures (SOPs) for Residential Exposure Assessments* (EPA, 1997a), EPA's SCI-GROW model for groundwater (http://www.epa.gov/oppefed1/models/water/), IRS application rates in Najeera and Zaim (2002), and others.
- Exposure parameter values were based on a survey of field implementing partners, EPA documents including *Exposure Factors Handbook* (EPA, 1997b) and *Supplemental Guidance for Dermal Risk Assessment* (EPA, 2004), various World Health Organization and USAID reports, and peer-reviewed literature.

Inputs for the toxicity assessment include cancer and noncancer toxicity benchmarks. For noncancer endpoints, the health benchmark "reference dose" (RfD) represents a point (in milligrams of pesticide per kilogram body weight per day) on the dose–response continuum below which adverse effects would not be anticipated. For cancer endpoints, the health benchmark "cancer slope factor" (CSF) represents a plausible upper-bound estimate of the lifetime probability of developing cancer associated with exposure to a specific quantity of a potential carcinogen.

Health benchmarks were identified from several sources according to the following order of preference:

a) EPA's Reregistration Eligibility Decision documents, or risk assessments supporting registration documented in the Federal Register

b) EPA's Integrated Risk Information System

c) EPA's Health Effects Assessment Summary Tables

d) Other sources

The primary information required for the risk characterization is the selection of threshold values with which to interpret the results of the risk calculations. The hazard quotient (HQ), which is the ratio between the estimate pesticide dose and the RfD, is the metric used to express noncancer hazard. An HQ greater than one is regarded as an indication of potential hazard because the dose exceeds the threshold at which effects may be observed. In environmental assessments in the United States, the acceptability of any calculated incremental cancer risk is generally evaluated relative to the risk management range of 1×10^{-6} to 1×10^{-4} described in the "National Oil and Hazardous Substances Pollution Contingency Plan" (40 CFR 300.430).

Key Findings

Worker Risks from IRS, Re-treating ITNs and Larviciding

Preparation of pesticide

4) HQ results for preparation of the pesticides without the use of personal protective equipment (PPE) are below the threshold of 1.0 for all pesticides with the exception of DDT, pirimiphos-methyl, chlorfenapyr, and fenitrothion. Cancer risks for the preparation of pesticides without the use of PPE, except for DDT, are below or within the 1×10^{-6} to 1×10^{-4} risk management range.

5) With PPE use, only DDT (HQs of 2 to 6) and pirimiphos-methyl (HQs of 1 to 4) had pesticide preparation HQ values above 1.0. With PPE use, only the high-end exposure for DDT (3×10^{-4}) was above the 1×10^{-6} to 1×10^{-4} risk management range. These results are protectively biased and may not indicate unacceptable exposures.

6) Workers should be adequately trained and provided with PPE during pesticide preparation, particularly if they are handling the pesticides described above. Worker and resident exposures due to spills during preparation can be minimized by following best management practices described in the USAID protocol (2010).

Application of pesticide

7) Exposure by dermal absorption resulted in much higher risks than exposure by inhalation for pesticides with HQ or cancer risk results above the thresholds.

8) With PPE use, only DDT (mid-range HQ = 70) had an HQ estimate well above the effects threshold of 1.0. With PPE use, DDT high-end exposure cancer risk was 1×10^{-4}, at the upper end of the risk management range.

9) The use of PPE in accordance with the USAID protocol (2010) is essential to protect worker health during spray application of pesticides, particularly for sensitive individuals. When applying DDT, the degree of protection provided by the use of respirators, protective overalls, and gloves may be inadequate for sensitive individuals.

Resident Risks from Groundwater and Surface Water Exposures

10) For the majority of IRS, ITN re-treatment and larviciding pesticides, the land disposal of quantities in excess of 1,000 kg per year are required to reach groundwater concentrations associated with cancer risk $> 1 \times 10^{-5}$ or HQ > 1.0. The land disposal of 90 to 340 kg per year of pirimiphos-methyl, etofenprox, and fenitrothion are required to reach these thresholds. For DDT and propoxur, the land disposal of quantities below 10 kg per year are required to reach the thresholds.

11) With the possible exceptions of DDT and propoxur, the land disposal of pesticides is unlikely to result in groundwater contamination affecting human health risks unless a groundwater well is located immediately down gradient of a burial location.

12) The use of larvicides as part of malaria vector control practice is unlikely to present significant risks to residents who use surface waters as a domestic water supply.

Resident Risks from Exposure to Residual Pesticide (except DDT) Following IRS

13) The only IRS pesticide with a calculated HQ (HQ = 8 for a child) above 1.0 was pirimiphos-methyl. Only etofenprox and propoxur had cancer risks reaching the 1×10^{-6} to 1×10^{-4} risk management range based on a 50-year exposure duration.

14) Potentially unacceptable acute exposures from ingestion of foods left uncovered during spraying were calculated for DDT, fenitrothion, malathion, and pirimiphos-methyl in the 2007 PEA (USAID, 2007). Acute exposures related to the re-use of IRS pesticide containers were found to be potentially unacceptable in the 2007 PEA for the majority of IRS pesticides.

15) The collection of samples of surface material from sprayed walls, and sampling of floor sweepings, at intervals following IRS should also be subject to chemical analysis.

16) Resident exposures due to foods left exposed during spraying, or due to re-use of pesticide containers, can be avoided by a combination of appropriate spray team protocols and resident education outreach.

Resident Risks for Pesticides Contained in LLINs, Re-treated ITNs and Wall Linings

17) HQ results for all LLIN/ITN pesticides were below the threshold of 1.0. Central-tendency and reasonable-maximum cancer risk estimates for permethrin over a 50-year period of washing LLINs/ITNs were 8×10^{-5} and 2×10^{-4}.

18) Reasonable-maximum calculations assume exposures at the mass balance limit for the amount of pesticide released from an LLIN/ITN during washings.

19) The exposure assessment is highly protective, and LLIN/ITN exposures are unlikely to result in cancer risks above the risk management range.

20) It is recommended that communities are discouraged to dispose of wash water (from washing the LLINs/ITNs) in sensitive ecosystems or near community water sources.

21) By analogy to LLIN/ITN results, and expected contact with wall lining, resident exposures to pesticides in wall linings are unlikely to present unacceptable risks.

Resident Risks for Exposures to DDT Used in IRS

22) Studies by the Research Triangle Institute (RTI) in Ethiopia and Mozambique, and Van Dyk et al (2010) in South Africa, suggest that DDT is migrating into the environment from sprayed homes following IRS.

23) Van Dyk et al (2010) and other researchers have found that blood levels of DDT are higher in sprayed villages than in unsprayed ones, indicating resident exposure to DDT used in IRS.

24) A risk calculation evaluating incidental soil ingestion, soil dermal absorption, inhalation, and vegetable and chicken ingestion pathways indicates that potential exposures by chicken ingestion are by far the most significant and may result in a lifetime cancer risk of approximately 1×10^{-2} and an HQ of 60. DDT exposures of infants via breast milk may also be significant.

25) In areas where chickens have access to the area in and around sprayed homes, sampling of DDT in chicken meat and eggs should be considered to determine the possible relevance of this pathway for the malaria vector control program.

ENVIRONMENTAL CONSEQUENCES

Objectives

Eliminating unnecessary human exposure to pesticides is the primary concern of the PEA; however, domestic livestock (particularly chickens) and organisms in the environment (nontarget aquatic species) may also be harmed if operations, cleanup, and disposal are not conducted according to best management practices. The Environmental Consequences section of the 2007 PEA provided a general ecotoxicological review and ranking of the effects of pesticides of concern on wildlife for the IRS and larviciding vector control intervention scenarios. This version of the PEA updates the ecotoxicological information and addresses three specific issues of concern identified based on the findings of 2007 PEA:

1) What degree of risk does exposure to post spray IRS DDT residues on crops and soils in village homesteads have on domestic livestock (chickens)?

2) What degree of risk does exposure to larvicides used in surface water bodies have on nontarget aquatic species?

3) What degree of risk does exposure to pesticides eluted from and the physical disturbance of LLINs/ITNs when used for fishing/washing by villagers have on nontarget aquatic species?

Methodology

The environmental consequences methods consist of "Problem Formulation and Ecological Effects Evaluation" and "Preliminary Exposure Estimate and Risk Calculations" as outlined in the EPA Ecological Risk Assessment Guidance for Superfund or ERAGS (U.S. EPA, 1997). These components of an ecological risk assessment are also consistent with the Guidelines for Ecological Risk (U.S. EPA, 1998) that considers prospective as well as retrospective evaluations of risk for a broad array of stressors. ERAGS provides an appropriate set of tools for assessing the environmental consequences of IRS, larviciding, LLIN, and wall lining and ITN re-treatment malaria vector control scenarios. The evaluation presented here is a screening level ecological risk assessment (SLERA) that is meant to be used to identify priorities and data needs for a baseline assessment that may include a biomonitoring component. The results of this evaluation will provide simplified representations of key site activities, receptors and site characteristics, as well as the link between activities and ecological impacts and provide the foundation for effects assessment. This evaluation is intended to be protective and not necessarily predictive of the actual risks at the site of concern because the parameters used are very conservative and represent the worst-case scenario.

Problem Formulation and Ecological Effects Evaluation. This evaluation consists of seven parts including the identification/description of:

1) the environmental setting including habitat types, observed species and species likely to be present based on habitat types documented, as well as any threatened, rare, and endangered species;

2) the chemical and physical stressors of potential ecological concern, which describes the pesticides and physical stressors, if any, that are associated with the malaria vector control intervention of concern along with the concentrations of pesticides present in each medium and degree of physical stress, if known;

3) the fate and transport mechanisms that may exist along with conceptual site model;

4) the chemical/physical properties affecting environmental behavior;

5) the ecotoxicity synopsis describing the mechanisms associated with each pesticide and the categories of wildlife receptors that may be affected;

6) complete exposure pathways; and

7) ecological screening levels (ESLs) taken from the peer reviewed literature.

The environmental setting is scenario specific, but emphasizes areas near human habitation. Specific assumptions made for each scenario evaluated are included in the subsection for each scenario. In general, the environmental setting will vary depending on the location of the country. Section 4 (Affected Environment) of this PEA should be consulted when applying the results of this assessment to specific locations.

The hierarchy of data sources used for the selection of ecological screening levels was as follows:

1) U.S. Environmental Protection Agency or other nationally recognized organizations such as the National Oceanic and Atmospheric Administration

2) Los Alamos National Laboratory ECORISK Database or other compendium of peer-reviewed values such as EXTOXNET, a cooperative effort of University of California-Davis, Oregon State University, Michigan State University, Cornell University, and the University of Idaho.

3) Primary peer-reviewed literature toxicity values (i.e., LC_{50}s for aquatic organisms)

Preliminary Exposure Estimate and Risk Calculations. This section consists of two parts: (1) risk calculations, which estimates risk by comparing exposure concentrations with the ecological screening values; and, (2) risk characterization, which discusses the results to provide input for risk managers to decide either that the SLERA is adequate to determine that ecological threats are negligible or to provide risk management options.

Key Findings

Post IRS DDT Toxicity for Domestic Livestock (Chickens)

- The risk calculations suggest that ingestion of DDT by wild birds (the American robin and the woodcock) eating primarily worms or both plants and invertebrates is a potential ecological risk because all the HQs, except for one as shown in Table 5-23, are greater than one (1). The ecological screening levels used were based on conservative assumptions. To address the uncertainty of using wild birds as a surrogate species to evaluate the risk to chickens, a chicken specific ecological screening level (TRV) was developed. All HQs calculated for soil and or crop ingestion were less than one (Table 5-24), suggesting there is no ecological risk to chickens ingesting soil or crops. However, the chicken HQ does not evaluate exposure to invertebrates as do the ESL models for the American robin and the woodcock, . Of the wild bird ESL exposure models evaluated here the woodcock eating primarily earthworms was at highest risk of adverse effects. A chicken ESL exposure model would address trophic transfer from soil to invertebrates, if invertebrate data is not available at a site. This refined screening suggests there is no risk of adverse effects that could affect the viability of raising chickens in sprayed villages.

- The data gap identified for assessing the risk of DDT exposure to chickens, specifically, remains in having actual data on the types of food ingested and the concentrations of DDT in those food types. With regard to types of food ingested, the ingestion of invertebrates is of greatest concern.

- In conclusion, based on the results reported here, the domestic chicken does not appear to be at risk for adverse effects from DDT exposures through ingestion of soil or crops.

Aquatic Toxicity of Larvicides

- A risk ratio was calculated, which compared larvicide concentration in the 10L10 liter (L) applicator tank to the minimum LC_{50} for each larvicide from Table 5-25. The risk ratio provides a very conservative estimate of risk because the 10L tank concentration is expected to be diluted by the body of water to which it is applied to at a site. Because the volume of water in the water body is unknown, another metric was calculated. The **Minimum Volume of Water Required for Application to Equal LC_{50}** (Table 5.26) represents, the amount of water needed to mix with the amount of larvicide in the applicator tank to equal the LC_{50} for the most sensitive non-target aquatic species. This approach was taken because this is a generic screening level assessment and the exposure concentration after applying the larvicide using a 10L applicator tank to a body of water at a specific site of concern will vary considerably depending on the size of the body of water. For this reason, a volume of water metric was selected, so that the environmental assessor performing the SEA prior to application of the larvicide can use best professional judgment to determine if the body of water at the site will experience severe adverse effects. A simplistic estimate of the volume of water at a site can be determined by using average measurements of the length, width and depth of the body of water. Both the LC_{50} and the **Minimum Volume of Water Required for Application to Equal LC_{50}** represent a severe adverse effect level (lethality to 50% of exposed population), and are not being used as a safe level in this evaluation, but rather as a red flag warning for adverse effects to non-target aquatic species. Further literature review is required to determine an acceptable risk level such as an EC_{20}, concentration affecting 20% of the population, which is beyond the scope of this screening assessment.

- All risk ratios are greater than one, indicating that these insecticides are acutely toxic to non-target aquatic species in 10 L of water. This result is not surprising. The more relevant question is how this applies to a specific-site and in this assessment the **Minimum Volume of Water Required for Application to Equal LC_{50}** is the metric used to answer this question.

- In order for a larvicide not to be acutely toxic to the most sensitive freshwater aquatic species, the minimum volume of water to which it may be applied is larvicide specific, and has to be greater than the **Minimum Volume of Water Required for Application to Equal LC_{50}** (Table 5.26). The data gaps identified in this screening assessment for assessing the acute toxicological risk of larvicide exposure to aquatic species include: data on the actual species present in the surface water, the type of surface water (fresh or saltwater), the volume of surface water; the flow rate of water, if not a closed system, and low or no effect levels.

- In conclusion, if larvicides are applied to surface water bodies that are static in nature, whose volumes are less than or equal to the **Minimum Volume of Water Required for Application to Equal LC_{50}** for the applied larvicide(s) and are observed to provide ecological habitat for non-target aquatic species, the results reported here indicate that there is a potential for severe lethality to non-target aquatic species. Further review of the toxicological literature is required to set low and no effect levels, and or a baseline assessment is required.

Aquatic Toxicity and Physical Disturbance from LLINs/ITNs

- A risk ratio was calculated, which compared the insecticide concentration in 10 L of water after fishing/washing with an LLIN/ITN to the minimum LC_{50} for each LLIN/ITN insecticide from Table 5-25. The risk ratio provides a very conservative estimate of risk because the 10 L tank concentration is expected to be diluted by the body of water to which it is applied to at a site. Because of this unknown volume of water issue, another metric was calculated and represents, the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** (Table 5.29).

This approach was taken because this is a generic screening level assessment and the exposure concentration after fishing or washing with an LLIN/ITN in a body of water at a specific site of concern will vary considerably depending on the actual size of the body of water. For this reason, a volume of water metric was selected, so that the environmental assessor performing the SEA prior to distributing LLINs/ITNs can use best professional judgment to determine if there are bodies of water at the site that could experience severe adverse effects from washing or fishing with LLINs/ITNs. Simplistically, the volume of water at a site can be determined by using average measurements length, width and depth of the body of water. Both the LC_{50} and the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** represent a severe adverse effect level (lethality to 50% of exposed population), and is not being used as a safe level in this evaluation, but rather as a red flag warning for adverse effects to non-target aquatic species. Further literature review is required to determine an acceptable risk level such as an EC_{20}, concentration affecting 20% of the population, and this is beyond the scope of this screening assessment.

- All risk ratios are greater than 1, indicating these insecticides are acutely toxic to non-target aquatic species in 10 L of water. This result is not surprising. The more relevant question is how this applies to a specific-site and in this assessment the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** is the metric used to answer this question.

- In order for an insecticide diffused from a LLIN/ITN used for washing or fishing not to be acutely toxic to the most sensitive freshwater and saltwater aquatic species, the minimum volume of water to which it may be applied is insecticide specific, and must be greater than the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** (Table 5.29).

- The data gaps identified in this screening assessment for assessing the acute toxicological risk of insecticides diffused from a LLIN/ITN used for washing or fishing exposure to non-target aquatic species include: data on the actual species present in the surface water, the type of surface water (fresh or saltwater), the volume of surface water; the flow rate of water, if not a closed system, and the number of LLINs/ITNs used at the same time and the number of times a net is used, and low or no effect levels. Also, the potential risk from LLINs/ITNs using deltamethrin and lambda-cyhalothrin were not assessed because toxicity data were not available. Also, the effect of the insecticide being either coated on polyester or incorporated into polyethylene was not evaluated due to lack of data on differences in diffusion rates for these different types of nets.

- In conclusion, if LLINs/ITNs are used for washing/fishing in surface water bodies that are static in nature, have a volume less than or equal to the **Minimum Volume of Water Required for Washing/Fishing with LLIN to Equal LC_{50}** for the LLIN/ITN insecticide(s), and are observed to provide ecological habitat for non-target aquatic species, the results reported here indicate that there is a potential for severe lethality to non-target aquatic species.

- In conclusion, the risk of adverse effects from physical stressors associated with fishing/washing with LLINs/ITNs is potentially a risk as is the overfishing of key species in the aquatic ecosystem. The degree of adverse effects will depend on several factors that would need to be evaluated at the site. The factors to consider include: 1) the size of the body of water of concern, 2) the complexity of the aquatic habitat present (e.g., supports invertebrates, small fish, and/or large fish), and frequency of use for fishing/washing. A smaller body of water with aquatic habitat would be expected to suffer more physical stress than a larger body of water because there is less buffer for recovery (i.e, the majority of the area in a small body of water will be affected with each fishing/washing event). The risk of adverse effects from physical stressors represents an uncertainty without site data on aquatic habitat.

Summary

In summary, of the three specific risk scenarios evaluated in this PEA, the aquatic pathways were found to be at potential risk of adverse effects to non-target aquatic species under the exposure model assumptions and data considered here. Table 5-30 indicates the risk scenarios evaluated here as well as the findings and recommendations for further action. A general recommendation would be to observe the environmental setting and characteristics of human use of larvicides and fishing/washing with LLINs/ITNs in surface water bodies in various representative locations to determine if a chemical and/or physical stress risk is plausible for these scenarios. Because this SLERA is generic, this recommendation assumes a qualitative assessment will be made in the SEA based on the professional judgment of environmental assessment expert prior to allowing larviciding or fishing/washing with LLINs/ITNs in surface water bodies at a site. There are specific methodologies from EPA guidance to use to determine site-specific ecological risk including an ecological scoping checklist.

The DDT domestic livestock (chicken) scenario did not indicate a potential concern for adverse effects, however invertebrate consumption was not evaluated here due to lack of site DDT concentrations in invertebrates.

In general, the exposure and toxicity data used in the three risk models for this screening assessment can be refined by obtaining site-specific data, particularly the existence of suitable habitat for aquatic species of concern.

HUMAN HEALTH AND ENVIRONMENTAL CONSEQUENCES – ENVIRONMENTAL MANAGEMENT

The environmental consequences associated with environmental management are location-specific. As a result, this PEA can only address the potential negative environmental impacts of environmental management interventions in a broad manner. The following is a summary of the findings in this PEA:

When wetlands are drained, their soils lose infiltration capacity. As a result, there is potential for increased surface water runoff and soil erosion. Clearing of wetland vegetation can also cause (or exacerbate, if the wetland has been drained) increased surface water runoff and soil erosion. Tree planting changes the ecosystem composition, and may increase or decrease plant and animal biodiversity. Impoundments may increase the availability of water resources for upstream communities, but may decrease water availability for downstream communities. Saltwater flooding may decrease habitat and forage for freshwater aquatic and terrestrial species. It may also decrease the availability of freshwater resources in the target community. The introduction of lLarvivorous fish into a natural environment could disrupt existing predator–prey relationships and alter ecosystem composition. Lining water sources and canals, in addition to increasing the risk of flooding, my also eliminate habitat for aquatic macro-invertebrates that support natural food chains and decompose organic matter. (*Note: a description of the benefits of these management methods to reduce mosquito larvae is in Section 3.2.4)*

CUMULATIVE IMPACTS OF MALARIA IVM INTERVENTIONS AND AGRICULTURE

A major problem faced by public health programs around the world is the diversion of public health pesticides to the private sector, primarily the agricultural sector but also private pest control enterprises. Use of public health pesticides in the agricultural sector may increase the risk that agricultural exports exceed importing-country minimal risk levels (MRLs), reducing economic gains from agricultural exports in the host country. This is of particular concern for DDT, which persists in the environment and accumulates in animal fat. The impact of public health pesticide use in communities that produce organic agricultural crops is of even greater concern than for those communities producing conventional agricultural crops. In areas where large quantities of pesticides are used for agricultural crops, resistance of mosquitoes may develop much faster than in areas that do not use large quantities of agricultural

pesticides. Agricultural development in Africa has contributed to land use changes and has resulted in the upsurge of malaria transmission in unstable malaria transmission areas. Significant agricultural practices such as urban agriculture, wetland cultivation, clearing of tropical forests and associated deforestation, and agricultural encroachment on highlands have been the primary drivers of malaria transmission in the affected areas.

CLIMATE CHANGE

Several studies suggest that climate can affect infectious disease patterns because disease agents and their vectors are sensitive to temperature, moisture, and other ambient environmental conditions. The extent of these effects continues to generate intense debate, especially in regarding the projected effect of climate change on the global distribution of malaria, in which different modeling approaches have resulted in widely varying estimates. The findings from climate change studies have important implications for malaria control since both the duration and timing of the malaria transmission season are important to inform efforts in malaria vector control. Longer seasons allow heightened transmission and high levels of infection in the population.

6. ENVIRONMENTAL MITIGATION AND MONITORING

Human health and environmental mitigation activities are intended to reduce adverse human health and environmental impacts that result from activity interventions. Mitigation measures can be categorized into the following types of actions: avoid impact, minimize or diminish effects, rectify or repair by rehabilitation, reduce or eliminate over time, or provide compensation. Monitoring is conducted to determine when mitigation is necessary and whether or not mitigation is working successfully. During implementation of the intervention, monitoring can identify negative human health or environmental impacts in time for mitigation measures to be adjusted or additional measures put in place. Therefore, monitoring is a necessary complement to the mitigation of negative human health and environmental impacts. Several monitoring activities are recommended for the Malaria Vector Control Program: Mitigation monitoring, environmental impacts monitoring, entomological monitoring, resistance monitoring, and malaria case monitoring. Based on the results of these monitoring activities, adaptive management of intervention implementation and the overall vector control strategy should be a part of every intervention. Organophosphate biomonitoring will be part of each program that will be using OPs.

ENVIRONMENTAL MITIGATION AND MONITORING PLAN (EMMP)

An Environmental Mitigation and Monitoring Plan (EMMP) present the best management practices and mitigation measures identified for each malaria control intervention, responsibilities for the implementation of the plan, and monitoring and reporting measures. It is a guiding document that will be provided to management teams and will be used as the tool for ensuring adherence to mitigation and monitoring practices and will assure initial and ongoing compliance with environmental requirement and guidelines. EMMPs are incorporated into work plans and budgets and project reporting track EMMP implementation.

7. REGULATORY, LEGAL AND INSTITUTIONAL SETTINGS

Partnerships with host country government and other agencies and organizations are an integral part of PMI's strategy and operational plans. The overarching regulatory framework for conducting environmental assessments for U.S. Agency for International Development (USAID) funded projects is U.S. Code of Federal Regulations (CFR) 22 CFR 216; however, host-country environmental policies, laws, and regulations must also be consulted and considered in preparing Supplemental Environmental Assessments (SEAs) and other required approval documents.

The international transport and use of pesticides are governed by three major international treaties:

- The *Basel Convention* on the Control of Transboundary Movements of Hazardous Wastes and their Disposal;
- The *Rotterdam Convention* on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; and,
- The *Stockholm Convention* on Persistent Organic Pollutants (POPs)).)

Several international and regional organizations fund and implement malaria control initiatives. Coordination and collaboration among these organizations is essential so as not to duplicate efforts and resources.

8. TRAINING AND INSTITUTIONAL CAPACITY BUILDING

Training and capacity building are essential components of efforts to assist the host country in developing a sustainable malaria vector control program that ensures the protection of human health and the environment. Different types of training and capacity building are necessary, ranging from in-field training of those who apply pesticides, to local-level management capacity, to ministry decision-making.

9. PUBLIC CONSULTATION PROCESS

The public consultation process for the PEA was conducted in two phases. The first phase involved a scoping meeting with relevant stakeholders from organizations, agencies, countries, consultants and companies who have a vested interest in malaria control activities and are affected by the Malaria Vector Control Program. Comments from the scoping meeting were carefully considered and included in the PEA.

The second public consultation phase involved a 30 day Public Review of the PEA. All comments received during this process have been carefully considered and included in the development of the Final PEA.

10. CONCLUSIONS AND RECOMMENDATIONS

THEMATIC CONCLUSIONS

Vector control is an important component of the malaria disease control program. Each vector control method has its advantages and disadvantages. Control operations are not mutually exclusive and should be combined whenever possible.

The widespread development of vector resistance to pesticides has resulted from their use on a vast and increasing scale. Monitoring vector resistance to pesticides should be an integral component of the planning and development of vector-borne disease and pest control programs. Reported resistance of a particular vector species in a particular area does not in itself justify an immediate change in policy for control programs in that area. If current measures are inadequate to control disease to the required level, the strategy or pesticide should immediately be adjusted. Nevertheless, even in the presence of resistance, the pesticide might be sufficient to suppress transmission, either because the level of resistance of the vector is not sufficiently high or because the pesticide has some effects. This underlines the need to document resistance and its impact on the efficacy of intervention carefully before adopting corrective measures.

All pesticides are toxic to humans to some degree; therefore the key to safe pesticide use is to minimize the possibilities of exposure during handling. The identification and implementation of best management practices for pesticide handling will minimize or avoid negative human and environmental health risks. Pesticides have the potential to be diverted from malarial disease control programs in the public health sector to the agricultural sector and, to a lesser extent, to private pest control enterprises. In areas where

large quantities of pesticides are used for agricultural crops, the resistance of mosquitoes to pesticides may develop much faster than in areas that do not use large quantities of agricultural pesticides. Agricultural development in Africa has contributed to land use changes and has resulted in the upsurge of malaria transmission in unstable malaria transmission areas. Inter-annual variability of malaria incidence and altitudinal malaria distribution may be influenced by climate change.

Human health and environmental mitigation activities can reduce adverse human health and environmental impacts that result from activity interventions. Monitoring is conducted to determine when mitigation is necessary and whether or not mitigation is working successfully. Partnerships with host country government and other agencies and organizations are an integral part of PMI's strategy and operational plans. Training and capacity building are essential components in the effort to assist the host country in developing a sustainable malaria vector control program that ensures the protection of human health and the environment.

SPECIFIC CONCLUSIONS BY INTERVENTION

IRS remains a valid intervention for malaria vector control. PPE, especially facemasks, gloves, and overalls, have been found to reduce the exposure when handling IRS pesticides. Appropriately located soak pits are important to avoid potential ground water contamination. Several of the pesticides are mobile in soil and are more likely to contaminate groundwater if disposed inappropriately. Pesticides such as DDT, etofenprox, fenitrothion, pirimiphos-methyl, propoxur and chlorfenapyr have a moderate to high risk for human and environmental impacts and should be used with caution and with strict best management practices. PMI will evaluate various approaches for monitoring sprayer exposure to organophosphates and will develop protocols for monitoring OPs based on these evaluations.

The use of ITNs and LLINS remains a valid intervention for malaria vector control. LLINs show a low risk for negatively impacting human and environmental health. This assessment was unable to determine the amount of pesticide released during washing nets, but recommended the use of appropriate best management practices to avoid potential human contamination. There is conflicting evidence for the potential misuse of the nets, especially for fishing. It is recommended that monitoring on how the nets are being used should be conducted. In addition, it is recommended that educational programs on appropriate use be conducted during distribution campaigns. Currently there is no information on the quantity of net material that will eventually need to be collected and disposed of in an appropriate manner once the nets are no longer viable. PMI will work with international organizations to develop a strategy/system to manage net waste. In addition, information to net users will address unintended uses of nets and should be tailored to reflect the local environment.

Larviciding can be a useful method for malaria control, particularly in areas where breeding sites are accessible and relatively limited in number and size. PPE, especially facemasks, glove and overalls, have been found to reduce the exposure when handling larvicide agents. There are negligible risks for human health when potable water is treated with larvicides. There is potential for adverse effects to sensitive non-target aquatic species to water bodies treated with larvicides, though bacterial larvicides have almost no impact on non-target species. Larvicide agents identified for the PMI program have been determined a low risk for negatively impacting human and environmental health. The microbial larvicides, such as Bti and Bs, have been previously determined to be low risk and are not extensively assessed in this PEA.

Environmental management is a particularly effective approach where mosquito-breeding habitats are located in relatively small-scale and readily identifiable areas. Environmental management methods range in the amount of impact they impose on the environment; the appropriateness of each method depends on careful analysis of the specific site

Wall lining has the potential to be a low risk intervention for the PMI program. Like LLINs, pyrethroid resistance could be an issue in the future. As this is a new product, there is no information on the quantity of material that will eventually need to be collected and disposed of in an appropriate manner

once the lining is no longer viable. As with LLINs, the pesticide used for wall linings have been determined a low risk for negatively impacting human and environmental health.

11. NEXT STEPS – APPLYING THE PEA

PLANNING

Knowing where the most malaria cases occur and where environmental conditions promote increased vector prevalence provides guidance in choosing locations where the intervention will have the most impact. Targeting areas for intervention, rather than implementing a broad-spectrum approach, will simultaneously protect more people from malaria and promote judicious use of insecticides, larvicides, and nonchemical interventions. The different interventions proposed in this PEA are more or less appropriate depending on the intervention location chosen. Choosing or emphasizing an intervention that is location-appropriate will ensure that pesticides are used judiciously. The chemicals used in IRS, LLINs, wall lining and larviciding all have different properties and are more or less appropriate in different circumstances. USAID should support interventions in host countries where the appropriate conditions prevail to ensure that the intervention will be sustainable.

SEA GUIDELINES

This PEA provides a broad view of the human health and environmental impacts that could result from implementation of malaria vector control interventions. However, the PEA cannot account for inter-country and interregional variation regarding issues such as the capacity to manage pesticides used for vector control and the environment likely to be impacted. For this reason, SEAs must be developed to describe in-country impacts of interventions and describe country-specific activities to minimize those impacts. SEAs are valid for five years, whereupon the SEA will need to be revised. Letter Reports are required annually to discuss and justify any revisions to the program.

ENVIRONMENTAL EVALUATIONS

Evaluations are a program management tool that links monitoring data to mitigation actions. Evaluations should be used to change or improve mitigation actions taken during an intervention, identify opportunities for improvement, and inform future decisions on interventions and their management. Independent environmental field evaluations should be conducted annually for each host country Malaria Vector Control program.

1. INTRODUCTION

1.1. DOCUMENT OVERVIEW

The Programmatic Environmental Assessment (PEA) serves as an umbrella evaluation of environmental and human health issues related to malaria vector control and to assist with the preparation of country and activity specific Supplemental Environmental Assessments (SEAs) for malaria vector control programs. The purpose of the PEA is to evaluate the potential impacts of the existing program interventions as well as new interventions that were identified as a result of the Scoping Process.

During the course of USAID involvement in the Malaria Vector Control Programs, two PEAs have been prepared to evaluate potential environmental and human health effects from the implementation of the malaria control interventions. In 2002, USAID identified the need for Insecticide-Treated Materials as an important tool in the integrated malaria control program, and prepared the *Programmatic Environmental Assessment for Insecticide-Treated Materials in USAID Activities in Sub-Saharan Africa*, which addressed the risks associated with the use of insecticide-treated materials. In 2007, a second PEA was prepared to address the expansion of the USAID malaria control programs and the Agency's prominent role as a key member of the Roll Back Malaria (RBM) Partnership. The *Integrated Vector Management Programs for Malaria Vector Control Programmatic Environmental Assessment* addressed the human and environmental risks associated with indoor residual spraying, insecticide-treated nets (ITNs), larviciding and environmental management activities.

Recently, it was acknowledged that an updated PEA was warranted to assess new pesticides, program changes, and lessons learned during the course of the program. This PEA evaluates the existing program interventions and new interventions and pesticides that were identified during the scoping process, and provides an assessment of the potential inadvertent human health and environmental impacts related to the malaria vector control actions.

This PEA sets out to meet the requirements of Title 22, Code of Federal Regulations, Part 216 (22 CFR 216)—Regulation 216.

The Integrated Vector Management Programs for Malaria Vector Control PEA is composed of the following sections:

- Section 1 – **Introduction**. The introduction provides the history and overview of the USAID Malaria Vector Control Program; describes the previous PEAs that have been prepared for this program and the objective of the 2012 PEA; includes the findings and recommendations from the Scoping Process; and discusses the limitations and assessment methodology of the PEA.

- Section 2 – **Background Information.** This section includes the WHO Malaria Fact Sheet that explains what is malaria, who is at risk, and prevention and elimination methods; discusses the Integrated Vector Management and the key elements if the IVM strategy; presents a discussion on Resistant Management and includes the types of resistance, factors that influence resistance and approaches for resistance management; and describes the current PMI Program (including the Best Management Practices for IRS).

- Section 3 – **Proposed Alternative and Interventions**. This section discusses the No Action Alternative and the Existing Program Alternative, which includes indoor residual spraying (IRS), Long Lasting Insecticidal-Treated Nets (LLINs) and Insecticide Treated Nets (ITNs), larviciding and

environmental management methods; it also discusses a new intervention, wall lining, and new pesticides that are being considered for the USAID Malaria Vector Program. Interventions that were considered but will not be assessed are also discussed.

- Section 4 – **Affected Environment.** This section provides an overview of issues to be considered when identifying environmental impacts from malaria interventions for country specific environmental assessments.
- Section 5 – **Pesticide Procedures and Human Health and Environmental Consequences.** This section outlines the Regulation 216, 12 Pesticide Procedures and how they are addressed in this PEA. It also provides an assessment of the potential inadvertent human health and environmental impacts related to the malaria vector control interventions. Included in this section is a discussion on the interrelationship of the malaria program and agriculture and their cumulative impacts; and also climate change and how it may impact the malaria program.
- Section 6 – **Environmental Mitigation and Monitoring**. This section describes the monitoring and mitigation recommendations intended to reduce adverse human health and environmental impacts that may result from the malaria control activities.
- Section 7 – **Regulatory, Legal, and Institutional Settings**. Partnerships between PMI, host country governments and other agencies are at the heart of PMI's strategy and operational plans. This section provides an overview of regulatory, policy, and institutional capacity issues to be considered during the preparation of country-specific environmental assessments.
- Section 8 – **Training and Institutional Capacity Building.** This section provides suggestions for training and institutional capacity building for program quality and sustainability.
- Section 9 – **Public Consultation Process.** This section summarizes the public consultation process that was conducted during the scoping process and during the public review of the draft PEA.
- Section 10 – **Conclusions.** This section provides conclusions and recommendations based on the findings from the environmental assessment.
- Section 11 – **Next Steps – Applying the PEA.** This section provides guidance for planning a malaria vector control program; preparing the country specific Supplemental Environmental Assessment (SEA); and conducting annual independent environmental compliance environmental evaluations of these programs.
- Section 12 – **List of Preparers.**
- Section 13 – **References.**

1.2. USAID MALARIA CONTROL PROGRAM

WHO estimates that the number of global malaria deaths have fallen from 985,000 in 2000 to about 781,000 in 2009. By the end of 2010, approximately 298 million ITNs and Long Lasting Insecticidal-Treated Nets (LLINs) will have been delivered to sub-Saharan Africa, enough to cover 76% of the 765 million persons at risk of malaria. It is estimated that 42% of household in Africa owned at least one ITN/LLIN in mid-2010, and that 35 % of children slept under an ITN/LLIN. Indoor residual spraying (IRS) programs have also expanded considerably in recent years, with the number of people protected in

sub-Saharan Africa increasing from 13 million in 2005 to 75 million in 2009, corresponding to protection to approximately 10% of the population at risk in 2009[1].

Since the start of USAID's Infectious Disease Initiative in 1998, the Agency has significantly increased its programs and funding to fight malaria, particularly in Africa, where 90 percent of malaria deaths occur. USAID's malaria programs focus on assisting countries to develop the capacity to effectively prevent and treat malaria through employment of four highly effective proven interventions –LLINs; IRS with residual insecticides; intermittent preventive treatment of pregnant women (IPTp), where appropriate; and treatment with artemisnin-based combination therapies (ACTs), ideally based on a laboratory diagnosis of malaria.

Malaria prevention and control is a major foreign assistance objective of the U.S. Government (USG). In May 2009, President Barack Obama announced the Global Health Initiative (GHI), a comprehensive effort to reduce the burden of disease and promote healthy communities and families around the world. The President's Malaria Initiative (PMI) is a core component of the GHI, along with HIV/AIDS, and tuberculosis. The PMI was launched in June 2005 as a five-year, $1.2 billion initiative to rapidly scale up malaria prevention and treatment interventions and reduce malaria-related mortality by 50% in 15 high burden countries in sub-Saharan Africa. With passage of the 2008 Lantos-Hyde Act, funding for PMI has now been extended through Fiscal Year (FY) 2014 and the PMI strategy was revised to achieve a goal of having Africa-wide impact by halving the burden of malaria in 70 percent of at-risk population in sub-Sahara Africa, or approximately 450 million people. The PMI program now targets 19 high malaria burden focus and two non-focus countries and two regional programs: (focus) Angola, Tanzania, Uganda, Malawi, Mozambique, Rwanda, Senegal, Benin, Ethiopia, Ghana, Kenya, Liberia, Madagascar, Mali, Zambia, Nigeria, Democratic Republic of the Congo (DRC), Guinea, Zimbabwe, (non-focus) Burkina Faso and Burundi, (regional program) Mekong and Amazon, and up to five additional endemic countries.

As a federal government agency, USAID is subject to U.S. environmental laws and regulations. Implementation of these through environmental impact assessment ensures that USAID development programs are both economically and environmentally sustainable. Title 22, Code of Federal Regulations, Part 216 (22 CFR 216), or more often called Regulation 216, define USAID's environmental impact assessment procedures. Based on the nature of the proposed activities and geographic coverage, a PEA approach is warranted for meeting Regulation 216 requirements and provides the protocols that assure the environmental soundness of project implementation. A PEA also expedites future USAID environmental documentation processes by providing reference material for Initial Environmental Examination (IEE), Supplemental Environmental Assessments (SEAs) or other individual environmental assessment that address country specific USAID support for malaria vector control activities.

During the course of USAID involvement in the Malaria control programs, two PEAs were prepared to evaluate potential environmental and human health effects from the implementation of the malaria vector control interventions. Recently, it was identified that an updated PEA was warranted to assess new pesticides, program changes, and lessons learned during the course of the program.

[1] World Health Organization. 2010. World Malaria Report.

1.3. PREVIOUS PEAs

In 2002, USAID identified the need for Insecticide Treated Materials (bed nets, curtains, eave strips, and other materials) as an important tool in the integrated malaria control program, and prepared the *Programmatic Environmental Assessment for Insecticide-Treated Materials in USAID Activities in Sub-Saharan Africa*, which addressed the risks associated with the use of these insecticide-treated materials. The purpose of the 2002 PEA was to assess potential environmental impacts resulting from USAID program activities involving insecticide-treated materials, and provide guidance on how to prepare activity-level assessments and action plans. The PEA addressed the health and environmental risks from potential exposure during distribution, storage, use and disposal of re-treatment pesticides, and exposure of persons using ITMs to pesticide vapors. LLINs were not thoroughly assessed as they were in the early stages of developed and were not widely distributed. Five pyrethroid and "near" pyrethroid pesticides recommended by WHO were reviewed, which include alpha-cypermethrin, cyfluthrin, deltamethrin, etofenprox, lambda-cyhalothrin and permethrin.

The following are issues that the 2002 PEA addressed:

- Loss of pesticide effectiveness from washing nets, based on insecticide properties, net material, number of washes and the resultant percent reduction in concentration. Most nets were found to be washed once a month; therefore net efficacy was 2-3 months.
- Greater risk of mosquito resistance development with the use of pyrethroids only.
- Selection of which insecticide to use (depends on price, availability, and efficacy in the region, as well as environmental concerns).
- Mitigating environmental risks, include using LLINs when possible and avoiding using permethrin EC formulations.

The 2002 PEA can be accessed through the following link on the PMI website:
http://pdf.usaid.gov/pdf_docs/PNACP696.pdf

In 2007, a second PEA was prepared. The *Integrated Vector Management Programs for Malaria Vector Control Programmatic Environmental Assessment* addressed the expansions of the USAID malaria control programs and the Agency's prominent role as a key member of the Roll Back Malaria (RBM) Partnership. The PEA evaluated potential generic environmental and human health effects of the various vector control methods, with an emphasis on Indoor Residual Spraying (IRS), Insecticide Treated Mosquito Nets (ITNs), Larviciding and Environmental Management Methods that reduced mosquito-breeding sites. The 2007 PEA was developed to serve as an umbrella evaluation of the environmental and human health issues related to malaria vector control and to assist with the preparation of country and activity specific SEA for malaria vector control programs. It provided USAID project managers with the policy, procedural and technical guideline to choose appropriate interventions and insecticides, and to develop and implement mitigation and monitoring and evaluation activities. The PEA conducted a screening risk assessment for the purpose of identifying the human health risks of using pesticides in IRS, ITNs and larvicides. The document also provided recommendations for mitigation, monitoring and evaluation as part of program implementation. An overview of the regulatory, policy and institutional capacity issues to consider during the preparation of SEAs was also included. The PEA recommended training and institutional capacity building to ensure program quality and sustainability. Three crosscutting issues were addressed: interaction with the agricultural sector, hazardous waste management, and prevention versus treatment interventions.

The following are the malaria control methods assessed in the 2007 PEA:

- No Action option to control malaria.
- Indoor residual spraying (IRS), using 12 pesticides recommended by WHO:
  - Bendiocarb, Propoxur, DDT, Fenitrothion, Malathion, Pirimiphos-methyl, Alpha-cypermethrin, Bifenthrin, Cyfluthrin, Deltamethrin, Etofenprox, Lambda-cyhalothrin
- Insecticide-treated nets (ITNs): the 2007 PEA addressed the Human health consequences of re-treating and using nets.
- Environmental management methods for larvae control for small-scale readily identifiable areas and areas with high human population density, including:
  - Environmental Modification – permanent, high cost changes such as filling breeding sites, lining water sources and canals, physical drainage of wetlands (surface, subsoil and coastal swamp) biological wetland drainage (tree planting), impoundments
  - Environmental manipulation – recurrent, moderate cost activities such as deepening and narrowing of old drains, vegetation manipulation, synchronized cropping and intermittent irrigation, larvivorous fish introduction, salt water flooding
- Larvicidal agents for standing water, shallow ponds, swamps and marshes
  - Bacterial larvicides, methoprene, temephos, monomolecular films, monomolecular oils

The 2007 PEA can be accessed through the following link on the PMI website: http://pdf.usaid.gov/pdf_docs/PNADI081.pdf

1.4. OBJECTIVE OF THE 2012 PEA

The objective of the 2012 PEA is to evaluate the potential impacts of the program at large. The PEA intent is to serve as an umbrella evaluation of environmental and human health issues related to Malaria Vector Control Program implementation and provide project managers with a technical, policy, and procedural guide for the preparation of country and activity specific Supplemental Environmental Assessment (SEAs) for individual malaria vector control programs. Together, the PEA and SEAs are intended to provide a clear basis for deciding for each country project, which malaria vector control technique USAID can promote and how they should be implemented to comply with the Agency's environmental regulations. This PEA fulfills the legal requirement of assessing environmental and health impacts of the Malaria Vector Control Program, and it is a tool for designing and implementing safe, environmentally and socially sound malaria vector control activities.

To ensure continuity of the USAID Malaria Vector Control Program, the 2012 PEA follows the format of the 2007 PEA and includes many of the same elements, most of which have been updated based on recent reports and studies, new information that has become available, and lessoned learned over the past five years. Some of these elements may be repetitive, but they have been included to ensure that the present document is comprehensive and includes all the fundamental information needed for preparing subsequent SEAs and other required submittal documents.

The intended audience and users of this PEA are USAID Washington Program Officers; USAID Mission Health and Environment Officers; cooperating country health and environment officials; USAID partners implementing malaria vector control programs; Office of Foreign Disaster Assistance (OFDA) Officers; consultants preparing Initial Environmental Examinations (IEEs), SEAs, and other required approval documents; and the general public.

This document meets the requirements of Title 22, Code of Federal Regulations, Part 216 (22 CFR 216)—Regulation 216 (see ***Annex A***), which defines USAID's environmental impact assessment procedures. Regulation 216, Section 216.6 (d) states that "Program Assessments may be appropriate in order to: assess the environmental effects of a number of individual actions and their cumulative environmental impact in a given country or geographic area; or the environmental impacts that are generic or common to a class of agency actions; or other activities which are not country-specific."

1.5. PEA SCOPING REPORT

The purpose of the PEA scoping was to define the extent of the new PEA and identify the full range of issues and potential impacts from the planned malaria vector control interventions funded under the USAID Malaria Control Program. The scoping exercise is the first step in preparing a full assessment study, in compliance with the requirements of USAID Regulation 216. The scoping process is carried out to facilitate a more efficient PEA preparation process and to define the issues and alternatives that will be examined in detail in the environmental assessment. See ***Annex B*** for the full scoping report.

Scoping was held in March 2011 and was based in Washington DC. The first scoping effort involved a review of the 2002 PEA that addressed the ITN, and also the 2007 PEA that addressed IRS, ITN, larviciding and environmental methods for the USAID Malaria Vector Control Program. The findings from this scoping helped identify issues that have been adequately addressed and do not need to be revised, as well as issues that were not addressed and should be included in the updated PEA. This review was followed by a scoping meeting that included relevant stakeholders from organizations, agencies, countries, consultants and companies who have vested interest in malaria control activities and are affected by the USAID Malaria Vector Control Program.

To accommodate stakeholders located in Africa and other locations throughout the world, a participatory scoping meeting was conducted on March 2. All identified stakeholders were invited to attend. Interested parties who could not travel to the meeting were invited to participate via webinar or conference call. The notes from the meeting were then sent to all stakeholders and additional comments and recommendations were requested.

The significant issues to be analyzed in the PEA based on the outcome of the scoping process (focusing on identifying the following issues which are relevant for updating the Malaria Vector Control Program PEA) are presented below:

- Issues not addressed in past PEAs
- Issues identified in past PEAs that should be further assessed
- Issues identified during past 5 years of program implementation
- New technologies or pesticides
- IRS Best Management Practices contribution to minimizing impacts

Issues not addressed in past PEAs

The previous PEAs are very comprehensive and thorough in their assessment of the malaria vector control interventions and their potential significant impacts to human health and the environment. As such, the updating of the PEA sought to not duplicate these efforts, but to address issues that were not previously addressed. These new issues include the following:

- LLINs: Though the past PEAs assessed the risk of ITNs, the PMI program is primarily distributing Long Lasting Insecticidal Treated Nets (LLINs), which will require different assessment parameters than the ITNs that require re-treatment every six months to one year.

- Personal Protection Repellents: USAID has identified the need to address personal protection repellents for workers in malaria prone areas. The 2012 PEA will assess the human and environmental impacts from the waste and exposure issues from the use of such repellents. *(After further review, it has been decided not to include personal protection repellents).*

- Climate Effects: There are reports that temperatures are rising due to climate change which lead to the spread of malaria. The effects of climate on malaria will be investigated as part of the effort to provide recommendations for an effective USAID Malaria Vector Control Program.

Issues identified in past PEAs that should be further assessed

The 2007 PEA screening of human health consequences included problem formulation, analysis, and risk characterization. This screening study identified four pesticides that are high risk and will require further assessment to identify if they remain a viable option for use in the USAID Malaria Vector Control Program., Any additional pesticides deemed to be at high risk based on the noncancer screening results, will also be evaluated during the 2012 PEA. The high-risk pesticides identified in the 2007 report include:

- DDT
- Fenitrothion
- Pirimiphos methyl
- Malathion
- Etofenprox

Issues identified during past five years of program implementation

Since the start of the USAID malaria program, in particular the scale up of the PMI, several issues have come to light that should be addressed in the updated PEA. These issues may have been addressed in past PEAs, but their persistence and complexity were not foreseen and are more significant than initially perceived. These include:

- Waste management (solid and effluent)
- Expired pesticides
- Resistance to insecticides
- Pilferage of insecticides for other use
- Excessive pesticide packaging
- Options to end-of-life care/disposal of nets
- Net efficacy after 20 washings
- Spraying under eaves

- Acute exposure from contact with residue on walls (children and adults touching sprayed walls)
- Residential chronic exposure and risks from IRS pesticides and LLINs/ITNs

Resistance and its impacts were identified in the previous PEA, but have become a challenge for the PMI program. The 2012 PEA will attempt to identify the resistance issues and update the management options. It will also look at the combined impacts from IRS, LLIN, wall lining and agriculture pesticide use (cumulative impacts).

New pesticides or technologies considered for the existing PMI program

Over the past five years, new technologies or pesticides have been introduced to control malaria-carrying mosquitoes. Per Regulation 216 section 216.3 (b) requirements, the new technologies or pesticides will need to undergo an environmental assessment in order to identify the human and environmental risks. They include:

- Chlorfenapyr (pyrroles class) for IRS
- Pirimiphos-methyl CS (new, long lasting formulation) for IRS
- Spinosad (larvicide) actinomycete
- Pyriproxyfen (larvicide) juvenile hormone mimic
- Wall Lining – laminated polyethylene incorporated with pyrethroids

IRS Best Management Practices contribution to minimizing impacts

The 2007 PEA recommended mitigation actions to avoid or minimize the risk associated with IRS activities. These actions were then developed into standard operation procedures (SOPs) by partners implementing the IRS program. The SOPs were then developed further into best management practices (BMPs) that provide standard guidelines for safe and low risk implementation of the IRS program. Many of these BMPs are recommended by WHO and FAO. As part of the human health exposure scenarios and environmental risk assessment, these BMPs will be evaluated for their effectiveness in avoiding or minimizing the risks associated with the IRS program.

1.6. PEA LIMITATIONS

Issues that were deemed not appropriate for assessment in this PEA during the scoping process were based on three criteria: 1) lack of relevance to the USAID Malaria Vector Control Program, 2) new technology not ready for mainstream use, with insufficient information available to be able to conduct a thorough environmental assessment on these technologies, and 3) issues previously adequately addressed in other PEAs.

Table 1-1 Issues ruled out for assessment in the 2012 PEA

Issue	Comments
Flexibility to include new pesticides products as they become available	There is insufficient information available to be able to conduct an environmental assessment on new pesticides products for the program at this time. When information becomes available these new products can be addressed in a PEA addendum.
Entomopathogenic fungi and Transgenic	This involves genetic engineering and requires a separate

Issue	Comments
fungi	approval from the USAID Biosafety officer, which would precede Reg. 216. This new technology is not ready for mainstream use in the field, and limited information is available to be able to conduct an environmental assessment
Personal Protection repellents (DEET, Picaridin, oil of lemon eucalyptus)	Currently the PMI Program is not considering repellents. Could be used in emergency situations.
Personal protection treated materials for mobile population, refugees, humanitarian activities, outdoor workers, outdoor sleeping (treated blankets, hammocks, clothing, plastic sheeting)	Currently the PMI Program is not considering personal protection treated materials. Could be used in emergency situations.
Topical and spatial repellents (Impregnated plastic strip)	This new technology is not ready for mainstream use in the field, and limited information is available to be able to conduct an environmental assessment
Space spraying (fogging)	Method of control in emergency response only. This method exposes humans and the environment to highly absorbable and potentially dangerous concentration of insecticides. It also wastes large quantities of insecticides and requires extensive coordination and infrastructure, making it a very costly option (2007 PEA).

The previous PEA's are very comprehensive and thorough in their assessment of the malaria vector control interventions and their potential significant impacts to human health and the environment. As such, the update of the PEA sought to not duplicate these efforts, but to update any issues where new information is available and to address issues that were not addressed in this document. The following issues in Table 1-2 are all included in this PEA, though the level of risk assessment that was conducted in previous PEA's as described under "comments", were not repeated.

Table 1-2 Issues addressed in previous PEAs that did not require updating

Issue	Comments
Retreatment of nets	Will not address the health and environmental risks from potential exposure during distribution, storage, use and disposal of re-treatment pesticides, and exposure of persons using ITMs to pesticide vapor that were addressed in the 2002 PEA. Nor will it address the human health issues through the net-retreatment process that were addressed in the 2007 PEA.
IRS 12 recommended pesticides deterministic screening	Will not address problem formulation, analysis, and risk characterization that were addressed in the 2007 PEA
Larvicides: Bacterial larvicides, Methoprene, Temephos, Monomolecular films, monomolecular oils deterministic screening	Will not address problem formulation, analysis, and risk characterization that were addressed in the 2007 PEA

Environmental Management Methods	Will not address problem formulation, analysis, and risk characterization that were addressed in the 2007 PEA

1.7. ASSESSMENT METHODOLOGY

This PEA was prepared using best practice methodologies as recommended by Regulation 216. This included using the numerous secondary sources found in professional journals and in publications by environmental and public health organizations, such as WHO, WHOPES, USAID, U.S. Environmental Protection Agency (EPA), and others. USAID Malaria Advisors and USAID Environmental Officers were consulted for updated information on the USAID Malaria Program. Public consultation and review was invited during the Scoping process and review of the initial draft of the PEA; and written comments from USAID Mission personnel and interested stakeholders.

2. BACKGROUND INFORMATION

2.1. BACKGROUND ON MALARIA

The following is taken directly from the WHO April 2010, Malaria Fact Sheet. In 2008, there were 247 million cases of malaria and nearly one million deaths – mostly among children living in Africa. In Africa a child dies every 45 seconds of Malaria and the disease accounts for 20% of all childhood deaths.

Malaria is caused by *Plasmodium* parasites. The parasites are spread to people through the bites of infected *Anopheles* mosquitoes, called "malaria vectors", which bite mainly between dusk and dawn.

There are four types of human malaria:

- *Plasmodium falciparum*
- *Plasmodium vivax*
- *Plasmodium malariae*
- *Plasmodium ovale.*

Plasmodium falciparum and Plasmodium vivax are the most common. Plasmodium falciparum is the most deadly.

Transmission

Malaria is transmitted exclusively through the bites of *Anopheles* mosquitoes. The intensity of transmission depends on factors related to the parasite, the vector, the human host, and the environment.

About 20 different *Anopheles* species are locally important vectors around the world. All of the important vector species bite at night. They breed in shallow collections of freshwater like puddles, rice fields, and hoof prints. Transmission is more intense in places where the mosquito is relatively long-lived (so that the parasite has time to complete its development inside the mosquito) and where it prefers to bite humans rather than other animals. For example, the long lifespan and strong human-biting habit of the African vector species is the underlying reason why more than 85% of the world's malaria deaths are in Africa.

Human immunity is another important factor, especially among adults in areas of moderate or intense transmission conditions. Immunity is developed over years of exposure, and while it never gives complete protection, it does reduce the risk that malaria infection will cause severe disease. For this reason, most malaria deaths in Africa occur in young children, whereas in areas with less transmission and low immunity, all age groups are at risk.

Transmission also depends on climatic conditions that may affect the abundance and survival of mosquitoes, such as rainfall patterns, temperature and humidity. In many places, transmission is seasonal, with the peak during and just after the rainy season. Malaria epidemics can occur when climate and other conditions suddenly favor transmission in areas where people have little or no immunity to malaria. They

can also occur when people with low immunity move into areas with intense malaria transmission, for instance to find work, or as refugees.

Symptoms

Malaria is an acute febrile illness. Symptoms appear seven days or more (usually 10–15 days) after the infective mosquito bite. The first symptoms – fever, headache, chills and vomiting – may be mild and difficult to recognize as malaria. If not treated within 24 hours, *P. falciparum* malaria can progress to severe illness often leading to death. Children in endemic areas with severe cases frequently develop one or more of the following syndromic presentations: severe anemia, respiratory distress in relation to metabolic acidosis, or cerebral malaria. In adults, multi-organ involvement is also frequent.

For both *P. vivax* and *P. ovale*, clinical relapses may occur weeks to months after the first infection, even if the patient has left the malarious area. These new episodes arise from "dormant" liver forms (absent in *P. falciparum* and *P.malariae*), and special treatment – targeted at these liver stages – is mandatory for a complete cure.

Who is at risk?

Approximately half of the world's population is at risk of malaria. Most malaria cases and deaths occur in sub-Saharan Africa. However, Asia, Latin America, and to a lesser extent the Middle East and parts of Europe are also affected. In 2008, malaria was present in 108 countries and territories.

Specific population risk groups include:

- **Young children** in stable transmission areas who have not yet developed protective immunity against the most severe forms of the disease. Young children contribute the bulk of malaria deaths worldwide.
- **Non-immune pregnant women** are at risk as malaria causes high rates of miscarriage (up to 60% in P. falciparum infection) and maternal death rates of 10–50%.
- **Semi-immune pregnant women** in areas of high transmission. Malaria can result in miscarriage and low birth weight, especially during the first and second pregnancies. An estimated 200 000 infants die annually as a result of malaria infection during pregnancy.
- **Semi-immune HIV-infected pregnant women** in stable transmission areas are at increased risk of malaria during all pregnancies. Women with malaria infection of the placenta also have a higher risk of passing HIV infection to their newborns.
- **People with HIV/AIDS** are at increased risk of malaria disease when infected.
- **International travelers from non-endemic areas** are at high risk of malaria and its consequences because they lack immunity.
- **Immigrants from endemic areas and their children** living in non-endemic areas and returning to their home countries to visit friends and relatives are similarly at risk because of waning or absent immunity.

Diagnosis and treatment

Early diagnosis and treatment of malaria reduces disease and prevents deaths. It also contributes to reducing malaria transmission.

The best available treatment, particularly for *P. falciparum* malaria, is artemisinin-based combination therapy (ACT).

WHO recommends that malaria be confirmed by parasite-based diagnosis before giving treatment. Results of parasitological confirmation can be available in a few minutes. Treatment solely on the basis of symptoms should only be considered when a parasitological diagnosis is not possible.

Drug resistance

Growing resistance to antimalarial medicines has spread very rapidly, undermining malaria control efforts.

When treated with an artemisinin-based monotherapy, patients may discontinue treatment early following the rapid clearance of malaria symptoms. This results in partial treatment and patients still have persistent parasites in their blood. Without a second drug given as part of a combination (as is done with an ACT), these resistant parasites survive and can be passed on to a mosquito and then another person. Monotherapies are therefore the primary force behind the spread of artemisinin resistance.

If resistance to artemisinins develops and spreads to other large geographical areas, as has happened before with chloroquine and sulfacoxine-pyrimethamine (SP), the public health consequences could be dire, as no alternative antimalarial medicines will be available in the near future.

WHO recommends the routine monitoring of antimalarial drug resistance, and supports countries to strengthen their efforts in this important area of work.

Prevention

Vector control is the primary public health intervention for reducing malaria transmission at the community level. It is the only intervention that can reduce malaria transmission from very high levels to close to zero. In high transmission areas, it can reduce child mortality rates and the prevalence of severe anemia. For individuals, personal protection against mosquito bites represents the first line of defense for malaria prevention.

Two forms of vector control are widely effective. These are:

- insecticide-treated mosquito nets (ITNs): Long lasting insecticide impregnated nets (LLINs) are the preferred form of insecticide treated nets for public health distribution programs. WHO recommends universal vector control coverage, and in most places the most cost effective way to achieve this is through provision of LLINs. The ultimate goal is that everyone in high transmission areas sleeps under a LLIN every night;

- indoor spraying with residual insecticides: Indoor residual spraying (IRS) with insecticides is a powerful way to rapidly reduce malaria transmission. Its full potential is realized when at least 80% of houses in targeted areas are sprayed. Indoor spraying is effective for 3–12 months, depending on the insecticide used and the type of surface on which it is sprayed. Drugs can also be used to prevent malaria. For travelers, malaria can be prevented through chemoprophylaxis, which suppresses the blood stage of malaria infections, thereby preventing malaria disease.

Insecticide resistance

Mosquito control is being strengthened in many areas, but there are significant challenges, including:

- an increasing mosquito resistance to insecticides, particularly DDT and pyrethroids, and

- limited number of WHOPES-approved insecticide classes.

The development of new, alternative insecticides is an expensive and long-term endeavor. Detection of insecticide resistance should be an essential component of all national malaria control efforts to ensure

that the most effective vector control methods are being used. The choice of insecticide for IRS is a decision that should always be informed by local and recent data on the susceptibility of the target vectors.

Economic impact

Malaria causes significant economic losses, and can decrease gross domestic product (GDP) by as much as 1.3% in countries with high levels of transmission. Over the long term, these aggregated annual losses have resulted in substantial differences in GDP between countries with and without malaria, particularly in Africa.

The health costs of malaria include both personal and public expenditures on prevention and treatment. In some heavy-burden countries, the disease accounts for:

- up to 40% of public health expenditures;
- 30% to 50% of inpatient hospital admissions;
- up to 60% of outpatient health clinic visits.

Malaria disproportionately affects poor people who cannot afford treatment or have limited access to health care, trapping families and communities in a downward spiral of poverty.

Elimination

Historically, many countries – especially in temperate and sub-tropical zones – have been successful in eliminating malaria. The global malaria eradication campaign, launched by WHO in 1955, was successful in eliminating the disease in some countries, but ultimately failed to achieve its overall goal, thus being abandoned less than two decades later in favor of the less ambitious goal of malaria control. In recent years, however, interest in malaria eradication has re-emerged.

Large-scale use of WHO-recommended strategies, currently available tools, strong national commitments, and coordinated efforts with partners, will enable more countries – particularly those where malaria transmission is low and unstable – to progress towards malaria elimination (adapted from WHO Malaria Fact Sheet 2010).

2.2. INTEGRATED VECTOR MANAGEMENT (IVM) APPROACH

Malaria remains the most important vector-borne disease in public health and the current intensification of malaria-control efforts includes the delivery of a package of vector-control interventions aimed at controlling transmission. The concept of Integrated Vector Management (IVM) was developed as a result of lessons learned from integrated pest management, which is used in the agricultural sector.

IVM is a rational decision-making process for the optimal use of resources for vector control. The aim of IVM is to improve the efficiency, effectiveness and ecological soundness of vector control interventions, and to contribute to achieving national and global targets set for vector-borne disease control. To achieve this, vector control needs to be increasingly based on local evidence, integrating interventions where appropriate, collaborating within the health sector and with other sectors, and actively engaging communities. The process of planning and implementing of IVM includes assessing the epidemiological and vector situation at the country level, analysis of the local determinants of disease,

identifying and selecting the vector control methods, assessing needs and resources, and developing locally-tailored implementation strategies.[2] (See Table 2-1 below).

Table 2-1 Key elements of the IVM strategy

Key elements	Description
Advocacy, social mobilization and legislation	Promotion and embedding of IVM principles in the development policies of all relevant agencies, organizations and civil society; establishment of strengthening of regulatory and legislative controls for public health; empowerment of communities.
Collaboration within the health sector and with other sectors	Consideration of all options for collaboration within and between public and private sectors; application of the principles of subsidiarity in planning and decision making; strengthening channels of communication among policymakers, vector-borne disease control program managers and other IVM partners.
Integrated approach	Ensure rational use of available resources through a multi-disease control approach, integration of non-chemical and chemical vector control methods, and integration with other disease control measures.
Evidence-based decision-making	Adaptation of strategies and interventions to local ecology, epidemiology and resources, guided by operational research and subject to routine monitoring and evaluation.
Capacity-building	Development of essential physical infrastructure, financial resources and adequate human resources at national and local level to manage IVM strategies based on a situation analysis

IVM requires a problem solving approach to vector control, where current and historical field observations, surveillance and situation analysis constitute the basis for a plan of action.

An IVM-based process should be intrinsically cost effective, have indicators for monitoring efficacy with respect to impact on vector populations and disease transmission, and use acceptable and sustainable approaches compatible with local health systems. It should also ensure compliance with local regulations and customs, and reduce the probability of pesticide resistance in mosquitoes. The Malaria Vector Control Program should recognize that malaria is focal and variable in nature—even within a single district or municipality, there may be great differences in transmission risk—and, as a result, there is no single answer to vector control that can be applied in all circumstances.

Well-managed vector control programs reduce malaria risk significantly, if they use proven methods for appropriate situations. These methods may include IRS, LLIN distribution, larviciding of mosquito breeding sites, environmental management or manipulation, and the new wall lining intervention. Even if a country's resources do not allow for full implementation of all chosen vector control interventions, partial implementation may still prove worthwhile.

USAID states that IVM emphasizes the management process—that is, the assessment and monitoring used to derive the maximum public health impact from control options.

[2] WHO Handbook on Integrated Vector Management (IVM). December 2010.

2.3. RESISTANCE MANAGEMENT

The recent progress in malaria control has been largely accomplished through a massive increase in vector control through LLINs and IRS. Since both of these prevention measures depend on the ability of insecticides to kill or reduce the lifespan of female mosquitoes, understanding and monitoring insecticide resistance is critical to their continued effectiveness. Responding to insecticide resistance is neither easy nor inexpensive, however, it is essential to develop entomological capacity to monitor, adapt, and respond to emerging insecticide resistance. [3] Mosquito resistance to one or more classes of insecticides is emerging as a major threat to the effectiveness of IRS and ITNs interventions across Africa.

Resistance to insecticides is defined as "*the selection of a heritable characteristic in an insect population that results in the repeated failure of an insecticide product to provide the intended level of control when used as recommended*" (IRAC). Various mechanisms that enable insects to resist the action of insecticides are grouped into four categories:

- *Metabolic resistance* is the most common form of resistance that occurs in insects. The insect enzyme systems are often enhanced in resistance strains enabling them to metabolize or degrade insecticides before they are able to exert a toxic effect.
- *Target-site resistance* occurs when the insecticide no longer binds effectively to the site of action within the insect, which results in the insect being unaffected or less affected.
- *Reduce uptake (cuticular resistance)* occurs when the cuticle or digestive tract linings in the insect are modified and prevent or slow the absorption of the insecticide.
- *Behavioral resistance* describes any modification in insect behavior that helps to avoid the lethal effects of insecticides (such as outdoor feeding to avoid indoor insecticide application).
- *Cross resistance* occurs when a resistance mechanisms, that allows insects to resist one insecticide also confers resistance to compounds within the same class, and may occur between chemical classes. For example, DDT and pyrethroid insecticides are chemically unrelated but both act on the same target site. Past use of DDT has resulted in a mutation at the target site. These insects that have retained the mutation have some resistance to pyrethroids in addition to DDT.

Resistance occurs when naturally occurring genetic mutations allow a small proportion of the population to resist and survive the effects of the insecticide. By continually using the same insecticides the resistance insect will reproduce, thereby increasing the resistant population. Populations of insects that have never been exposed to insecticides are usually fully susceptible, and resistance genes are rare. Factors that influence resistance development include the following:

- *Frequency of application* – How often an insecticide is used is one of the most important factors that influence resistance development
- *Dosage and persistence of effect* – The length of time that an insecticide remains effective (persistence), an insecticide that persists for months or years will provide selection pressure against many generations.
- *Rate of reproduction* – Insects that have a short life-cycle and high rates of reproduction are likely to develop resistance more rapidly than species with a lower rate of reproduction.

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[3] PMI Guidelines for Entomological Monitoring and Insecticide Resistance Monitoring, Draft.

- *Population isolation* – The goal is often to eliminate all of the population, however the greater the selection pressure that is put on a population, the faster susceptibility may be lost.

Resistance selection in disease vectors from non-public health pesticides such as agricultural insecticides contributes to selection pressure.

Insecticides remain the mainstay of many tropical disease control programs; therefore, the potential for this type of program to be compromised by insecticide resistance is of major concern. Although efforts are under way to develop new insect control products that will effectively control insect strain resistant to currently used insecticides, the need to protect and extend the useful life for current insecticides will remain. For this reason, resistance management must be given high priority in the decision-making process in vector-control programs. Effective resistance management requires not only a sound understanding of the vector's biology and the monitoring of vector population, but also the detection, monitoring and consequences of resistance, as well as an understanding of the principles of resistance management.[4] Understanding modes of action of the pesticides is essential for devising a strategy of switching or rotating insecticides.

Insecticide resistance management can be undertaken using insecticide-based approaches in conjunction with other non-insecticidal vector control methods. The simplest form of resistance management is likely to be insecticide based and can take several forms.

- *Rotation* strategies are based on the rotation over time of two or more insecticide classes with different modes of action. The time frame for rotation needs to be sufficiently short to prevent significant levels of resistance to develop.

- *Fine scale mosaics* are the use of spatially separated applications of different compounds against the same insect, such as using two insecticides in different dwellings within the same village.

- *Mixtures* is the co-application of two or more insecticides of different classes and can take the form of a single formulation containing more than one insecticide, two or more insecticide formulation being applied in the same spray tank or LLIN treated with two or more insecticides.

- *Combination interventions* involve using different insecticide classes applied in different forms within a house (such as using carbamate for IRS and pyrethroid on LLIN)

The USAID Malaria Control Program is currently not supporting mixtures (combinations) and mosaics because they are economically and technically difficult to deploy, or difficult to manage logistically.

In the context of vector control, synergists can be defined as compounds that enhance the toxicity of some insecticides by inhibiting the enzymes that metabolize insecticides within the insect. In certain types of resistant insects, synergists can significantly enhance insecticide performance and overcome metabolic resistance. The use of synergists has a valuable place in increasing the activity of certain insecticides on insects with specific resistance mechanisms and prolongs the useful life of those insecticides where resistance is developing. However, there is currently insufficient evidence to determine whether synergists can influence the frequency of resistance genes in a vector population.

Integrated Resistance Management is (IRM) an integral part of the USAID Malaria Vector Control Program. Only through active management of insecticide resistance can the available resource be optimally and sustainably used. As previously discussed, insect resistance develops in an insect population when individuals carrying genes that allow them to survive exposure to the insecticide pass

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[4] IRAC. Prevention and Management of Insecticide Resistance in Vectors of Public Health Importance. 2010.

these genes on. Thus any activities that control the individuals with the resistance trait will delay the spread of the resistance gene. IRM, in the content of the Malaria Vector Control Program, therefore also includes activities such as habitat management, community education and mosquito larviciding. Mosquitoes with reduced susceptibility to an insecticide, based on laboratory testing, may still be controlled at the recommended label rate (application rate recommended by manufacturer). However, exposure to sub-lethal rate application may allow these individuals to survive and pass on the resistance genes. Sub-lethal exposure may arise in IRS due to poor choice of product, under dosing during application or poor application technique. LLIN may also deliver sub-lethal doses within their expected lifetime due to poor product choice, inappropriate storage use or washing. These factors which reduce the efficacy of a vector control program, can lead to a shift in the susceptibility status of the mosquito population, and should be avoided through informed product choice, effective IRS application and LLIN distribution and education (IRAC 2010).

2.4. EXISTING PMI PROGRAM AND BEST MANAGEMENT PRACTICES

In the past year, the President's Malaria Initiative (PMI) has scaled up the coverage of control measures across the original 15 PMI countries, and have increased activities in four proven malaria prevention and treatment measures: insecticide-treated mosquito nets (ITNs); indoor residual spraying with insecticides (IRS); intermittent preventive treatment for pregnant women (IPTp); and improved laboratory diagnosis and appropriate treatment, including artemisinin-based combination therapies (ACTs).

Note: The PEA identifies the significant issues associated with the integrated vector management program actions targeting malaria. The two treatment programs, IPTp and ACTs, do not target the vector but instead target the disease; therefore the PEA does not address these interventions.

In addition to the 15 high malaria burden countries, the PMI program has also recently expanded its efforts into the Democratic Republic of the Congo (DRC), Nigeria, Guinea, Zimbabwe, Burkina Faso and Burundi, the Mekong and Amazon regions and up to five additional endemic countries.

Partnerships are at the heart of PMI's strategy and operational plans. PMI works closely with host country governments; other U.S. Governments agencies; international organizations; other bilateral, multilateral, and private donors; nongovernmental and faith-based organization; and the private sectors.

PMI has focused a large proportion of its resources on procuring and distributing nets, educating people on the dangers of malaria, and encouraging them to sleep under a net every night. During the past two years a consortium of partners, including PMI, Global Fund, UNICEF, and others have made strides to increase net distribution, with the goal to provide one net per every two persons at risk. ITNs are distributed for free, primarily through antenatal and child health clinics or integrated health campaigns that include other interventions. The distribution mostly targets the most vulnerable - pregnant women and children under the age of five. Since 2005, PMI has procured more than 45 million ITNs and distributed more than 30 million. The program has also distributed more than 15,000,000 nets that were procured by other donors. The nets will lose their effectiveness as they become old or damaged after an average of three years, and must be eventually replaced. PMI, in partnership with national malaria control programs, monitors ITN coverage levels and is working to develop cost-effective and efficient replacement strategies. Over the past few years, several new challenges have emerged:

- Identifying the best approaches for sustaining a high rate of ITN ownership.
- Prolonging the useful life of nets by providing guidance on how to care for the nets properly.

- Dealing with the impact of the increasing resistance of *Anopheles* vector mosquitoes to pyrethroid insecticides used in ITNs (PMI 2011).

Since the start of the PMI IRS program in 2006, the use of IRS in Africa has grown substantially, both within PMI focus countries, and in other countries. To ensure best practices, the program follows the following approaches:

- Conduct entomological assessments to measure the operational quality, IRS impact on vector densities, and to monitor mosquito resistance.
- Conduct environmental assessments and adhere to mitigation plans.
- Recruit and train local village and government health staff to carry out and supervise IRS in their own communities.
- Educate residents about IRS before spray campaigns.
- Build in-country capacity for planning and managing spraying activities.
- Manage insecticide stock from procurement to disposal (adapted from PMI 2011).

During 2010, more that 6.6 million structures were sprayed and all PMI countries achieved greater than 85 percent coverage of targeted houses. A significant achievement was the production and release of IRS standardized best management practices(BMPs), developed to ensure that all workers handle the pesticides in an appropriate manner from transportation, storage, stock control to spraying and waste management, and that all residents are protected from unnecessary exposure to the pesticides. BMPs are state-of-the-art mitigation measures applied on a site-specific basis to reduce, prevent, or avoid potential adverse human health, environmental or social impacts. They include physical, structural and managerial practices that decrease the likelihood of the occurrence of adverse impacts on human health or the environment. BMPs can be used alone or in combination as appropriate to a particular situation. The IRS BMPs are based on WHO and FAO recommendations, implementing partner standard operation procedures and lessons learned from five years of program implementation.

Table 2-2 IRS BMPs

IRS Best Management Practices	Description
Environmental Assessment	Establishes a uniform approach for the environmental assessment of indoor residual spraying activities intended to ensure compliance with USAID and host country environmental regulations. It also describes the content requirements of the Supplemental Environmental Assessment (SEA).
Worker and Resident Health and Safety	Provides acceptable safety standards and practices for the handling, storage, transportation and use of pesticides used in indoor residual spraying (IRS) as part of the PMI program, to minimize the risk for human exposure. It is drawn largely from guidelines from the World Health Organization and (WHO) Food and Agricultural Organization (FAO).
Pesticide Storage, Stock Control and Inventory	Provides guidance on the management of pesticide stocks from the point that they have been received in country through the various storage options and eventually to the spray operators and their subsequent return as empty sachets. Close scrutiny is paid to storage and commodity chain-of-custody to avoid the inadvertent loss or leakage of pesticide stocks. In addition, careful management of storage facilities, stock control and inventory control will minimize the risk of migration into other sectors (e.g. agricultural sector) or the market.
Pesticide Transport	Addresses transport activities involving large quantities of pesticides carried in motorized vehicles, typically trucks or pickup trucks. Frequently, because of the nature of the program, these pesticides are being transported to remote rural areas, over poor roads, where supervision and assistance becomes more difficult in the event of an accident.
Spraying Techniques	Provides appropriate safety standards and practices for spraying activities and addresses best practices for appropriate equipment, preparing the pesticide mixture, spraying techniques and cleaning spray pump and nozzles.
Effluent Waste Disposal	Addresses site considerations, standard design and construction, proper use, and decommissioning protocols for the IRS effluent cleaning and disposal facilities.
Solid Waste Disposal	Provides acceptable safety standards and practices for the storage and disposal of solid wastes generated during IRS operations.
Spill Response	Provides acceptable safety standards and practices for responding to pesticide spills in the event of an accident.
DDT Special Considerations	Provides acceptable safety standards and practices for the handling, storage, transportation and use of DDT in indoor

	residual spraying (IRS) as part of the PMI program, to minimize the risk of human exposure.

The BMP Manual can be accessed through the following link on the PMI website:
http://www.fightingmalaria.gov/technical/pest/bmp_manual_aug10.pdf

3. PROPOSED ALTERNATIVES AND INTERVENTIONS

The purpose of the PEA is to analyze alternative design options and strategies in terms of environmental costs and benefits. There are only two alternatives for the USAID Malaria Vector Control Program, either no action, where no interventions would be implemented to control the progress of malaria, or the continuation of the USAID Malaria Vector Control Program, where existing interventions and pesticides would continue to be implemented. Existing interventions include indoor residual spraying (IRS), long lasting insecticidal-treated net (LLINs), larviciding and environmental management methods. During the scoping process one additional intervention, wall lining, and several new pesticides for IRS, larviciding and LLINs were identified as potential options for malaria vector control.

The malaria control interventions that were considered but not included in this environmental assessment are also discussed in this section. These interventions have been excluded as they are not considered viable options for the USAID Malaria Vector Control Program now, nor in the foreseeable future. Any interventions or pesticides that are identified and determined appropriate for the USAID Malaria Control Program after the completion of this PEA will be assessed in a PEA Addendum.

3.1. NO ACTION ALTERNATIVE

The primary impacts of taking no action are disease, human pain and suffering, mortality, a reduction in the quality of life, and economic losses. Malaria affects the health of individuals and national economies alike. Taking no action to control this disease is equivalent to ignoring a major constraint to development. Public and personal expenditures on treatment and prevention, and public-sector expenditures to maintain health care programs and facilities dedicated to malaria create a heavy burden for developing countries and their traditional donors in the health sector. For example, countries with malaria-endemic areas are less able to develop tourism and regional markets or to expand economic activity. The poor quality of life resulting from malaria outbreaks is reflected in suffering and loss of productivity and income on an individual and household level. As the quality of life decreases in general, the natural environment is also affected. For these and many other reasons, the no-action alternative is rejected outright, as a nonviable option.

3.2. EXISTING PROGRAM ALTERNATIVE

The USAID's Malaria Control Program President's Malaria Initiative (PMI) focuses on assisting countries to develop the capacity to effectively prevent and treat malaria through an integrated approach—Integrated Vector Management (IVM) — that uses a range of interventions designed to eliminate or greatly reduce malaria transmission. These interventions can be used in combination and synergistically, or individually, depending on the needs of each country and their specific situation and conditions. The IVM approach emphasizes the development of country and region specific programs that integrate the use of chemical and nonchemical vector control methods in a way that reduces or interrupts the transmission of disease.

The existing program alternative includes the two principle malaria vector control interventions that are currently the mainstream of the USAID Malaria Control program:

- **Indoor residual spraying (IRS)** using the 12 pesticides recommended by the World Health Organization Pesticide Evaluation Scheme (WHOPES)

- **Long Lasting Insecticidal-Mosquito Nets (LLINs)** using the 10 LLINs currently recommended by WHOPES, as well as future LLIN products that receive WHO interim or full recommendation status and further technical, quality, and financial review. The re-treatment of Insecticide-Treated Nets (ITNs) is also included in the program.

In addition to the LLIN and IRS programs that target adult mosquitoes, the USAID Malaria Control Program includes two interventions that target mosquitoes at the larvae stage, also called larval source management (LSM). These include the following:

- **Larvicidal agents**, including bacterial larvicides, methoprene, temephos, and molecular films and oils.

- **Environmental management methods**, including filling breeding sites; lining water sources and canals; physical wetland drainage; biological wetland drainage; impoundment planning; deepening and narrowing of old drains; vegetation manipulation; synchronized cropping and intermittent irrigation; larvivorous fish introduction; and saltwater flooding

3.2.1. INDOOR RESIDUAL SPRAYING (IRS)

Overview

Evidence over several decades has confirmed the effectiveness of IRS in reducing levels of infection and incidence of malaria.

IRS is a commonly used malaria vector control method that is typically implemented by teams of spray operators who spray houses in at-risk localities prior to the rainy season, before heavy rains prompt increases of the *Anopheles* vector population. It is implemented by applying residual insecticides (to which female *Anopheles* 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. The residual effect of the insecticide is sufficient to kill resting mosquitoes for a period ranging from 3 to 12 months depending on the insecticide, 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 a method for community protection, and given its mode of action the highest possible level of coverage (>80% of the homes) is required to achieve the maximum impact on malaria transmission. Achieving this level of coverage and timing spraying correctly (in a short period of time before the onset of the transmission season) are crucial to realize the full potential of IRS.

IRS is most effective in areas with seasonal malaria transmission. However, IRS can be effective in almost all of the following settings:

- In unstable, epidemic-prone malaria transmission areas, will prevent and control epidemics and can be used for the elimination of local transmission of malaria.

- In stable-endemic malaria areas with moderately intense but seasonal transmission, IRS can prevent seasonal increase in transmission and reduce levels of infection prevalence and highly seasonal morbidity and mortality.

- In stable-hyperendemic areas where very intense seasonal or perennial transmission occurs, IRS, with a higher frequency of application than in above instances, can reduce the level of transmission and reduce levels of infection prevalence, morbidity and mortality. (WHO IRS Position Statement 2006)

WHO currently recommends only twelve chemicals for use in IRS. The WHO recommended IRS pesticides that are assessed in this PEA are listed in Table 3-1.

Table 3-1 Existing Program IRS Insecticides

Insecticide compounds	Formulations	Class Group
DDT	wettable powder	Organochlorines
Malathion	wettable powder	Organophosphates
Fenitrothion	wettable powder	Organophosphates
Pirimiphos-methyl	wettable powder, emulsifiable concentrate and capsule suspension (new)	Organophosphates
Bendiocarb	wettable powder	Carbamates
Propoxur	wettable powder	Carbamates
Alpha-cypermethrin	wettable powder and suspension concentrate	Pyrethroids
Bifenthrin	wettable powder	Pyrethroids
Cyfluthrin	wettable powder	Pyrethroids
Deltamethrin	wettable powder and water dispersible granule	Pyrethroids
Etofenprox	wettable powder	Pyrethroids
Lambda-cyhalothrin	wettable powder and capsule suspension	Pyrethroids

Important Considerations

Management

IRS requires effective leadership and management for planning, organization and implementation. Operation must be managed by skilled professional staff, based on an analysis of local epidemiological data and a sound understanding of transmission patterns, vector behavior and insecticide resistance status. Significant strengthening of human and technical resources, accompanied by sufficient financial resource, is needed to develop IRS operations. Public Information, Education and Communication (IEC) is invaluable to ensure community acceptance of house spraying and cooperation, such as allowing access and removing household contents prior to spraying, is critical for the program to be successful.

Personal Protective Equipment (PPE)

In accordance with WHO health and safety regulation, all persons working on IRS must be adequately protected against potential harm due to exposure from pesticides. All persons who may be exposed to pesticides during handling, transportation, storage, use and cleaning of pesticide contaminated materials must wear appropriate personal protective clothing in accordance with the BMP Manual and the safety instruction on the product label or material safety data sheet (MSDS).

Unauthorized Pesticide Use

There is a possibility that IRS pesticides may be pilfered for resale and/or other uses, though, overall, the total amount is relatively small. Storage facilities should have a proper system of stock management and should maintain a daily accounting of stocks received, held and distributed. In the field, distribution of pesticide sachets should be accounted for from issuance to the spray operator, to the receipt of empty or unused sachets at the end of the day. All workers should receive training on the importance of the operations and the need for the pesticide to reach its target use.

It is critical to ensure that adequate regulatory control is in place to prevent unauthorized and un-recommended use of public health pesticides in agriculture or other endeavors. Strict measures must be in place and the authorities alerted if there is any incidence of wrongdoing. Pesticide contamination of agricultural products can have serious ramifications on trade and commerce for countries exporting these products.

Waste Management

IRS activities produce waste during the course of the operations. Effluent wastes are generated during the clean-up activities at the end of the day when the spray pumps are cleaned as standard practice for maintaining the pumps. PPE is also washed daily to reduce worker exposure to pesticides. The wash water will contain traces of pesticide which need to be disposed of properly.

Solid wastes are also generated during spray activities. These wastes include contaminated wastes that have come in contact with pesticides (either through packaging, from accidental spills or leaks, or through spray activities such as damaged PPE) and uncontaminated wastes (such as cardboard outer packaging that have not come in contact with the pesticide). Manufacturers often package pesticides in large plastic containers, which are especially difficult to dispose of properly. Also, pesticides in liquid concentration come in plastic bottles. There is a concern that both types of containers may be reused for personal use, such as for drinking water, and it cannot be guaranteed that they do not contain some residual amount of pesticide. There should be close coordination with the pesticide manufacturers to minimize unnecessary waste where possible.

Expired Pesticides

Pesticide stocks need to be closely managed from the time they are received in country to their eventual use in the field. Careful planning of required pesticide quantities is essential to avoid accumulation of pesticide stock. Pesticides are distributed on a first-in first-out basis at every point of distribution chain to avoid the risk of stocks reaching their expiration date. Occasionally, programs overprocure pesticide stock that they are unable to use during the course of the spray season, or due to resistance issues, a different pesticide is identified for the following spray season, resulting in a supply of expired pesticides which must be properly disposed of as per the BMP Manual.

DDT

Concerns over the safety of DDT, a persistent organic pollutant, have been comprehensively addressed in the framework of the Stockholm Convention of Persistent Organic Pollutants (POPs). The convention bans the use of DDT, except for public health purposes. Therefore, DDT can be used for IRS where it is deemed appropriate based on country-level decision making, provided that stringent measures are taken to avoid its misuse and leakage outside public health.

Resistance

The development of resistance to insecticides constitutes a major threat to the chemical control of malaria vectors. In the past, countries deploying IRS have often been forced to switch to alternative and

more expensive insecticides on account of the development of vector resistance. In Africa, resistance to public health insecticides is significant. Resistance to DDT and pyrethroids in major malaria vectors has been found throughout West and Central Africa, in some areas at a high level, as well as in several parts of Eastern and Southern Africa. Resistance to carbamate has been found in countries of West Africa, with a mechanism that also induces cross-resistance to organophosphates. The selection of resistance in most malaria vectors is thought to be largely the result of past and present use of insecticides in agriculture, though the scale up of malaria control programs may be beginning to influence resistance also. A comprehensive assessment of resistance using entomological monitoring as per Section 6.1.1 of this document at the local level must be carried out before planning any IRS program.

3.2.2. LONG LASTING INSECTICIDAL MOSQUITO NETS (LLINS)

Overview

Conventional mosquito nets provide a protective barrier around the people who are sleeping underneath, but mosquitoes are still able to feed through the nets (when the net is in direct contact with the skin). Nets that are treated with pesticides repel and also can kill the mosquitoes, thus providing an additional level of protection (CDC/WHO). The potential epidemiology advantages and public health benefits of treating nets with insecticide for protection against malaria were recognized in the mid-1980s. There are an estimated 500 million people at risk of malaria in Africa, approximately 250 million nets are required to cover this population and if a net has an average life span of three years this means 83.3 million nets a year are needed to maintain coverage. Achieving and overcoming the challenges of large-scale coverage requires the development of national ITN/LLIN strategies.

ITNs/LLIN are most likely to reduce malaria transmission where malaria vectors bite indoors, feed at night when people are asleep, rest indoors and bite humans preferentially. ITN/LLIN programs in endemic areas with intense malaria transmission target the most vulnerable groups such as children under five years of age (as they have not yet developed protective levels of immunity) and pregnant women (as protective immunity that adult develop in areas of high or moderate transmission is impaired during pregnancy which can lead to anemia and low birth weight). Programs should aim for full population coverage, for many countries with endemic high transmission it will be rational to undertake campaigns that provide one ITN/LLIN per two people in all age-groups as a means of reaching the poorest most underserved populations (WHO 2007).

There are several types of materials used for mosquito nets. Most are made of polyester or polyethylene, but they can also be made of cotton or polypropylene (CDC). The two principle kinds of LLIN are polyester nets that are resin coated with the insecticide and polyethylene or polypropylene nets where the insecticide is incorporated into the fiber.

Only pyrethroid insecticides are approved for use on ITNs/LLINs due to their safety for humans and repellency, high knock down effect, and mosquito irritancy and efficacy at low dosages. These insecticides have been shown to pose very low health risks to humans and other mammals, and do not rapidly break down unless washed or exposed to sunlight. Traditionally the insecticide is applied to the surface of the material and does not keep efficacy after washing, requiring that the nets be re-treated every 6-12 months (or more frequently depending on how often they were washed). The need for frequent re-treatment has been a barrier to the effective use of ITNs in endemic countries. Insecticide for net treatment is an unfamiliar commodity in Africa. Where insecticides have been available, re-treatment of nets has been disappointingly low (20% or less).

The development of Long-Lasting Insecticidal-Treated nets (LLINS) has addressed this problem. LLINs maintain effective levels of insecticide for an average of 3 years of recommended use under field conditions and for at least 20 standard WHO washes in the laboratory conditions (WHO 2006). *Note: depending on conditions and net material, the viable life of the net may vary.* Insecticide is incorporated within the

net's polyethylene fibers during manufacture, for slow release over a sustained period of time. Only the concentration on the surface of the material is depleted by washing or decomposed by sunlight. There are two principle kinds of LLINs - Polyester nets that are resin coated with the insecticide and polyethylene or polypropylene nets that are incorporated with insecticide. Both types of nets are either coated or incorporated with the insecticide so that the bioavailability of active ingredient is controlled through a slow release process.

In 2005, two LLINs were recommended by WHOPES (Olyset® and Permanet®). As of April 2011, there are now 10 nets recommended by WHO, as shown in Table 3-2. Strict quality control standards are necessary to ensure both safety for the user and efficacy as a public health tool. WHOPES evaluation of a new LLIN involves a three-phase testing and evaluation process that involves long-term studies. Interim recommendation may be given until it meets all criteria and has full recommendation (WHO 2005). The position statement from "WHO Global Malaria Programme calls upon national malaria control programs and their partners involved in insecticide-treated net interventions to purchase only long-lasting insecticidal nets (LLINs)." (WHO /GMP) Currently, the USAID Malaria Control Program is only distributing LLINs recommended by WHO.

Table 3-2 WHO recommended LLINs*

Product Name	Product type	Status of WHO recommendation
DawaPlus ®2.0	Deltamethrin coated on polyester	Interim
Duranet®	Alpha-cypermethrin incorporated into polyethylene	Interim
Interceptor®	Alpha-cypermethrin coated on polyester	Interim
LifeNet®	Deltamethrin incorporated into polypropylene	Interim
Netprotect®	Deltamethrin incorporated into polyethylene	Interim
Olyset®	Permethrin incorporated into polyethylene	Full
PermaNet® 2.0	Deltamethrin coated on polyester	Full
PermaNet® 2.5	Deltamethrin coated on polyester with strengthened border	Interim
PermaNet® 3.0	Combination of deltamethrin coated on polyester with strengthened border (side panels) and deltamethrin and PBO incorporated into polyethylene (roof)	Interim
Yorkool® LN	Deltamethrin coated on polyester	Full

*Note: new products may be added as they move through the WHOPES approval process

In addition to the pesticides mentioned above that are coated or incorporated onto the nets by the manufacturers, lambda-cyhalothrin will also be included in this assessment, as it is considered an option for use for LLINs and is recommended as a long lasting treatment in ICON®MAXX.

Table 3-3 Existing Program LLIN/ITN Insecticides

Insecticides compounds	Class Group
Alpha-cypermethrin	Pyrethroid
Deltamethrin	Pyrethroid
Lambda-cyhalothrin	Pyrethroid
Permethrin	Pyrethroid

All mosquito nets should comply with the following attributes:

- *Protect against insect/vector entry* – efficacy of a net to provide an effective barrier to mosquito entry is based on warp-knitted polyester netting or mesh count; LLINs may have larger holes (56 holes per square inch) than non-treated mosquito nets (156 holes per square inch) because they present both physical and chemical (repellent and killing) barriers, which are expected to remain effective throughout the normal service life of the net.
- *Be strong and durable* – strength of netting material can be measured by its bursting strength of the netting material and seams. Bursting strength is the maximum pressure that can be applied to a given surface area of netting before it burst under the strain.
- *Keep its dimension after washing* - the 2000 WHO specification states that shrinkage in either direction of the netting material should be no more than 5% (with minimum puckering of seams).
- *Be safe for users.* (WHO 2005)

Important Considerations

Storage

LLINs are essentially non-perishable, but have a limited shelf life as a pesticide product. Prolonged storage should be avoided. The nets are usually individually packaged in plastic or polypropylene bags. Individual nets are packaged and bundled in bales of 40-50 (WHO 2007). The bales should be stored on pallets in a cool, well-ventilated place, away from sources of ignition and direct sunlight, and the storage facilities should be clean and dry. The bales can be stacked up to 5 meters high, without any damage to the bottom bales. The principal concern for storage is volume, rather than weight, which makes it critical that there is adequate storage capacity at all levels. Stock management should be based on the "first in, first out" rule (WHO 2007). Nets are considered Class 1 material or non-flammable, according to 16 CFR Part 1610. (WHO 2005)

Catch-up – the aim is to achieve a rapid increase in the proportion of pregnant women and children under five years who are sleeping under an ITN. Routine systems can be used to catch-up coverage to deliver the intervention, and are necessary as campaigns do not cover the complete target group.

Keep-up – the aim is to ensure that INTs are available to all pregnant women and all children under five years at all times. Keep-up aims not only to maintain high levels of household ownership of ITNs but also to ensure that they are used regularly and in the most appropriate manner by the target group for maximum effectiveness.

Source: Webster, et al for WHO, 2005

Distribution

Strategy to "catch-up" coverage must be linked to a strategy to "keep-up" coverage. The USG goal for LLIN coverage is "when funding is limited, LLIN coverage should emphasize protection for pregnant women and children under five, since these high risk groups will receive individual benefit from sleeping

under an LLIN. However, limiting coverage of these vulnerable groups will limit the effectiveness of LLINs by reducing the benefits of the mass killing effect on mosquitoes that universal net coverage confers. Therefore the overall goal of the program should be to attain universal coverage of families with enough LLINs to cover all those sleeping in the household".

When community coverage is high, LLINs not only protect those who sleep under them, but also those in the same dwelling and those living nearby (community effect). A variety of targeting and delivery mechanisms have been used including:

- LLINs distributed free during specific, time-limited campaigns and routine programs by the health system.
- LLINs sold at a subsidized price to qualifying beneficiaries at government health clinics as part of a regular service delivery
- LLINs provided at a subsidized price or free through community-based groups in coordination with health systems, though a coupon/voucher system.
- LLIN vouchers delivered through the health system to qualifying beneficiaries, providing a substantial discount on commercially available LLINs.

While rapid scale-up of LLIN distribution in Africa represents an enormous public health achievement, it also represent a formidable challenge for the future in ensuring that the high levels of coverage are maintained. Because of the limited lifespan of the current generation of LLINs (average of 3 years) it is critical to ensure the sustainability of mechanisms for their replacement. Failure to replace non-viable nets could lead to a resurgence of malaria cases and deaths.

Resistance

For reason of efficacy and safety, only pyrethroid insecticides are currently recommended for the treatment of mosquito nets. Pyrethroid resistance already exists in some major malaria vectors, especially Africa. The widespread use of a single class of insecticides increases the risk that mosquitoes will develop resistance, which could rapidly lead to a major public health problem. The operational impact of resistance on the efficacy and effectiveness of LLIN interventions is not yet fully understood (WHO 2007).Effective non-pyrethroid alternatives are being sought because of the consequence that the emergence of strong resistance to pyrethroid would have on the effect of insecticide-treated mosquito nets (WHO 2006).

User impacts

Transient side effects among net users include nose, eye and skin irritation, and objections to the smell. These occur mainly during the first few days after net has been installed, but most lasted for less than 24 hours.

Net Efficacy

The life of the net varies widely from place to place and house to house. In general, 3 years is a realistic estimate for expected life of the net between the durability of the fabric and the effectiveness of the insecticide. WHOPES is developing guidelines for monitoring LLIN durability in the field. This includes the overall "survivorship" or retention vs. attrition and loss of net; the physical integrity of the nets and a classification and quantification of holes; and the bio-efficacy (the residual insecticidal activity and the interaction between insecticide and holes) (RBM 2011).

Recommended Care

As previously mentioned, there are two principle kinds of LLINs – polyester nets that are resin coated with the insecticide, and polyethylene and polypropylene nets where the insecticide is incorporated into the fiber. Pyrethroids bind strongly to the fabric and even in washing with soap and water, only part of the insecticide is removed. The nets regain efficacy (regenerate) within 24 hours of washing (up to 15 days after washing in tropical climates), to allow time for the pesticide to recharge the surface. Some manufacturers recommend to air out the nets for 24 hours before use. It is recommended to wash the net gently in soapy, cold water without prolonged soaking, and not more than four times per year (WHO 2002). Do not wash and rinse the net in rivers, lakes or ponds. Always dispose of water used for washing and rinsing the net in the latrine or on the ground, away from home and animals (not near water bodies) (WHO 2002).

Waste Management

Nets that are no longer viable (i.e.: holes are too large to mend), are often reused within the household as curtains, eave screens and other uses for pest control, all of which can be considered viable and safe. Currently there is no information on the quantity of net material that will eventually need to be collected and disposed of in an appropriate manner. WHO is currently conducting a study to identify the proportion of overall plastic waste that will occur after the nets lose their efficacy.

Polyethylene and polyester nets can be recycled, but presently there is very little information available on the subject and it is currently being researched.

Behavior Modification/Misuse

Experience has shown that possession and appropriate use of LLINs do not automatically go hand-in-hand. In the past, insufficient attention has been paid to designing and implementing locally appropriate communication strategies to accompany LLIN distribution, to inform communities of the importance of LLINs and of how to hang, use and maintain them properly. As a result, many people who receive LLINs did not sleep under them, re-sold them, reduced their efficacy through inappropriate washing practices, or failed to repair or replace them when they became damaged or torn. (WHO 2002)

A small percentage of LLINs are sometimes used for other purposes. There are a wide variety of misuses of mosquito nets that have been observed ranging from nets being made into wedding dresses, to nets being used to protect garden crops from insects and foraging animals, or even as fishing nets or for drying fish. It is not yet clear what amount of pesticides remain in non-viable nets; therefore there is a concern when nets are repurposed for uses where they come in contact with food or the natural environment. Human behavior monitoring and post distribution follow-up campaigns are just now being deployed. *Note: This PEA recognizes that the amount of misused LLINs is minimal, but feels these issues are important to note as they could potentially pose a risk to human and environmental health.*

Re-Treatment of ITNs

Several programs continue to distribute ITNs that require re-treatment, though most nets procured by national malaria control programs currently are LLINs. However, it will take a few more years before LLINs fully replace the current generation of conventionally treated nets. These nets will still require re-treatment with insecticide one to two times a year or after every three washes to ensure their effectiveness. (Roll Back Malaria, 2007).

There are two general approaches employed for net treatment *(a third method includes factory pre-treated nets, which was discussed previously)*:

- "'Do-it-yourself" treatment kits are available for home use. The pesticide is supplied in liquid, powder, or tablet form to be dissolved or dispersed in water. The nets are dipped in the resulting pesticide solution/suspension, and then dried.
- Treatment done by a central service run by trained personnel. Net owners can bring their nets for treatment or re-treatment, thus reducing the risks of exposure of untrained members of the public. (WHO 2004)

The USAID malaria control program is using the WHOPES recommended K-O TAB 1-2-3, or ICON MAXX, both of which are available as a "dip-it-yourself" kit for treatment of individual polyester mosquito nets. K-O TAB is a water dispersible tablet (WT) formulation of deltamethrin and includes a binder that resists repeated washing. A single treatment, which has been shown to increase the wash resistance to 15 standard washes, may be adequate to maintain the effectiveness of ITNs for much of their remaining life span (Roll Back Malaria 2007). The K-O TAB tablet is packaged in an individual foil packet, and disperses in 30 seconds once it is mixed with water. A single treatment has been shown to increase the wash resistance to 15 standard washes, which may be adequate to maintain them effectively as ITNs for much of their remaining life span., (Roll Back Malaria 2007). ICON MAXX is available in twin sachet pack containing 6 ml of lambda-cyhalothrin 10% slow release capsule suspension (CS) and 6 ml of polymer binding agent. Its knock down effectiveness can last up to 20 washes, but the mortality effectiveness varies. ICON MAXX has been given a time limited interim recommendation. (WHOPES 2007).

Table 3-4 WHO recommended insecticide products for re-treatment of mosquito nets for malaria vector control (December 2007)

Insecticide	Formulation	Dosage mg/m²
Alpha-cypermethrin*	Suspension concentrate 10%	20-40
Cyfluthrin*	Emulsion, oil in water 5%	50
Deltamethrin	Suspension concentrate 1%; water dispersible tablet 25%; and water dispersible table 25% + binder (K-O TAB 1-2-3)	15-25
Etofenprox*	Emulsion, oil in water 10%	200
Lambda-cyhalothrin	Capsule suspension 2.3%	10-15
permethrin*	Emulsifiable concentrate 10%	200-500
Long lasting treatment		
ICON®MAXX	Lambda-cyhalothrin; capsule suspension 10% + binder	50

* The USAID Malaria Control Program is currently not using these pesticides in the net re-treatment program; therefore they have not been included in this risk assessment for net re-treatment.

Important Considerations

The efficacy of re-treated ITNs is dependent on the loss of insecticide by volatilization over time and through washing. Generally, a single treatment will remain effective from six months to up to one year, depending on the pesticide used when the net is not washed. However, pesticide concentrations may drop drastically as a result of washing. The amount of loss depends on several factors including the use of soap, water temperature, washing action, the wash-resistance of a particular pesticide and the type of

net material. Based on interviews with 1,000 people from five African countries, it was determined that nets were washed at least once a month, resulting in lost efficacy after only 2-3 washes, or 2-3 months (2002 PEA).

The overall risks from the use and treatment of ITN are essentially the following:

- Risks to humans from exposure to ITN pesticides during pesticide storage and transport, during net treatment and during use, and accidental ingestion of the packet contents may be hazardous to a child.
- Risks to the environment (including non-target organisms) from accidental exposure to ITN pesticides during storage and transport, from improper disposal of waste material and from the washing of nets in natural bodies of water. (2002 PEA)

During the re-treatment process, deposition of dilute insecticide on the skin will occur during dipping of the net, wringing it out, and hanging it out to dry. (WHO 2004)

3.2.3. LARVICIDAL AGENTS

Overview

Larviciding is the general term for killing immature mosquitoes in the larvae and/or pupae stage using chemical agents (i.e. larvacides). Most mosquitoes spend much of their life cycle in the larval stage where they are highly susceptible to both predation and control efforts. Larvae often are concentrated within defined water boundaries, immobile, with little ability to disperse. It is critical to have a thorough knowledge of the biology of the targeted species in order to determine the appropriate larvicide, timing of application and the amount of product to apply. Larvicides can be applied from either the ground (by truck, boat and hand held devices) or by air.

The USAID Malaria Vector Control Programs is implementing very few larvicide programs at this time, but will continue to consider larviciding as an option. The 2007 PEA evaluated the five traditional larvicidal agents: bacterial, methoprene, temephos, molecular films, and molecular oils.

Key Larvicides

Methoprene, an insect growth regulator, mimics the natural juvenile hormone that interferes with normal insect growth and maturation. The level of applied methoprene in the larvae's water environment must be higher than the level of juvenile hormone circulation in the larvae's body in order for the disruption of endocrine processes to occur. The application of methoprene is most efficacious during late 4th instar. Treated larvae reach the pupal stage and then cannot emerge to become adults. Consequently, control of mosquito larvae is relatively slow. The EPA lists methoprene as a biopesticide and a general use pesticides (GUP). When used according to label directions, methoprene is considered safe for humans and for almost all non-target organisms, and will not leach into the ground water. Methoprene represents a small acute and chronic risk to some fish and freshwater invertebrate species. It is effective in a wide variety of both fresh and saltwater habitats. It does not bioaccumulate, and deactivates in sunlight. Methoprene is applied at monthly intervals, usually in highly confined habitats. However, it is also commonly applied to larger bodies of water in the form of time-release briquettes which can last from one to five months. Altosid is the common trade name for methoprene.

Microbial larvicides are formulated to deliver a natural toxin to the intended target organisms. Bacteria are single-celled parasitic or saprophytic microorganisms that exhibit both plant and animal properties. Their effects range from harmless and beneficial to intensely virulent and lethal. **Bacillus thuringiensis (Bt)** is the most common registered microbial pesticide. Bt is a bacterium which occurs naturally in soil and aquatic environments. Bacillus thuringiensis isreaelensis (Bti) was collected from an Israeli riverbed, thus the name. The active ingredients in Bti are delta-endotoxin crystals which are separated from

bacteria near the end of manufacturing processes. These toxic crystals are incorporated into various products which allow their release into water so that they may be ingested by mosquito larvae. The crystals are activated by the enzymes in the mosquito's midgut, pro-toxins are released and bind to the gut which cause cells to rupture resulting in loss of body fluids and death. This rapid action typically controls larvae in 4-24 hours and lasts from 5-10 days. Bti's are GUPs and are safe for non-target organisms in the environment. The crystalline d-endotoxins are not activated in the gut of human or other animals. Bti's will last only a few weeks in water and pose no danger to humans, non-targeted animal species, or the environment when used according to directions. They are typically available in granular form under the names Aquabac, Teknar, Vectobac, LarvX and VectoLex CG. The water-dispersible granular formulations (WG/WDG) are applied as liquid with handheld or knapsack sprayers. The corn granules (CG) are applied by hand motorized granule spreaders. Weekly treatment with Bti can reduce pupae production by 64-94%. The susceptibility of mosquitoes to microbial larvicides is inherent to the species and not the ecological settings. Microbial larvicides also exhibit the highest environmental safety to non-target organisms and application personnel and are unlikely to lead to the development of resistance.

Bacillus sphaericus (Bs) is a naturally occurring spore-forming bacterium found throughout the world in soil and aquatic environments. Bs acts similar to Bti, except that it has been shown to recycle, thus maintaining some residual activity. Once Bs is ingested, partial digestion enables the release of pro-toxins which attach to the gut wall where they disrupt, paralyze and rupture the gut. Bs toxins are much slower acting than Bti toxins and can be more persistent. Bs is a GUP and does not activate in the gut of humans or other animals. Formulation effectiveness depends on the mosquito species and environmental conditions including water quality. Bs is available in water-dispersible granular formulation (WDG) and corn granule (CG) under the name VectoLex. The best results are obtained when applications are made in the 1 to 3 instars. Larval mortality may be observed as soon as a few hours after ingestion, but typically occurs after two to three days, depending upon the dosage and ambient temperature.

Temephos is an organophosphate compound. Organophosphate pesticides modify the normal functions of some nerve cells, causing loss of coordination which leads to paralysis and, ultimately, death. Temephos can be used in many habitats including tidal marshes, woodland pools, polluted water, tires, and as a pre-hatch treatment. It is a GUP with a low toxicity, with little or no detrimental effects on non-target organisms when used according to directions. Temephos is marketed as Abate and ProVect. Because only a small amount of temephos is needed and it breaks down quickly, it does not pose an unreasonable health risk to humans. However, at large doses it can cause nausea or dizziness. Temephos does not present a large risk to terrestrial species; however, because it poses a toxic concern for non-targeted aquatic species, its use should be limited to sites where less hazardous larvicides are ineffective and to adequate intervals between applications. As an organophosphate, temephos also needs careful resistance management.

Surface oils and films are applied to the water surface of breeding sites to suffocate the mosquito larvae. Waste motor oil and diesel have been replaced with new thin layer surface films and highly refined oils that are virtually colorless and odorless, and which exhibit the same larval and pupal control properties as waste oils. (Note that the use of motor oil and diesel is not recommended as an alternative for the malaria control program). **Larviciding oils** are probably the least studied of the mosquito larvicides. Emulsifiers help them spread over the water's surface and suffocate the larvae. The oils can work within four to seven days or less, depending on the dosage. The oils are GUPs that are non-selective. They have low toxicity, with minimal detrimental effects on non-target organisms when used according to directions. An "oil slick" can be viewed on the water surface. Both the odor and appearance may be objectionable. **Monomolecular surface films** are biodegradable ethoxylated alcohol surfactants made from renewable plant oils. They produce an extremely thin film on the water's surface. These films

do not kill by toxic action, but by drowning. They form an ultra-thin film that reduces the surface tension of water, disorienting the emerging adult mosquitoes, and drowning them.

Important Considerations

Larviciding can be a useful method for malaria control, particularly in areas where breeding sites are accessible and relatively limited in number and size. These criteria are often met in urban areas where man-made habitats are located near human dwellings. These small water bodies are less likely to be significant habitat to sensitive species and are suitable for larval control methods.

Target area

Before undertaking larviciding, surveys should be carried out to estimate the relative importance of different types of mosquito breeding sites, which varies considerably depending on the species and local environmental. Targeting the most important sites might improve operational cost-effectiveness (WHO 2006).

Larviciding is recommended only for vectors which tend to breed in permanent or semi-permanent water bodies that can be identified and treated, and where the density of the human population to be protected is sufficiently high to justify the treatment of all breeding places at relatively short intervals (WHO). Larvae habitats can be small, widely dispersed, and transient. Some important malaria vectors can breed in numerous small pools of water that form due to rainfall. It is difficult to predict when and where breeding sites will form, and to find and treat them before the adults emerge. Methods which are less disruptive to the environment are preferred; therefore, larval mosquito control for the prevention of malaria in Africa has not been attempted on a large scale (CDC).

Insecticides

The period of effectiveness of chemical larvicides depends greatly on the nature of the breeding site and its exposure to the sun: it can vary from months in clean water to only a few days in polluted water. Higher dosages are usually recommended for turbid water.

Application

Modified sprayers can be used for effective application of liquid or granule larvicides. Hand-applying granules is not the preferred method of application. The interval for re-treatment with chemical and bacterial larvicides is usually 7-10 days, but can be longer for standing clear water or with treatment at higher dosages.

Precautions

Care must be taken not to exceed the recommended dosage of insecticides applied to water bodies that might be used by humans or domestic animals or that contain wildlife of importance to the human environmental (WHO 2006).

3.2.4. ENVIRONMENTAL MANAGEMENT METHODS

Overview

Environmental management approaches to vector control aim at modifying the environment to deprive the target vector population of its requirements for survival. This reduces human-vector contact and renders the conditions less conducive to disease transmission. For some mosquito species habitat elimination is not possible. Instead chemical insecticides can be applied directly to the larval habitats (Please refer to the previous larvicidal agents discussion).

Environmental management for mosquito control aims to induce changes in the environment to disrupt the mosquito life cycle and reduce its propagation by eliminating breeding sites. As the aquatic environment is critical to the mosquito life cycle, environmental management introduces changes to the local hydrology or water-use practices.

Environmental management is a particularly effective approach where mosquito-breeding habitats are located in relatively small-scale and readily identifiable areas. It is well suited to areas that have a high human population density (e.g., urban settings). Environmental management is not intended to replace other control strategies, but rather it aims to provide a foundation for an integrated approach while reducing human and environmental exposure to insecticides (Lindsay, Summary Report).

Environmental management was used extensively in the early 1900s to control malaria, and was the mainstay of vector-borne disease control in the pre-DDT era. Beginning in the 1950s, insecticides and antimalarial drugs became the primary tools used to combat this disease. Over the course of time, it has become apparent that environmental management's lack in short-term effectiveness (compared with insecticides) is compensated by its ability to control the disease in the long term (Lindsay, et al. 2004).

Although little cost-benefit analysis has been done to determine the long- and short-term impacts of environmental management, its greatest limitation appears to be the potential initial high cost of implementation. However, the initial costs associated with environmental management may be negligible if they are conducted as part of a broader development initiative. For example, a city drainage scheme may be designed in a manner that also helps to reduce mosquito-breeding sites (Lindsay, Summary Report).

The USAID Malaria Control Program does not generally employ environmental management methods for vector control, but will continue to consider it as an option for the Malaria Vector Control Program. The environmental modification and environmental manipulation approaches were reviewed in the 2007 PEA. No new methods have been identified for the 2012 PEA.

Environmental management can be divided into two compatible approaches:

4) **Environmental Modification.** Environmental modification implies permanent changes such as landscaping, drainage, land reclamation and filling. It will often entail minor or major infrastructure that may require significant capital investment.

5) **Environmental Manipulation.** Environmental manipulation is a recurrent activity requiring proper planning and operation. Examples include the removal of aquatic weeds from irrigation and drainage canals, environmental clean-up in urban areas, and the introduction of larvivorous fish to breeding areas. Environmental manipulation can be incorporated into conventional agricultural practices. Its costs are usually modest, but recurrent.

Both of these approaches are discussed in more detail below.

Environmental Modification

Filling Breeding Sites. Potential mosquito breeding sites can be removed by filling abandoned ditches, borrow pits, ponds, and puddling areas. Filling breeding sites is particularly effective in decreasing malaria transmission if they are located close to human settlements. Refuse can be used for filling such sites, provided the refuse is compacted and covered in earth to reduce fly problems.

Lining Water Sources and Canals. Hoof- and footprints make ideal breeding habitats for some mosquito species. Lining the edges of community water sources and irrigation canals, or building bridges across common water crossings, can reduce the formation of mosquito breeding habitat. Lining

irrigation canals with concrete not only reduces the risk of creating mosquito-breeding sites, but also saves water. Concrete lining will increase water flow that, in turn, washes the aquatic stages of mosquitoes out of canal networks. Additionally, if the lining is kept clean of vegetation, it will prevent the establishment of some species of mosquitoes. The reduced water seepage associated with lined canals may also reduce mosquito breeding.

Physical Wetland Drainage

- **Surface Drainage -** A well-constructed drainage system can prevent the formation of small bodies of water which are suitable habitat for the aquatic stages of mosquitoes. The straightening of streams and the removal of vegetation from stream banks creates conditions for the aquatic stages of mosquitoes to be washed into streams, potentially becoming prey to larvivorous fish.

  Surface drainage modifications include improving watercourses and constructing ditches. These modifications should be constructed to follow the existing watercourse in order to prevent water pooling along the drainage channel. Lining drains with concrete, stone, or brick will increase water flow and reduce siltation and weed growth.

- **Subsoil Drainage -** Subsurface drainage is used in wet areas to prevent water logging, improve aeration, and reduce salinization. With this technique, drainage channels are constructed to provide an outlet for accumulated water. Channels can be filled with rock, rubble, or gravel and covered with vegetation, stones, or pipes.

- **Coastal Swamp Drainage -** Constructing embankments to prevent seawater inundation at high tides can assist the drainage of some coastal swamps. Pipes fitted into the embankments with an automatic outflow gate will allow water from the lagoon to be drained at low tide.

Biological Wetland Drainage – Tree planting also has been used to drain wetlands. It has been used in Gujarat, India as part of an integrated program to reduce malaria transmission, increase reforestation, to provide wood, and to improve water management. This approach combines improved drainage and filling with the planting of *Eucalyptus* trees. The biological wetland drainage approach has been used in Zambia to convert a once-prolific area of mosquito breeding in a peri-urban area into a public park.

Impoundments – Impoundments hold water behind an artificial barrier. Examples include reservoirs behind dams or small storage ponds. When dams are constructed, mosquito numbers generally fall because many small water bodies are combined into one large area of water. If mosquito larvae occur within dams, the larvae are usually confined to the shoreline, as many fish are rapacious predators of mosquito larvae. Mosquito populations will only increase if floating vegetation shields the aquatic stages of mosquitoes from predators. There are several design and operation techniques that can be used to reduce the threat of malaria in impoundments.

Environmental Manipulation

Deepening and Narrowing of Drains – The deepening and narrowing of existing drains can be used to change the rate of water flow. This technique can be used to create conditions that are not conducive to mosquito breeding.

Vegetation Manipulation – The manipulation of vegetation can be an effective tool to create conditions that are not suitable for mosquito breeding. Tree planting can be used to create shade, and tree removal can be used to expose mosquito-breeding sites to direct sun light. Vegetation manipulation can also be used in combination with other environmental modification or manipulation interventions (e.g., swamp draining and ditch filling).

In coastal regions, saltwater lagoons with high algae populations are preferred habitats for some mosquito species. Algae populations can also increase the incidence of mosquito breeding in irrigation canals as the algae may reduce the flow of water. The clearing of algae from these areas has led to high mosquito larvae mortality because it increases fish predation on the mosquito larvae. The algae are most often cleared manually with hoes or rakes.

In some locales, vegetation is actually added to the body of water to reduce the preferred habitat for vectors. Plants in the *Azollaceae* family have substantially reduced malaria vector breeding habitats in various locations in India and Sri Lanka.

Synchronized Cropping and Intermittent Irrigation – Synchronized cropping can reduce mosquito populations. An example of synchronized cropping is the method used for growing rice. Rice paddies are left dry for 2 months each year. The periodic wet and dry rice agriculture has led to a significant reduction of adult mosquito populations in Indonesia. Alternatively, fields can be flooded for several days and then left to dry.

Larvivorous Fish Introduction – As its name suggests, this approach introduces fish into mosquito breeding sites that prey on mosquito larvae. The use of predatory fish to feed on water-borne mosquito larvae has been one of the most effective biological control interventions for malaria. *Gambusia affinis*, a native of Texas, and *Poecilia reticulate*, a native of South America, have been used in vector control programs around the world for the past 50 years.

To be successful, certain characteristics are required of the fish species. The fish selected must be a surface feeder, as mosquito larvae are only found on the water surface. In addition, the fish must be hardy enough to survive transport to the breeding area, and variations in water quality, turbidity, and temperature.

Several potential negative environmental impacts are associated with introducing larvivorous fish to a water body. For example, the introduced fish could potentially have a severe impact on local indigenous fish populations. For this reason, introducing fish into natural environments (e.g., rivers, streams, and ponds) is not recommended. Instead, the introduction of larvivorous fish should be limited to man-made environments—underground and overhead tanks, abandoned septic tanks, open and blocked drains, storm water drains, road culverts, irrigation canals, abandoned wells, and commercial fish ponds.

With the above considerations in mind, the use of local indigenous fish species are preferred over the introduction of exotic fish species. Unfortunately, there remains a need to find species that are adapted to survival under local conditions and in temporary habitats.

Saltwater Flooding - Saltwater flooding can be used to create a habitat that is not conducive to mosquito breeding. For example, flood dikes can be constructed to flood lagoons with salt water. Saltwater flooding can also be used in association with drainage systems (e.g., fish ponds and irrigation systems).

Important Considerations

Environmental modification projects require regular maintenance. For example, poorly maintained drainage projects may increase larval breeding habitat. The efficacy of environmental manipulation projects also depends on how well the intervention is matched to the specific ecological requirement of local vector mosquito populations. Information on the distribution of breeding sites is essential. Furthermore, different environmental conditions, including humidity, rainfall and soil composition may affect particular interventions, the malaria vector and disease transmission.

Environmental management for vector control is a particularly powerful approach in development projects, especially those of an infrastructural nature (e.g. dams, irrigation schemes, roads and railroads, airport, flood control projects and urban development). These projects usually offer important opportunities to minimize the adverse effects on the health of local and resettled populations in an efficient and sustainable manner. The WHO Water, Sanitation and Health Programme is developing a methodology to estimate the fraction of the burden of vector-borne diseases that can be attributed to water resources development, the promotion of good practice in water management, and environmental management approaches.

Early large-scale environmental modification projects required significant inputs of labor by paid workers as well as voluntary or obligatory labor contributions by communities. More recent efforts to control malaria vectors through environmental methods have focused more on voluntary community participation.

3.3. NEW INTERVENTION AND PESTICIDES FOR THE EXISTING PROGRAM

During the scoping process, new malaria control intervention and pesticides were identified as a possible option for the USAID Malaria Vector Control Program. Insecticide-Treated Plastic Sheeting (ITPS), also called wall lining or durable lining, is a new intervention which is currently being evaluated in field trials in several sub-Saharan African countries. Based on the results of these trials, this new malaria control method could be included as a malaria control intervention along with LLINs and IRS.

Pesticide products are continuously being developed and researched for malaria vector control. Several products under WHOPES laboratory and or field-testing and evaluation have been included in this PEA as new options for controlling the malaria vector for the PMI program. They include spinosad for larviciding, chlorfenapyr and a new CS formulation of pirimiphos-methyl for IRS, and pyriproxyfen and piperonyl butoxide (a synergist) for incorporation into other vector control interventions. The following descriptions are general. More detailed information on each pesticide is provded in the human and envrionmental risk assessments, in Sections 5.2 and 5.3 respectively.

Each of these new options for the Malaria Vector Control Program are described below.

3.3.1. NEW INTERVENTION - WALL LINING

Overview

In situations of conflict and disaster, the affected population may be severely exposed to vector mosquitoes. To address this problem, attempts have been made to render temporary shelters insecticidal either by spraying tents with pyrethroid or by impregnating polyethylene tarpaulins with insecticide during manufacture. This development, coupled with the widely recognized operational constraints associated with IRS campaigns in conventional rural setting, has given rise to the concept of using insecticide-treated plastic sheeting (ITPS) indoors, fixed to ceilings or walls (Chandre et al 2010).

ITPS, sometimes known as wall lining or durable lining, has potential as a long-lasting insecticidal surface for malaria vector control when used as lining for interior walls and ceilings inside the home. The lining is a new product that is currently being tested for efficacy and practicality as a vector management control technique. ITPS is comprised of laminated polyethylene woven plastic shade cloth impregnated at the factory with deltamethrin or permethrin insecticide. This lining is attached using a nail combined with a special nail cap. It can be affixed to any wall surface, such as mud, brick or wood. When mosquitoes come in contact with the treated surface they receive a lethal dose of insecticide. Because the impact of the product has been correlated with surface area covered, maximum efficacy is attained when the home is fully lined. To have a major impact on malaria, a majority of the sleeping rooms

should be furnished with ITPS. Used outdoors, the material deteriorates within a year under the under the hot tropical sun, therefore indoor use is optimal. The lining comes in rolls approximately 2.3 meters by 100 meters, which weigh 13 kg. The target concentration of pesticide is 4.4 g/kb at 15%.

Important Considerations

Storage

Storage is similar to that for LLINs. Storage stability is a minimum of 2 years. The properties of the product may change if stored incorrectly. Rolls should be stored away from direct sunlight, preferably in and cool and dark place. They should be protected from temperatures above 50C, and stored in the original packaging, in a dry, well-ventilated place. The rolls should be protected against contamination and physical damage.

Installation

The installation of ITPS will probably be completed in a mass effort, similar to IRS. Since the wall lining should last three years, the effort can be completed in zones or stages to be repeated every three years. It is recommended that the worker wear rubber gloves while installing the lining as pyrethroid insecticides have been shown to cause temporary skin irritations. Food should not come in contact with the wall lining.

User Impacts

If they come in contact with the lining, users may experience itching on the skin or burning sensation in the eyes of facial areas and should wash their skin or rinse out their eyes. The plastic has a temporary odor.

Care

The insecticide migrates to the surface of the lining over time, which limits the amount of pesticide concentrations on the surface at any one time, thus reducing the exposure risk for homeowners. Effectiveness is diminished when the wall lining is covered with dust, dirt or grime. The surface should be cleaned periodically when a build-up of dust is noticed.

Disposal

When the wall lining is removed and replaced, the handling, storage and disposal of large quantities of these solid wastes will be a foreseeable issue. As mentioned in the LLIN section, polyethylene can be recycled. Also, as with LLINs, there is a possibility of misuse; appropriate ways to re-use the material will need to be determined. There is no information on the possibility of re-treating the lining material once the pesticide is no longer viable. Once the wall lining is no long viable, it will need to be collected and disposed of appropriately. Disposal should be done in accordance to prevailing country, federal, state and local regulations (ZeroVector, Vestergaard Frandsen).

Resistance

As is the case for LLINs, the operational impact of pyrethroid resistance on the efficacy and effectiveness of wall lining should be considered. The widespread use of a single class of insecticides increases the risk that mosquitoes will develop resistance, which could rapidly lead to a major public health problem.

3.3.2. NEW LARVICIDE PESTICIDE - SPINOSAD

Spinosad is a microbial larvicide derived from a naturally occurring soil bacterium. The bacterium, *Sacchrapolyspora spinosa,* produces spinosyns A and D (collectively called spinosad) during fermentation.

Spinosad works by altering the function of insect nicotinic acetylcholine receptors that causes continuous nervous impulses, leading to paralysis and death. The active ingredient works immediately when ingested or contact, and visible effects are seen within hours of applications. Optimal control is reached within 24-72 hours. It degrades rapidly in sunlight and does not bioaccumulate in the environment. In 2008, Natular® larvicide became the first public health label for spinosad, and is available in liquid, granule and tablet form. Spinosad is the only larvicide for mosquito control registered as a Reduced Risk pesticide by the US EPA, which means it has low impact on human health, lower toxicity to non-target organisms (birds, fish , plants), low potential for groundwater contamination, low use rates, low pest resistance, and potential compatibility with integrated pest management practices. Mammals metabolize spinosad rapidly, and any by-products are excreted. It also meets Organic and Sustainable Practice Standards, allowing it to be used in organic production and processing. Spinosad is also designated "Group 5" by IRAC, which means it has no cross-resistance with existing products and is therefore an option for resistance management.

3.3.3. NEW IRS PESTICIDE - CHLORFENAPYR (PYRROLES CLASS)

Chlorfenapyr is the first commercial pesticide to be derived from a class of compounds known as halogenated pyrroles. Synthesized in 1988 from naturally produced chlorinated pyrrole, chlorfenapyr is a "proinsecticide" in that it requires activation through metabolism. Chlorfenapyr has low volatility and water solubility, is lipophilic, binds strongly to solid particles and degrades slowly in soil, sediment and water. Biological evidence presented by the manufacturer (BASF) indicates that chlorfenapyr is rapidly metabolized and excreted by mammals, birds, and fish, hence unlikely to bioaccumulate in individual organisms or biomagnify between tropic levels (USGS 2011). Chlorfenapyr insecticide is very effective against insects and mites that are resistant to organophosphates, carbamates, pyrethroids, and chitin-synthesis inhibitors. Chlorfenapyr is a pro-insecticide that is metabolized to the active form by mixed function oxidase enzymes in the target pest. The active form inhibits production of adenosine triphosphate, the primary source of cellular energy. Because it is a relatively new product, symptoms of acute exposure are not well characterized in humans, but chlorfenapyr is moderately to highly toxic in acute oral tests in rodents. Chlorfenapyr was characterized as "cannot be determined, suggestive" in EPA carcinogen classification.

3.3.4. NEW IRS PESTICIDE FORMULATION - PIRIMIPHOS-METHYL CS

The new capsule suspension (CS) formulation of Pirimiphos-methyl is longer lasting. It has been specifically designed for use in IRS program to provide long lasting residual control on a range of surfaces. Typically, pirimiphos-methyl EC has a residual effect of 2-3 months, whereas CS has an efficacy of up to 8 months (Syngenta)

3.3.5. NEW VECTOR CONTROL PESTICIDE - PYRIPROXYFEN

Pyriproxyfen is also an insect growth regulator (such as methoprene) and mimics the natural juvenile hormone that interferes with normal insect growth and maturations, preventing larvae from developing into adulthood and thus rendering them unable to reproduce. It is marketed as Sumilarv and is available in granules or water dispersible granules. Pyriproxyfen has a unique mode of action affecting the morphogenesis, reproduction and embryogenesis of insects. The acute toxicity of pyriproxyfen is relatively low, with transient and minimal signs of toxicity observed only at high oral dosages. It may cause brief and minor eye and skin irritation. Chronic feeding studies in dogs suggest that pyriproxyfen is a possible liver toxicant as well as a possible blood toxicant. EPA has not developed a carcinogenicity classification for pyriproxyfen.

3.3.6. NEW VECTOR CONTROL SYNERGIST - PIPERONYL BUTOXIDE

Piperonyl butoxide (PBO) is a synergist used in a wide variety of pesticides. Synergists are chemicals that lack pesticidal effects of their own but enhance the pesticidal properties of other chemicals (though not

all). Piperonyl butoxide is used in pesticides containing chemicals such as pyrethrins, pyrethroids, rotenone, and carbamates. Researchers developed piperonyle butoxide in 1947 using naturally occurring safrole as a key raw material. Piperonyl butoxide inhabits the ability of insects to metabolize certain insecticides. This allows products containing piperonyl butoxide to be equally effective with lower concentrations of insecticides. The EPA determined that piperonyl butoxide degrades somewhat rapidly in the environment, and therefore has a moderately low chance of contaminating water sources. For Chlorfenapyr, PBO acts as an antagonist and should not be used together.

3.4. ALTERNATIVES CONSIDERED BUT NOT ADDRESSED IN THIS ASSESSMENT

The following is a discussion of additional methods for controlling the malaria vector that are not addressed in this PEA.

This PEA does not address malaria control interventions for areas "outside of the house", such as for mobile populations, refugees, IDPs, humanitarian crises, forest workers and rubber tappers, and general outdoor sleeping. Many of these issues would apply to emergency relief for displaced populations. There are a variety of personal protection technologies for these situations, such as the following:

- **Topical repellents**
- **Spatial repellents**
- **Treated clothing, sheets, and blankets**
- **Treated hammocks and hammock nets**
- **Insecticide treated plastic tents**

The PEA also does not address **space spraying or fogging.** Space treatments are usually designed to provide a rapid knockdown and mortality with little or no residual effect. Space spraying provides a rapid method of control in emergency or epidemic situations and may be used for seasonal control of flying insect pests or vectors. However, it may not be ideal for all situations and as such may not be an economical method of control. (WHO, 2002). Space spraying (fogging) needs to be repeated frequently, at times coinciding with target flight activity of the local target species, and under suitable meteorological conditions. For malaria vectors, it would usually have to be applied at night. While space spraying can be useful for nuisance biting species and flies, there is no evidence to support its use in malaria epidemic prevention and control. Nevertheless, space spraying may sometimes be used as an initial measure, when (a) transmission is already ongoing; (b) populations are congregated, as in a refugee camp. (WHO 2005)

The 2007 PEA identified various **developing technologies** that have not been thoroughly studied, developed or commercialized. In various developing country settings, some of these agents may help supplement other control tactics in Malaria Vector Control Programs. The 2012 PEA does not address these technologies, which include neem oil, nightshade extract, natural pyrethrum, copepods, flatworms, nematodes, fungi, diatoms/brown algae, microsporidia/protozoan mosquito viruses, predatory vertebrates, predatory bugs, and predatory mosquitoes.

This PEA does not address **evolution-proof insecticides** or late-life acting insecticides (LLA) for Malaria control, including the different use of existing chemical insecticides (lower dosages or changing concentrations), biopesticides (entomopathogenic fungi, Wolbachia and densorviruses) and novel chemistry (irritancy without lethality). Evolution-proof insecticides are part of alternative strategy that addresses insecticide resistance.

Genetically engineered fungus carrying genes (transgenic) for a human anti-malarial antibody or a scorpion anti-malarial toxin could be a highly effective, specific and environmentally friendly tool for combating malaria. Genetic modified organisms programs are complex and require additional USAID approval procedures. USAID's Biosafety Procedures for Genetic Engineering Research state that "if an activity will potentially involve the use of genetically modified organisms in research, field trials, or dissemination, the activity must be reviewed and approved for compliance with applicable U.S. requirements by the Agency Biosafety Committee in Washington before the obligation of funds and before the transfer, testing, or release of biotechnology products into the environment." This guidance further states that biosafety review is separate from and should precede the Regulation 216 review. (USAID ADS 211) A biosafety review was not completed before commencement of this environmental assessment; therefore this PEA does not address genetic modified alternatives.

4. AFFECTED ENVIRONMENT

CFR 22 §216 requires that environmental assessments describe the affected environment in detail and identify any potential adverse effects on that environment. Additionally, it requires that environmental assessments of pesticide use describe the "conditions under which the pesticide is used, including climate, flora, fauna, geography, hydrology, and soils." This Programmatic Environmental Assessment (PEA) is broad by nature; and, as such, it cannot provide adequate descriptions of the diverse environments where USAID will support malaria control interventions. Thus, Supplemental Environmental Assessments (SEAs) or other required approval documents that are the next tier of the environmental assessment process must address the affected environment on a country-by-country basis.

The following aspects should be addressed in detail in the SEA:

- Malaria incidence and prevalence in the country and identification of endemic and epidemic-prone areas
- Population in targeted area
- Administrative boundaries
- Socioeconomic data
- Land area targeted
- Ecological zones
- Climate of affected/targeted area
- Flora and fauna in affected/targeted area, with specific concern for
    - Endangered species that could be harmed by pesticide exposure
    - Protected areas, forest and water resources where spraying of pesticides should not take place, and where buffer zones may be warranted
- Geography of affected/targeted area

- Hydrology of affected/targeted area
- Soils of affected/targeted area

Further guidance on writing the Affected Environment section of SEAs and other required approval documents is provided in the SEA Guidelines in ***Annex C***.

5. PESTICIDE PROCEDURES AND HUMAN HEALTH AND ENVIRONMENTAL CONSEQUENCES

5.1. REGULATION 216 PESTICIDE PROCEDURES

The Pesticide Procedures portion of Regulation 216 states that "all proposed projects involving assistance for the procurement or use, or both, of pesticides shall be subject to the procedures prescribed in §216.3(b)(i)". This section fulfills the requirement that "the Initial Environmental Examination for the project shall include a separate section evaluating the economic, social and environmental risks and benefits of the planned pesticide use to determine whether the use may result in significant environmental impact." Included in the PEA are the following factors that are to be considered in such an evaluation and where they are discussed within this document.

a) **The USEPA registration status of the requested pesticide**
USAID is effectively limited to using pesticide active ingredients registered by the USEPA for the same or similar uses. Other pesticides not registered in the U. S. may be authorized, but only if the USAID program can show that no alternatives are available. Host country pesticide registration procedures must also be identified and followed. Table 5-3 in Section 5 of this document includes the USEPA registration status for each of the pesticides in the USG Malaria Control Program.

b) **The basis for selection of the requested pesticide**
Pesticide selection may be driven by efficacy, price, availability, safety, etc. All things being equal, a program should choose the pesticide active ingredient and formulation that presents the least overall risk. The pesticides selection is based on WHO Pesticide Evaluation Scheme (WHOPES) recommendations for the IRS, LLIN, ITN re-treatment and larviciding interventions for malaria control. Other bases for the selection include country specific and depend on country registration, entomology evaluations, resistance levels, toxicity issues and costs.

c) **The extent to which the proposed pesticide use is part of an integrated pest management program**
Integrated vector control is USAID's public health policy because it is the most effective, economical and safest approach to pest control. The extent of pesticide use will depend on host government approval and the needs of the country specific programs.

d) **The proposed method or methods of application, including availability of appropriate application and safety equipment**
Section three of this document describes the method(s) of application for each malaria control intervention. All methods of application will meet WHO requirements for best management practices.

e) **Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use and measures available to minimize such hazards**
This is the key section of the environmental assessment. Section 5 of this document examines the acute and chronic toxicological data associated with the proposed pesticide. Section 6 of this document discusses the recommended measures to mitigate any identified toxicological hazards. A complete discussion of the acute and long-term toxicological hazards for each pesticide is located in ***Annex E.***

f) **The effectiveness of the requested pesticide for the proposed use**
The effectiveness of pesticides chosen is a factor of vector resistance and residual persistence. Monitoring activities conducted by vector control specialists will determine the effectiveness and residuum in the effected ecosystems.

g) **Compatibility of the proposed pesticide with target and non-target ecosystems**
The application of the recommended pesticides should be compatible with non-target ecosystems, provided that training and supervision are adequate. Section 6 includes a complete discussion on appropriate mitigation measures.

h) **The conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils**
This refers to particular environmental factors that might accentuate the effects of exposure to pesticides, and the potential need for measures to reduce those risks. The 2012 Programmatic Environmental Assessment (PEA) is broad by nature; and, as such, it cannot provide adequate descriptions of the diverse environments where USAID will support malaria control interventions. Thus, Supplemental Environmental Assessments (SEAs) or other required approval documents must address the affected environment on a country-by-country basis. Guidelines for developing the affected environment discussion are included in Section 4 of this document.

i) **The availability and effectiveness of other pesticides or non-chemical control methods**
Particular vector control methods are chosen based upon the specific needs and situations of each country. The interventions described in this PEA (IRS, LLIN/ITN re-treatment, larviciding, environmental management methods and wall linings) have been determined to be the most appropriate methods for malaria vector control, based on information available at this time. New pesticides or non-chemical control methods will be considered as new information becomes available.

j) **The requesting country's ability to regulate or control the distribution, storage, use and disposal of the requested pesticide**
The PMI works within the overall strategy and plan of the host country's National Malaria Control Program (NMCP) and planning and implementation of PMI activities are coordinated closely with each Ministry of Health. Regulatory, legal and institutional settings are discussed in Section 7 of this document. Host country's ability to regulate pesticides should be evaluated on a country by country basis in the SEA.

k) **The provisions made for training of users and applicators**
USAID recognizes that safety training is an essential component in program involving the use of pesticides. Recommendations for training are discussed in Section 8 of this document.

l) **The provisions made for monitoring the use and effectiveness of the pesticide**
Evaluating the risks and benefits of pesticide use should be an ongoing, dynamic process. Recommendations for pesticide monitoring are including in Section 6 of this document.

5.2. HUMAN HEALTH RISK ASSESSMENT

This section of the report provides an assessment of the potential inadvertent human health impacts related to the malaria vector control actions described in Section 3. The human health risk assessment focuses on the risks to workers and residents from IRS, use of LLINs, /ITNs, re-treating of ITNs and larviciding. The relationship between the HHRA in the 2007 PEA (USAID, 2007) and the HHRA in this revision is described in Section 5.2.1.1. The methods and structure of the HHRA are summarized in Section 5.2.1.2.

5.2.1. OVERVIEW

Summary of 2007 PEA Human Health Risk Assessment

The 2007 PEA (USAID, 2007) included a screening-level (aka, Phase I) human health risk assessment (HHRA) focusing on the health risks of pesticides used in malaria vector control for workers and residents. The 2007 HHRA addressed activities related to IRS, ITN re-treatment, and larviciding. For workers, health risks related to mixing and spraying pesticides for IRS were evaluated, as well as risks from possible spillage events. Resident risks were evaluated for acute exposures in the home following spraying, for mixing and applying pesticides to re-treat ITNs, and for mistaken re-use of pesticide storage containers. Chronic risks for residents were evaluated for use of groundwater contaminated by burial of pesticides. A review of the 2007 PEA exposure pathways, based on Table 8 of the 2007 PEA (USAID, 2007), is provided in Table 5-1.

Table 5-1 2007 PEA HHRA Pathways by Intervention

Process	Pathway	Receptor
Preparation		
Mixing	Inhalation Dermal	Worker Resident
Indoor Residual Spraying		
Spraying	Inhalation	Worker
Spraying, application on walls	Dermal	Resident
Insecticide Treated Nets		
Treating Nets	Dermal	Resident
Disposal		
Burying, groundwater	Dermal Ingestion	Resident
Reuse of Pesticide Containers		
Food/Drink Storage	Ingestion	Resident
Storage		
Spillage	Inhalation	Worker

As summarized in Tables 9 and 10 of the 2007 PEA (USAID, 2007) only two of the process-pathway combinations shown in Table 5-1 "passed" both noncancer and cancer screening assessments for all

pesticides evaluated; resident mixing of pesticides for re-treatment of ITNs, and worker exposure to IRS pesticides following a spill. However, the 2007 PEA results were also qualified as being "based on several assumptions and simplifications that are intended to produce conservative estimates of risk" (USAID, 2007; Section 5.1.3.3). The Phase I screening results were interpreted in a series of bullets, the first of which states, "The very high predictions of noncancer hazard and cancer risk are not supported in the literature or by the experience in other countries" (USAID, 2007; Section 5.1.3.3).

The HHRA in the 2007 PEA (USAID, 2007) concludes with five recommendations for a Phase II evaluation to improve the relevance of the risk screening results to support decision making related to integrated vector management. Two of these recommendations (developing a severity scale for noncancer hazards to support risk management, and convening an expert panel to improve DDT dose-response estimates) are beyond the scope of this revision of the 2007 PEA. Recommendations of the 2007 PEA HHRA that are addressed in this revision include:

1) Conduct simple follow-on modeling related to scenarios where remedial steps are recommended;

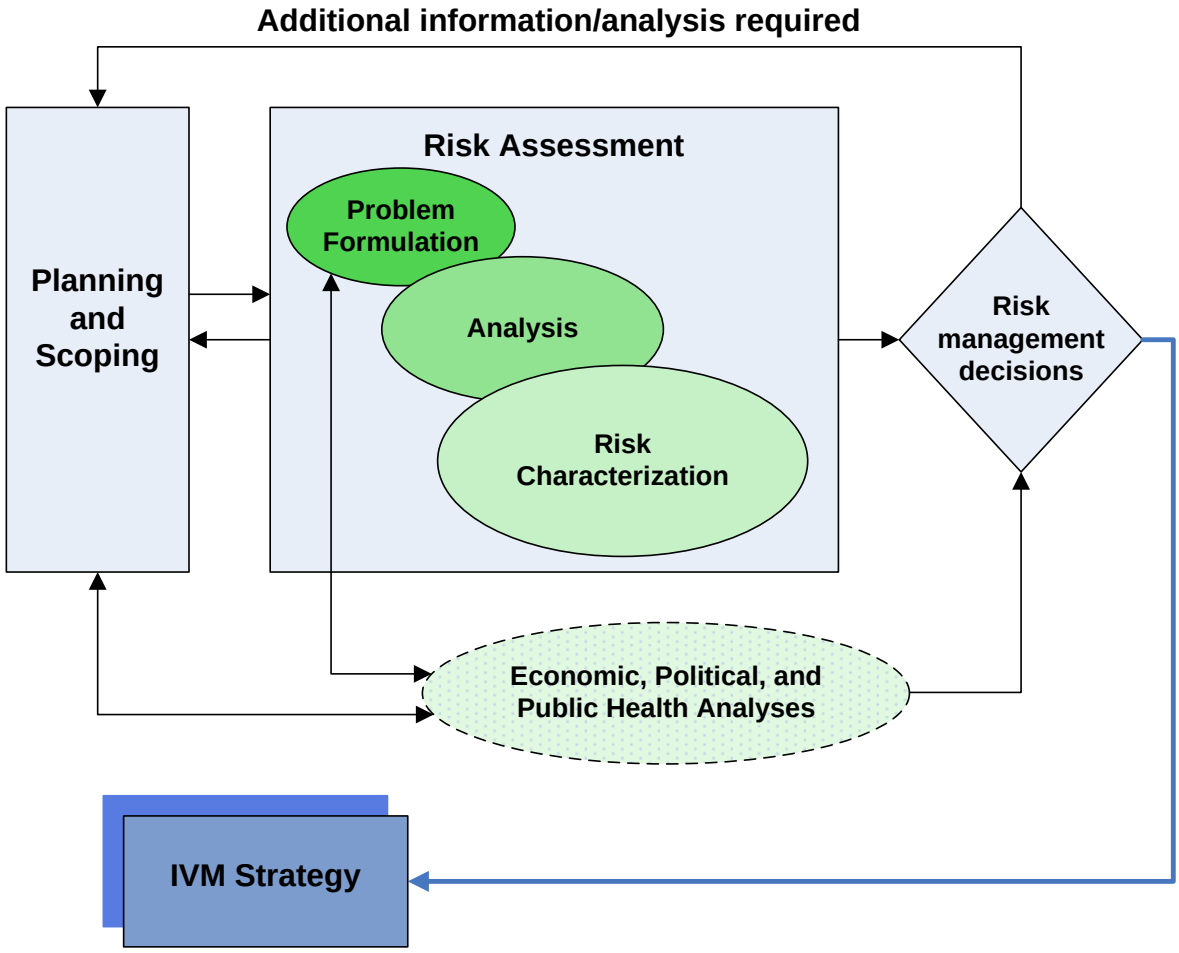
2) Apply an environmental modeling approach to predict the environmental fate of persistent, bioaccumulative pesticides; and,

3) Refine the exposure model for IRS worker and resident receptors.

Human Health Risk Assessment Approach

The human health risk assessment process as described by the EPA is generally structured in four steps according to Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual, Part A (U.S. EPA, 1989). These steps are (1) data collection and evaluation, (2) exposure assessment, (3) toxicity assessment, and (4) risk characterization. More recent EPA risk assessment guidance, particularly in relation to ecological assessment, presents a methodology that is laid out according to three major phases—problem formulation, analysis, and risk characterization—that feed into the decision-making process (U.S. EPA, 1998a). As Figure 5-1 suggests, these three phases are not only linked in an iterative framework, but the risk assessment is itself linked to the decision-making process. Therefore, the results of the risk assessment may be used to support decisions regarding the appropriateness of the malaria vector control strategy as well as to inform additional data collection and analysis.

Figure 5-1 Role of the Risk Assessment Framework in Developing Malaria Vector Control Strategy



The analysis phase shown in Figure 5-2 includes primary components related to exposure assessment and assessment of toxic effects (U.S. EPA, 1998a). Because these components are distinct in a HHRA, they will be broken out into separate subsections of the risk assessment.

The remainder of Section 5.2 describes the HHRA process, as follows:

- **Section 5.2.2, Problem Formulation,** describes the malaria vector control practices and pesticides addressed in this HHRA and presents the conceptual models developed to frame the exposure assessment. Pesticide application practices and formulations, and potentially complete exposure pathways, are identified to define exposure scenarios for each receptor. The relationship between the 2007 PEA HHRA and this revision of the HHRA is detailed.

- **Section 5.2.3, Exposure Assessment,** focuses on identifying how much of a chemical a receptor may be exposed to, and quantifying the rate of exposure, for each exposure pathway. The exposure assessment describes the selection of algorithms and the key assumptions and data inputs (e.g., exposure duration) used to quantify exposure.

- **Section 5.2.4, Toxicity Assessment,** identifies the different types of potential adverse health effects associated with the pesticide exposures described in Section 5.2.3. The selections of toxicity criteria for cancer risk and noncancer hazard are presented.

- **Section 5.2.5, Risk Characterization,** describes the methods for using the exposure and toxicity information to estimate noncancer hazard and cancer risk. The results for each exposure scenario identified in the problem formulation are presented. In addition to summarizing the quantitative results, the risk characterization includes a narrative discussion that interprets the results and identifies key uncertainties and data gaps in the assessment.

- **Section 5.2.6, References,** lists the sources cited in the report.

5.2.2. PROBLEM FORMULATION

This section describes the problem formulation phase of the risk assessment process, by focusing on defining the "dimensions" for the assessment. For this risk assessment of pesticides used in malaria vector control these include (1) identifying the relevant activities contributing to human exposure, (2) identifying the specific pesticides and pesticide formulations related to these activities, and (3) describing the potentially complete exposure pathways (e.g., worker exposure via dermal contact when mixing pesticide for IRS). The focus of the problem formulation is to develop a conceptual model of all potentially complete exposure pathways and identify those pathways for which quantitative risk estimates will be provided in the risk assessment.

5.2.2.1 Malaria Vector Control Interventions and Pesticides

The following three types of interventions are considered in this HHRA:

1) IRS
2) LLINs/ITNs and wall linings
3) Larviciding

IRS and larviciding interventions were evaluated in the 2007 PEA (USAID, 2007), as well as resident exposures related to treating nets with insecticides. Use of ITNs that must be periodically treated by residents was evaluated in the 2007 PEA, but consistent with current WHO recommendations this practice has been limited in the malaria vector control program in favor of pre-treated LLINs that are not re-treated by residents. The use of pre-treated wall linings as a potential vector control practice that was not addressed in the 2007 PEA. In addition to assessment of risks related to LLINs and wall linings, the screening calculations in the 2007 PEA related to IRS, ITN re-treatment and larviciding practices are updated in this HHRA. Conceptual exposure models for these interventions are described in Section 5.2.2.2.

Pesticides used for malaria vector control practices vary with respect to physical, chemical, and toxicological properties and cost. In addition, mosquitoes can quickly build up resistance to a particular pesticide. Therefore, effective vector management requires that several alternative pesticides be available for each practice. Table 5-2 summarizes WHO and U.S.EPA classifications and status for the pesticides evaluated in this HHRA. Insecticides recommended by the WHO for IRS, ITN re-treatment and LLINs (see http://www.who.int/whopes/en/) are addressed. Two of the WHO recommended insecticides for net treatment (deltemethrin and lambda-cyhalotrhrin) are addressed. Two larvicidal agents approved by EPA, methoprene and temephos, are addressed in the HHRA (see http://www.epa.gov/pesticides/health/mosquitoes/larvicides4mosquitoes.htm). Two additional larvicides – spinosad and pyriproxyfen – are also evaluated, as discussed in Section 3 of this PEA.

In addition to chemical insecticides, the microbial larvicides Bacillus thuringiensis (Bt) and Bacillus sphaericus (Bs) were described in Section 3.2.3. The mechanism of action for these larvicides relates to the binding of bacterial toxins on unique receptor cells present in the gut of mosquito larvae (Poopathi and Abidha, 2010). These receptors are not present in the tissues of humans or other animals (U.S. EPA,

1998b). Because of this unique mechanism of action, toxicity to nontarget organisms related to the active component of these microbial larvicides has not been observed (U.S. EPA, 1998b). However, EPA notes that other bacterial toxins may be produced as impurities during industrial fermentation and therefore requires quality control testing and manufacturing standardization during commercial production of Bt (U.S. EPA, 1998b). Because the nature and quantity of such potential impurities is variable and batch-specific, and because controls have been put in place to mitigate their inclusion in commercial Bt, they are not evaluated in this risk assessment.

The relative lack of human toxicity of Bt is described in the Reregistration Eligibility Document for Bt (U.S. EPA, 1998b). As stated in Section III B3 of U.S. EPA (1998b), risks from occupational exposure to mixers, loaders, and applicators are minimal "because of a lack of mammalian toxicity". Similarly, although residential nondietary exposures could occur, EPA states that these are also "expected to be negligible", as are risks from aggregate exposures by oral, inhalation, and dermal routes. Because there is no known mammalian toxicity for Bt, no human toxicity criteria are derived by EPA. A Reregistration Eligibility Document for Bs has not been developed by EPA, but based on common mechanism of action a presumption of no mammalian toxicity may also be made for Bs. EPA states in regard to human health risks for both Bt and Bs, "They are essentially nontoxic to humans, so there are no concerns for human health effects when they are used according to label directions" (http://www.epa.gov/pesticides/health/mosquitoes/larvicides4mosquitoes.htm#microbial).

Table 5-2 Pesticide Classification and Status, by Intervention

Pesticide	IRS	LLINs/ITNs	Wall Lining	Larviciding	Pesticide Class	WHO Class[1]	EPA Status[2]	EPA Class[3]	EPA Restrictions[4]
Alpha-cypermethrin	●	●			Synthetic Pyrethroid	II: Moderately Hazardous	Cancelled	No concensus value	n/a
Bendiocarb	●				Carbamate	II: Moderately Hazardous	Cancelled	II: Warning	GUP, RUP
Bifenthrin	●				Synthetic Pyrethroid	II: Moderately Hazardous	Active	II: Warning	RUP
Chlorfenapyr	●				Pyrazole	II: Moderately Hazardous	Active	II: Warning	GUP
Cyfluthrin	●				Synthetic Pyrethroid	II: Moderately Hazardous	Active	I, II: Danger, Warning	GUP, RUP
DDT[5]	●				Organochlorine	II: Moderately Hazardous	Cancelled	II: Warning	n/a
Deltamethrin	●	●	●		Synthetic Pyrethroid	II: Moderately Hazardous	Active	II, III: Warning, Caution	GUP, RUP
Etofenprox	●				Synthetic Pyrethroid	U: Unlikely to present acute hazard in normal use	Active	III: Caution	GUP

Pesticide	IRS	LLINs/ITNs	Wall Lining	Larviciding	Pesticide Class	WHO Class[1]	EPA Status[2]	EPA Class[3]	EPA Restrictions[4]
Fenitrothion[6]	●				Organo-phosphate	II: Moderately Hazardous	Active,	III: Caution	GUP
Lambda-cyhalothrin	●	●			Synthetic Pyrethroid	II: Moderately Hazardous	Active	II: Warning	RUP
Malathion	●				Organo-phosphate	III: Slightly Hazardous	Active	III: Caution	GUP
Methoprene				●	Insect Growth Regulator	U: Unlikely to present acute hazard in normal use	Active	IV: No Labeling Requirement	GUP
Permethrin		●	●		Synthetic Pyrethroid	II: Moderately Hazardous	Active	II III: Warning, Caution	GUP, RUP
Piperonyl butoxide		●			Unclassified; synergist	U: Unlikely to be hazardous	Active	III: Caution	GUP
Pirimiphos-methyl	●				Organo-phosphate	III: Slightly Hazardous	Active	II III: Warning, Caution	GUP
Propoxur	●				Carbamate	II: Moderately Hazardous	Active	I, II, III: Danger, Warning, Caution	GUP, RUP
Pyriproxyfen				●	Pyridine, juvenile	U: Unlikely to be	Active	IV: No labeling	GUP

Pesticide	IRS	LLINs/ITNs	Wall Lining	Larviciding	Pesticide Class	WHO Class[1]	EPA Status[2]	EPA Class[3]	EPA Restrictions[4]
					hormone mimic	hazardous		requirement	
Spinosad				•	Spinosyn, microbial	U: Unlikely to be hazardous	Active	IV: No labeling requirement	GUP
Temephos				•	Organo-phosphate	U: Unlikely to present acute hazard in normal use	Active	III: Caution	GUP

GUP, General Use Pesticide; RUP, Restricted Use Pesticide. RUPs can only be used in the United States by trained, certified applicators; usually an indication of risk concerns that must be mitigated in some way.

[1] The classification distinguishes between the more and the less hazardous forms of each pesticide, in that it is based on the toxicity of the technical compound and on its formulations. In particular, allowance is made for the lesser hazards from solids as compared with liquids. The classification is based primarily on the acute oral and dermal toxicity to the rat since these determinations are standard procedures in toxicology. Where the dermal LD_{50} value of a compound is such that it would place it in a more restrictive class than the oral LD_{50} value would indicate, the compound will always be classified in the more restrictive class. Provision is made for the classification of a particular compound to be adjusted if, for any reason, the acute hazard to man differs from that indicated by LD_{50} assessments alone. Table 5-3 below indicates how WHO determines the toxicity class for pesticides; the terms "solids" and "liquids" refer to the physical state of the active ingredient being classified.

[2] EPA *Registration Status* refers to whether there are any brands or formulations of the pesticide that are registered with EPA as legally available for sale in the United States. If there are, the chemical has an "Active" status; if not it has a "Cancelled" status. It is important to note that the United States, where EPA registration is effective, does not have a malaria problem, does not perform IRS, and has little market for pesticides with important health uses (and where it does use them, generally uses small amounts). Therein lies one of the issues with relying heavily on EPA registration. Many markets are too small for manufacturers to attempt to gain registration status. Therefore, many products that might receive active registration status for the small amounts of insecticide used in health programs, had the United States had a problem with malaria and performed wall spraying, never do. Likewise the EPA will not have specific user risk data for IRS applications nor would it have conducted a risk assessment for that specific use pattern, because IRS applications are not performed in the United States. On the other hand, a product may be registered by EPA, but due to risk concerns, risk mitigation measures could be imposed on its continued use. These risk mitigation measures are often relatively sophisticated and may be difficult to use under developing country conditions.

[3] This column indicates how EPA determines the toxicity class for pesticides.

[4] Some trade names and formulations for the same insecticide active ingredient may be either RUP or GUP, depending on formulation.

[5] DDT is listed in Annex B of the Stockholm Convention on Persistent Organic Pollutants. Parties must register with the Secretariat to use DDT for disease vector control and comply with information collection requirements on production and use of DDT.

[6] Fenitrothion is listed as a GUP. This classification is for the ant bait formulation. Outdoor uses of fenitrothion needed to be RUP for acute and chronic toxicity to non-target species.

Table 5-3 U.S. Pesticide Registration Status Determination of Same or Similar Use Patterns

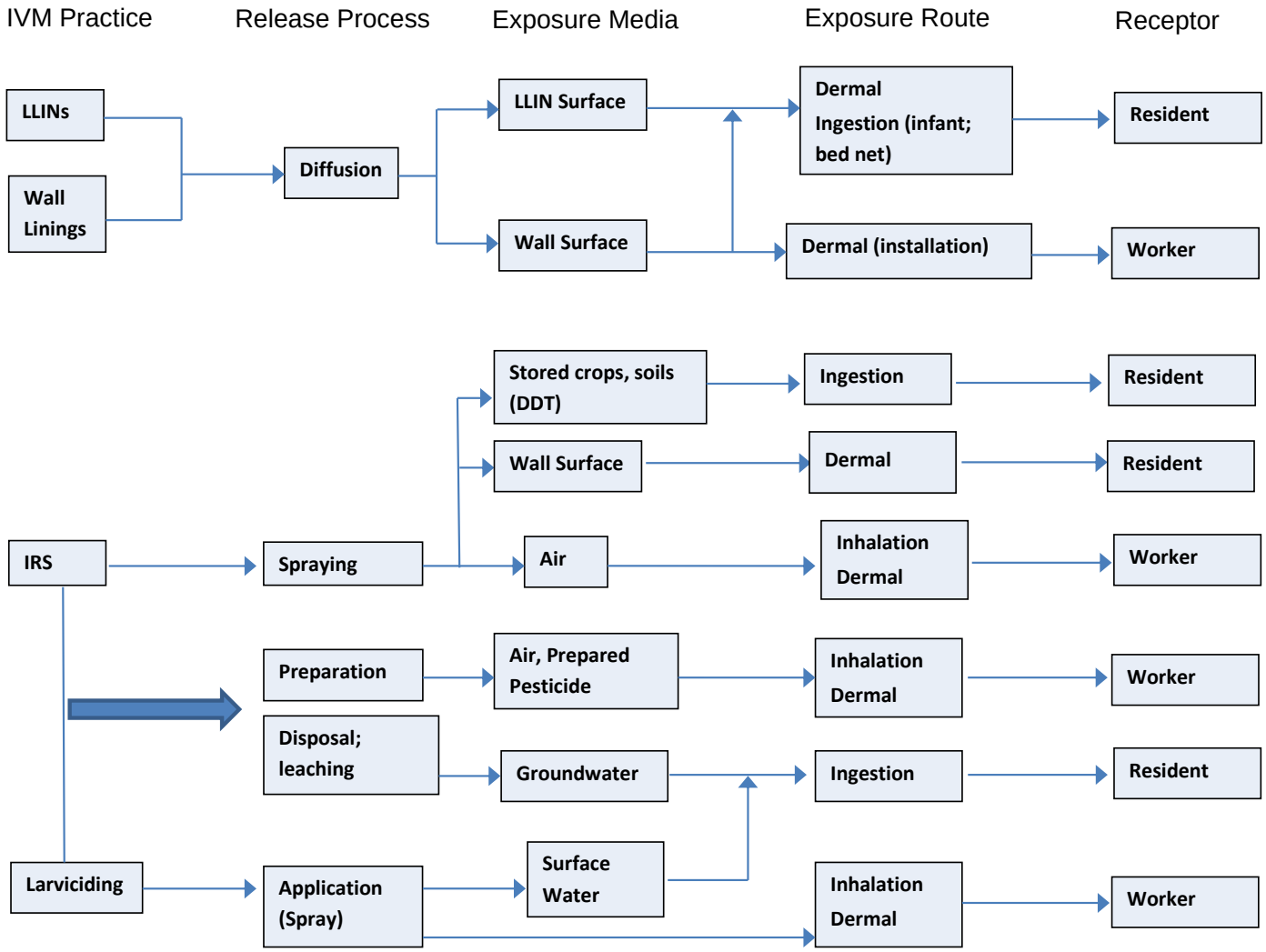
Pesticide	IRS	LLINs/ ITNs	Larviciding	U.S. Registration for Same or Similar Use Pattern	U.S. Registration but No Same or Similar Use Pattern	No U.S. Registration	Notes
Bifenthrin	•			•			Bed nets, indoor carpet, floors, aerosols, and bedding treatments
Cyfluthrin	•			•			Multiple residential uses, including foggers and indoor carpets
Deltamethrin	•	•		•			Multiple residential uses, including paint additive, human bedding, and clothing
Etofenprox	•			•			Multiple residential uses, including foggers and aerosols
Lambda-cyhalothrin	•	•		•			Multiple residential uses, including bedding
Methoprene			•	•			Larvicide; indoor fog use
Permethrin		•		•			Dust, aerosol, fogger, lice bedding spray, and residential uses
Piperonyl butoxide		•		•			Aerosol or fogger for adult mosquito control
Propoxur	•			•			Multiple residential uses, fogger, and aerosols
Spinosad			•	•			Registered as a mosquito larvicide Also: insect pests of field crops, fruits, vegetables, ornamentals, turf, public health
Temephos			•	•			Larvicide; multiple public health uses
Chorfenapyr	•				•		Labeled for household/structural pests: Ants, Asian Lady Beetles, Bed Bugs, Beetles, Boxelder Bugs, Centipedes, Cockroaches, Confused Flour Beetles, Crickets, Earwigs, House Flies, Pill bugs, Sawtoothed Grain Beetles, Scorpions, Silverfish, Spiders, Termites, Wasps and Yellow Mealworms Also for greenhouses, outdoor nurseries
Fenitrothion	•				•		Many uses broad-spectrum insecticide uses cancelled; only US registered use is in ant/roach baits, child resistant packaging
Malathion	•				•		No residential uses
Pirimiphos-methyl	•				•		No residential uses
Pyriproxyfen			•		•		Fleas/ticks on dogs Adult mosquito control (not larvae) when mixed with cyphenothrin
Alpha-Cypermethrin	•	•				•	Not Registered—but other forms of cypermethrin registered for residential uses
Bendiocarb	•					•	Cancelled—All uses voluntarily cancelled, 1999; did include residential (carpets, furniture, baseboards, and floors); risks of concern identified
DDT	•					•	Cancelled

5.2.2.2 Conceptual Models of Exposure for Malaria VECTOR CONTROL Interventions

Each malaria vector control intervention involves different activities, such as the preparation of the pesticide formulation, disposal of excess pesticide, or use of treated materials. Figure 5-2 presents an overall conceptual model that shows the potentially complete exposure pathways that could lead to pesticide exposure for residential and occupational receptors. More detailed conceptual exposure models are provided below for the following activities:

- IRS, ITN re-treatment and larviciding; preparation of pesticide. Includes assessment of worker risks with and without use of personal protective equipment (PPE).
- IRS, ITN re-treatment and larviciding; disposal of surplus. Includes resident exposure related to leaching of buried pesticide to groundwater.
- IRS; spraying. Includes assessment of worker risks with and without use of PPE, and exposure of residents to residual pesticide on walls.
- LLINs/ITNs; use. Includes assessment of resident risks from sleeping beneath nets.
- Wall linings; installation and use. Includes assessment of worker risks with and without use of PPE during installation, and resident risks from contact with the lining.
- Larviciding; application and residual. Includes assessment of worker risks during application and resident risks from residual larvicide in surface water.

Figure 5-2 Conceptual Exposure Model for All Malaria Vector Control Exposure Pathways



IRS, ITN Re-treatment and Larviciding; Preparation of Pesticide

Most of the pesticides used in malaria vector control do not come in ready-to-use form. Therefore, the worker or resident must first prepare the applied form from the concentrated form. Table 5-4 lists the concentrated and applied forms of each pesticide evaluated for IRS, ITN re-treatment or larviciding in this HHRA.

To prepare liquid solutions (for IRS and liquid larviciding), the worker mixes the concentrated pesticide (either a wettable powder or concentrated solution) with a solvent (usually water) to the recommended use concentration (which varies by pesticide). For IRS and liquid larviciding, the worker pours the solution into an aerosol canister (sprayer). To prepare liquid solutions for ITN re-treatment, the resident mixes the concentrated pesticide (either capsule suspension or water dispersible tablet) with water in a basin where the net is then submerged (as per WHO 2002 net treatment instructions). For granular larvicides, the worker may be exposed during loading of the granules for dispersal. It is assumed that there is negligible potential for significant dermal or inhalation exposures for tablet, pelletized, or briquette forms of larvicides which do not require preparation for their application.

Figure 5-3 presents a more detailed conceptual model for exposure from preparation of pesticides (see Figure 5-2). Preparing pesticide solutions can involve mixing, stirring, and pouring. Spills can also occur during preparation. These processes can lead to exposures via inhalation and dermal contact from releases of pesticide vapors, particulate matter (from powders), and solutions. Vapor releases can occur when liquid concentrated emulsions are diluted. Particulate releases can occur when mixing powdered forms. Workers can inhale the vapors or particulates, or be exposed through dermal contact. Spills during preparation could also result in worker exposure, or resident exposure if the spills occurred in or near a home, although the magnitude and frequency of such exposures is uncertain. Possible exposures related to spill events are evaluated qualitatively in this assessment.

Exposure of the worker to pesticides during preparation can be greatly reduced if the worker follows best management practices (BMPs) as described in the *President's Malaria Initiative BMP Manual* (USAID, 2010).

Table 5-4 Formulation of IRS, ITN Re-treatment and Larviciding Insecticides Evaluated in this PEA

IRS Pesticide	Formulation
alpha-cypermethrin	WP
bendiocarb	WP
bifenthrin	WP
chlorfenapyr	EC
cyfluthrin	WP
DDT	WP
deltamethrin	WP, T
etofenprox	WP
fenitrothion	WP
lambda-cyhalothrin	WP, CS
malathion	WP
permethrin	WP
pirimiphos-methyl	EC and CS
propoxur	WP and EC
Larvicide	**Formulation**
methoprene	G and EC
spinosad	G, EC, T and CG
temephos	G and EC
pyriproxyfen	G and EC

EC: emulsifiable concentrate
WP: wettable powder
CS: capsule suspension
G: granular
T: Tablet
CG: Coated Granular

Figure 5-4. Conceptual Model of Exposure Pathways for Disposal of Excess Pesticide Formulation

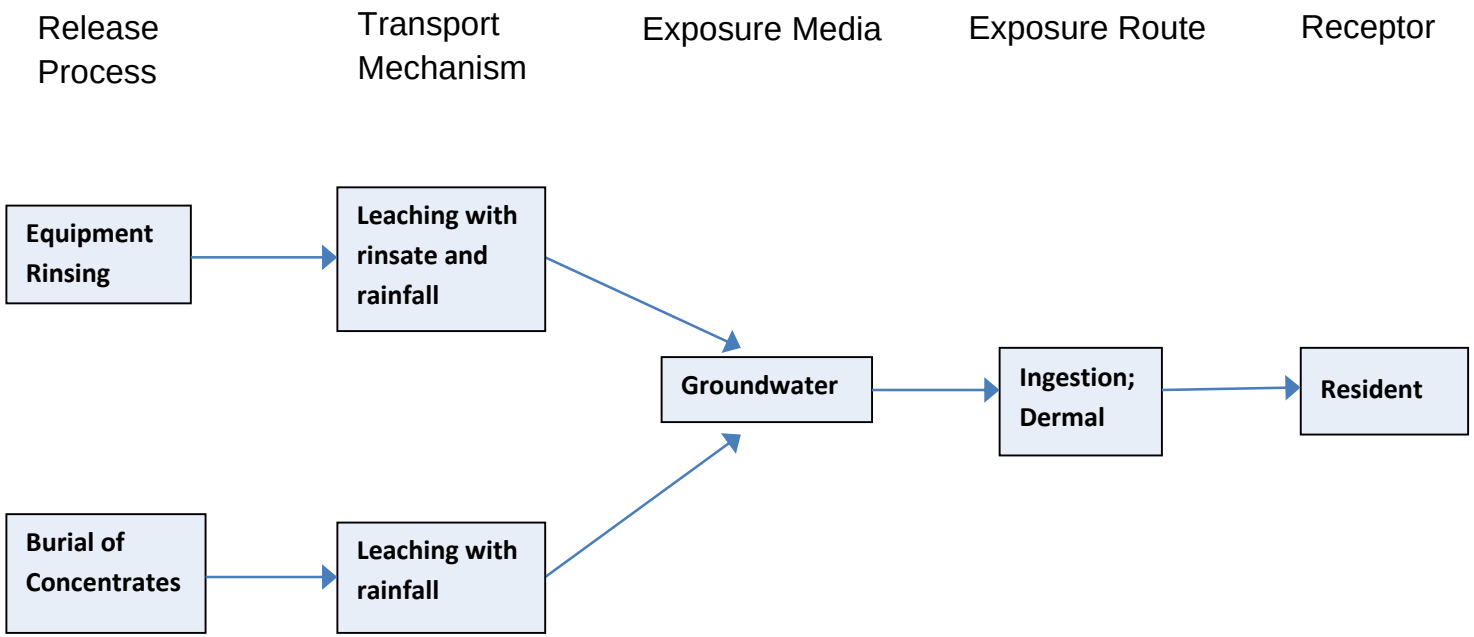
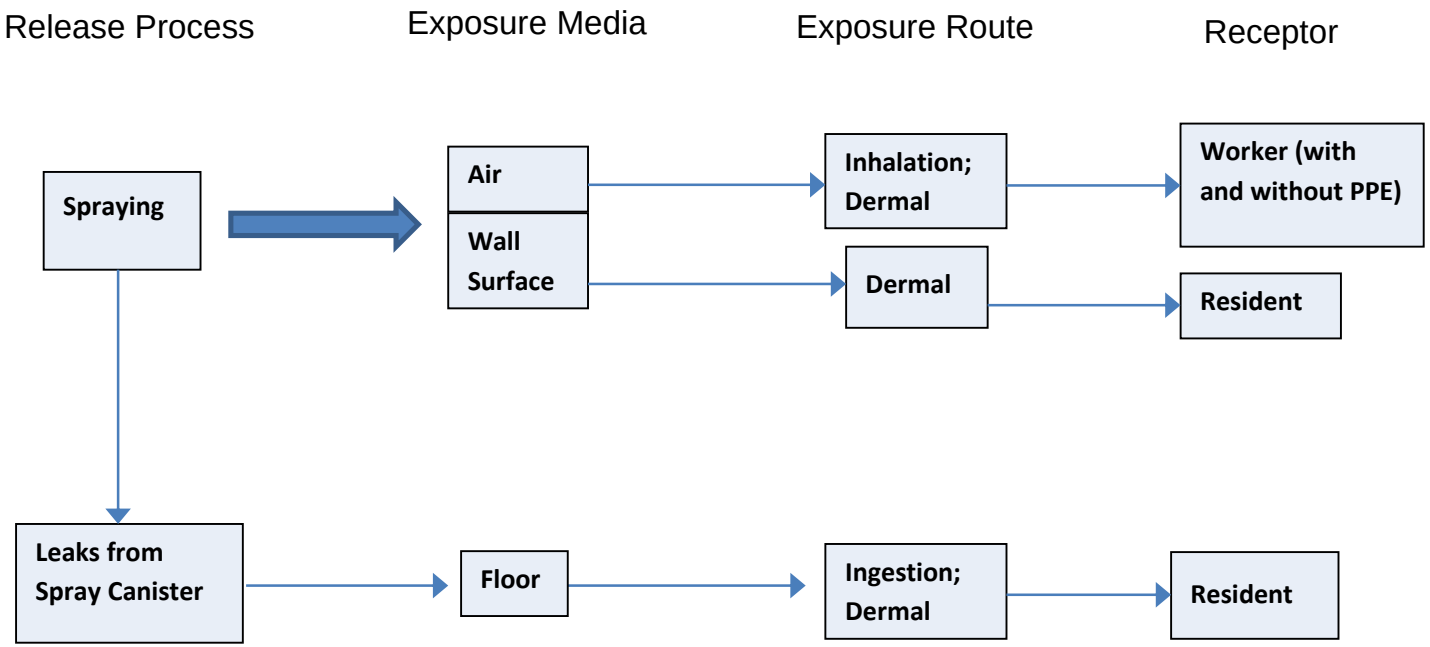


Figure 5-5. Conceptual Model for IRS Exposure Pathways



Long-Lasting Insecticidal-Treated Nets (LLINs) and Re-treated Insecticide Treated Nets (ITNs); use

A conceptual model for resident exposure to pesticides in LLINs/ITNs is presented in Figure 5-6. In the 2007 PEA (USAID, 2007), the primary route of exposure for bed nets was identified as dermal exposure while re-treating the nets with pesticide. The 2007 PEA stated that dermal exposure to residents, and possibly ingestion route exposure for infants, can theoretically occur through the use of the bed nets. Although the 2007 PEA noted that the potential exposure via these pathways was likely to be minimal, risk calculations for resident exposures to nets were only conducted in the previous PEA for net re-treatment. The 2007 PEA concluded that of the six pyrethoid pesticides recommended by WHO, only the acute exposure to etofenprox during re-treament posed a potential risk via dermal contact, and recommended individuals involved in the process at least wear protective gloves.

Since the 2007 PEA was issued, re-treatable nets have been replaced in the malaria vector control program with LLINs that do not require re-treating. Therefore, further evaluation of resident exposures related to re-treating nets is not relevant in this risk assessment.

Potential resident exposures to LLIN/ITNs pesticides may occur when nets are periodically washed, or if nets are used for other purposes, such as fishing. Inhalation exposures for synthetic pyrethroids (deltamethrin) was screened in Barlow et al (2001) and determined to be far below any observed effects level. Therefore, this assessment focuses on exposure by dermal absorption.

To quantify dermal pesticide exposure from incidental LLIN/ITNs contact requires estimation of the mass of pesticide transferred from the net to skin during a contact event. Information to characterize such exposures was not available from WHO Pesticide Evaluation Scheme (WHOPES) testing to support LLIN/ITN recommendations (http://www.who.int/whopes/recommendations/wgm/en/) nor was such information discovered in the peer-reviewed literature. However, WHOPES testing does address loss of pesticide from LLINs/ITNs due to repeated washings. Resident risks related to LLIN/ITN pesticides is quantified in this risk assessment based on exposures during washing, and these results are used as a basis to discuss the potential significance of exposure due to incidental dermal contact or oral exposures of infants.

Wall Linings; Installation and Use

Insecticide-treated wall linings consist of a woven plastic fabric that has been impregnated with insecticide and hung on interior walls, similar to LLINs. Therefore, as shown in Figure 5-2, the exposure pathways related to use of wall linings in a residence are similar to the incidental contact pathways for LLINs. A conceptual model for exposure to pesticides in wall linings is presented in Figure 5-7.

Dermal contact with the pesticide-impregnated cloth hanging on walls is expected to be the dominant exposure pathway for residents. However, the degree of resident skin contact with wall linings is difficult to estimate. As discussed in relation to LLINs, an estimate of the mass of pesticide transferred from lining to skin during a contact event is necessary to quantify dermal pesticide exposure from incidental contact. No information was discovered to support such estimation. Because wall linings employ the same types of pesticides as are used in LLINs, the results of the LLIN risk calculations will be used as a basis for discussing potential resident risks related to the presence of wall linings in a home.

For workers installing the wall linings, potential exposure is by dermal contact through the hands. If workers wear chemical-resistant gloves while installing the lining, exposure will be negligible.

Figure 5-6 Conceptual Model for LLIN/ITN Exposure Pathways

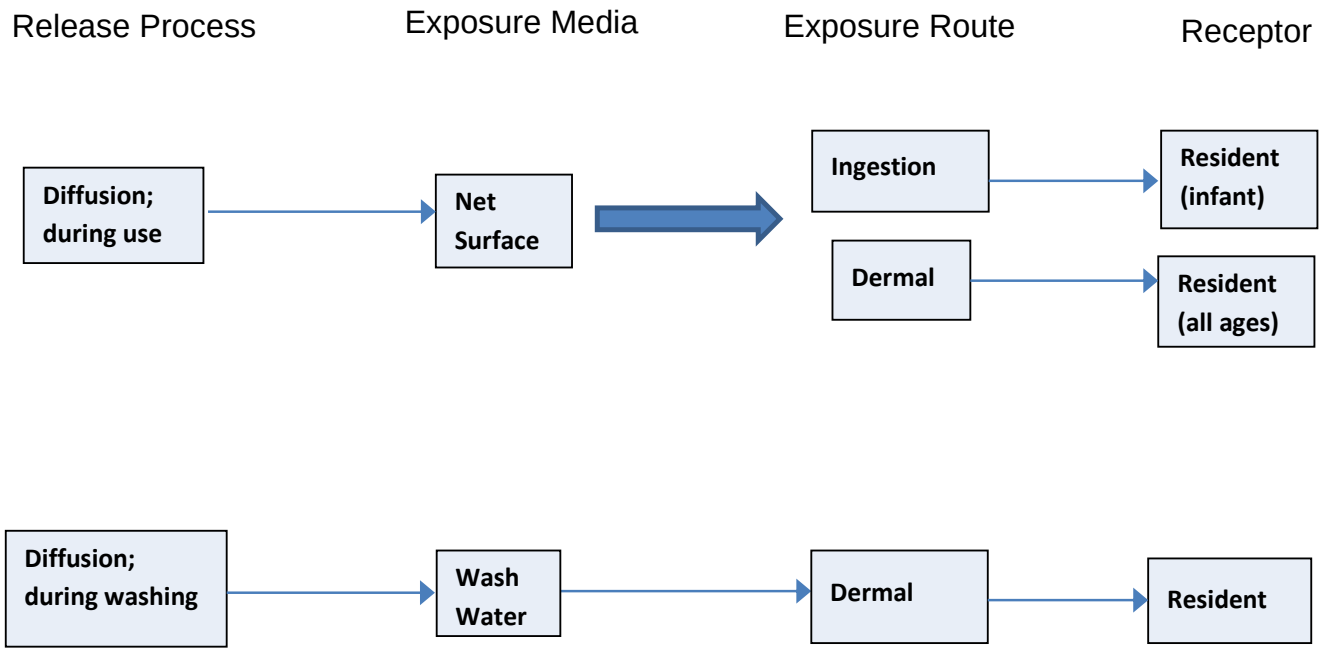
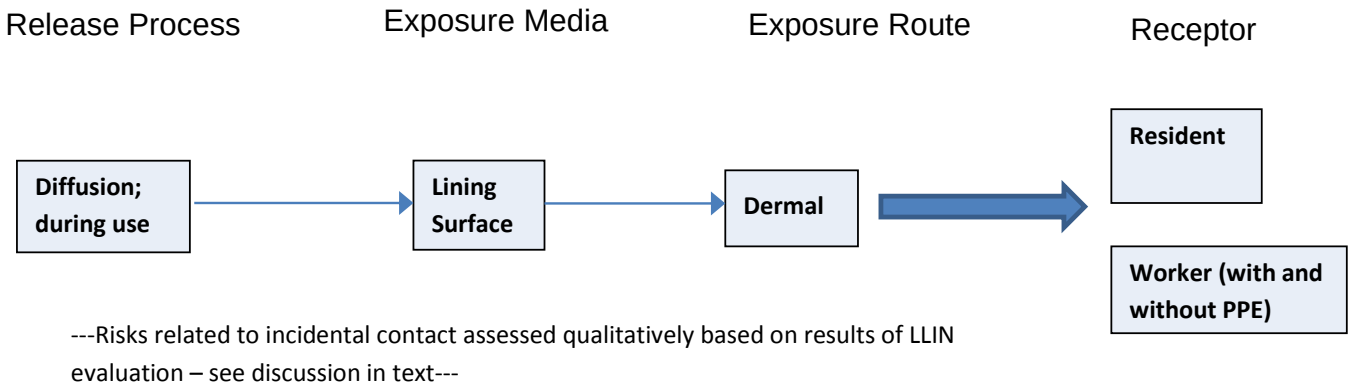


Figure 5-7 Conceptual Model for Wall Linings Exposure Pathways

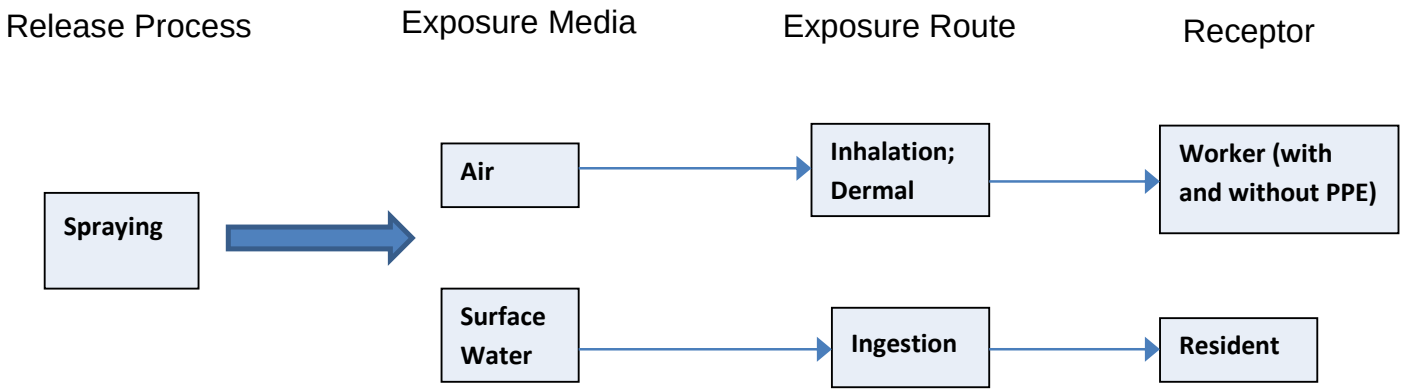


Larviciding; Application and Residual

The conceptual model for exposure during the application of larvicides, and for subsequent exposures to larvicide residual, is presented in Figure 5-8. The four larvicides evaluated in this risk assessment (methoprene, spinosad, temephos, and pyriproxyfen) are available as liquid concentrates as well as solid formulations like granules and pellets. Worker exposure during application is expected to be negligible for the solid forms of larvicides, which are distributed directly on surface water. Liquid larvicides, which are sprayed onto surface water, may result in application exposures similar to those described for IRS. Worker exposure can be greatly reduced by using appropriate PPE.

Worker risk calculations are performed with, and without, use of PPE to evaluate the degree of risk reduction afforded by PPE use. Inhalation of aerosol particulates and vapors, and dermal absorption, are the main processes for worker exposure during spray application of larvicides. Residents may be exposed to larvicide residuals through ingestion of surface water where the larvicide has been sprayed. The potential exposure concentration is related to characteristics of the water body, primarily volume and the rate of mixing. Because exposure concentrations are not generically quantifiable, potential risks related to resident exposure to larvicide residuals is evaluated in a qualitative manner in the risk assessment.

Figure 5-8 Conceptual Model for Liquid Larviciding Exposure Pathways

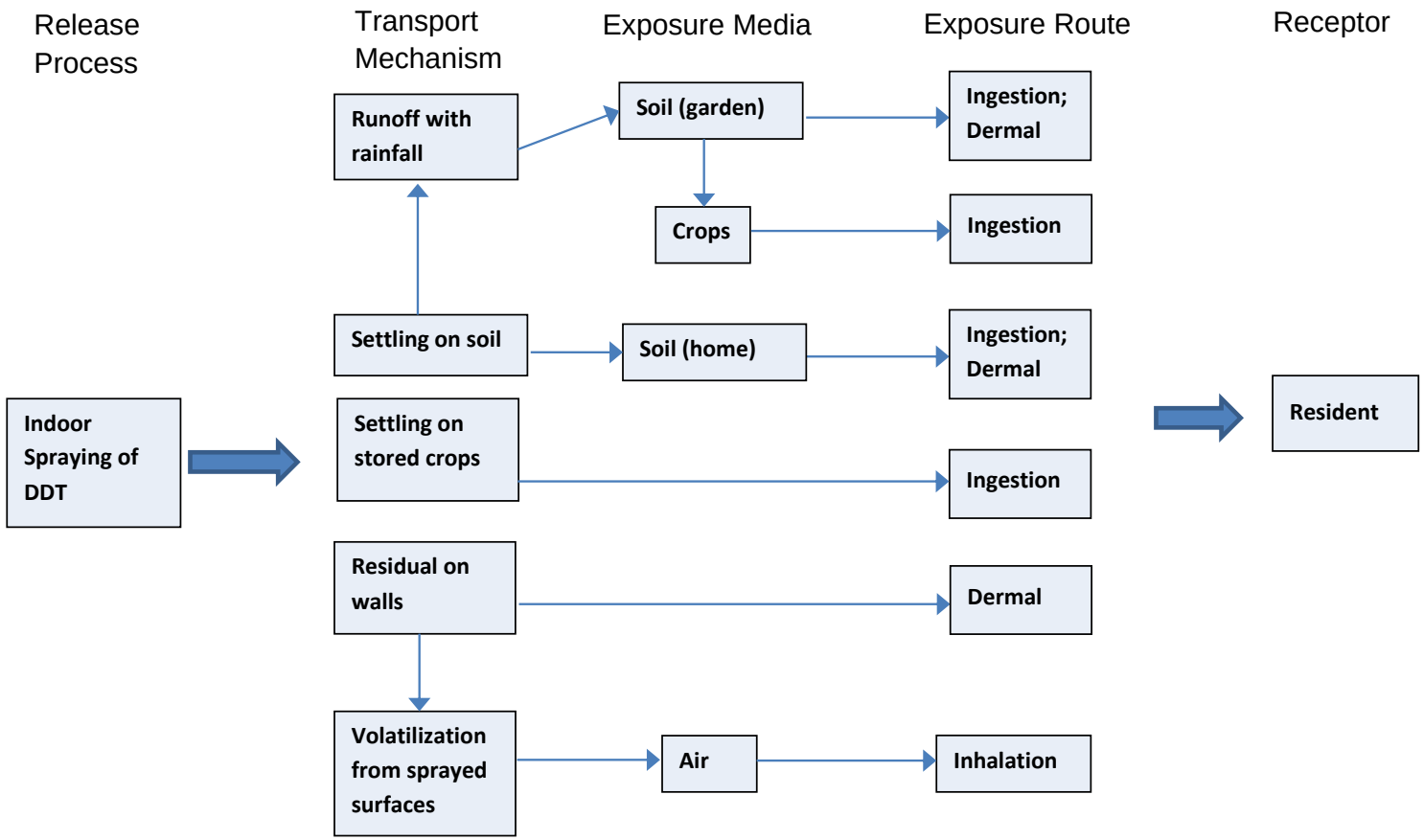


5.2.2.3 Supplemental Conceptual Exposure Model for DDT Use in IRS

In addition to the six processes summarized in bullets for Section 5.2.2.2, an analysis of the migration of DDT from sprayed homes, and possible contamination of stored crops and soils near the home by DDT, is also provided in this risk assessment. This analysis includes an assessment of potential chronic health risks related to residual DDT concentrations on stored crops and in soil.

Environmental data for this analysis are available from DDT routine monitoring and other DDT sampling conducted in Mozambique and Ethiopia by Research Triangle Institute (RTI 2011a; 2011b, and 2011c). A recent publication examining the human and environmental impacts of IRS with DDT in South Africa (Van Dyk et al, 2010) will also be used to support the evaluation. The conceptual model of DDT migration and potential human exposures pertaining to this analysis is shown in Figure 5-9.

Figure 5-9 Conceptual Model for DDT Migration and Exposure Pathways



5.2.3. EXPOSURE ASSESSMENT

This section describes the methodology used to evaluate potential exposures associated with pesticide use in the various malaria vector control interventions described in Section 5.2.2.1. Section 5.2.3.1 presents an overview of the exposure assessment methodology. Section 5.2.3.2 presents the route-specific exposure equations and input parameter values for each of the six malaria vector control activities described in Section 5.2.2.2.

5.2.3.1 Overview of Exposure Assessment

In order for exposure to an environmental toxicant to occur, one or more potentially complete exposure pathways must exist. As described in EPA risk assessment guidance (U.S. EPA, 1989), an exposure pathway describes the course a contaminant takes from a source to a receptor. Every complete exposure pathway contains the following elements (U.S. EPA, 1989):

- a toxicant source and/or release;
- an exposure medium (and, if exposure occurs at a location other than the source, one or more transport mechanisms);
- a point of exposure with the affected medium; and,
- an exposure route by which the receptor contacts the toxicant in the affected medium.

The exposure assessment focuses on identifying how much of a toxicant is present in an environmental exposure medium and quantifying the rate of exposure to potentially exposed individuals. Major groups of data inputs for the exposure assessment include the following:

- **Concentration parameters** were derived from empirical data and are primarily a function of the physical characteristics associated with handling and application (e.g., formulation type) rather than the chemical properties of individual active ingredients (see U.S. EPA, 1997).
- **Pesticide use parameters** (e.g., application rates) generally describe how pesticides were applied and were largely taken from field personnel that described the use of pesticides for malaria vector management practices.
- **Receptor exposure factors** represent the characteristics of the receptor populations evaluated. These include children and adult residents of areas in Africa where malaria vector control interventions are active, and workers implementing the malaria vector control activities.

The exposure assessment methodology is designed to produce protective estimates of exposure to pesticides based on experiences in countries where malaria vector control tools have been utilized. Worker exposures during application as well as post-application residential exposures are considered for the dermal, inhalation, and ingestion routes for both adults and children, as described in Section 5.2.2.2. This exposure assessment builds upon the assessment developed for the 2007 PEA (USAID, 2007), which focused on specific pathways identified by vector control specialists in the field based on their extensive experience in integrated vector management. The specialists were instrumental in describing and providing parameters for exposure scenarios that would most likely result in the highest doses to workers and residential receptors.

This exposure assessment includes evaluation of exposures that were not quantified in the 2007 PEA, including exposures related to the use of larvicides and the use of pre-treated LLINs and wall linings. In addition, this exposure assessment employs methods to refine the exposure estimates provided in the 2007 PEA and support risk management decisions. These methods include:

1) Use of current information for pesticide use and receptor exposure parameters, as available from implementing partners;

2) Calculation of risks using a range of exposure parameter values;

3) Calculation of worker exposures both with, and without, the use of PPE; and,

4) Use of a more realistic model for estimating potential groundwater concentrations that may result from rinsing equipment and disposal of excess pesticide.

Information on current practices related to IRS was solicited from field personnel for this revision of the 2007 PEA. Survey forms were developed to acquire this information. Completed survey forms were received with information provided from field personnel in Burkina Faso, Uganda, and Madagascar. A fourth form was received with information pertaining to field implementation in several different countries. Copies of these completed survey forms are included as ***Annex F*** of this report.

As noted above, this risk assessment includes an evaluation of risks pertaining to a range of exposure parameter values. For residential receptors, this range relates to best-estimate exposure (also referred to as the central tendency exposure (CTE)) and reasonable maximum exposure (RME). The RME calculation pertains to individuals whose behavioral characteristics may result in higher potential exposure than seen in the average individual. A CTE calculation pertains to an average member of the target population. The inclusion of both RME and CTE calculations provides a semi-quantitative measure of the range of expected risks that may occur under a particular exposure scenario. For workers, risk estimates are provided based on low-end, middle, and high-end exposure parameter values based on survey responses received from field implementation personnel (see Annex F).

Table 5-5 summarizes the potentially complete exposure pathways for the six activities described in Section 5.2.2.2 and identifies the specific pesticides for which these exposures are evaluated in this risk assessment.

Table 5-5 Summary of Exposure Pathways, by Pesticide and Activity

Activity	Exposure Route	Receptor	alpha-	bendiocarb	bifenthrin	chlorfenapyr	cyfluthrin	DDT	deltamethrin	etofenprox	fenitrothion	lambda-	malathion	methoprene	permethrin	pirimiphos-methyl	propoxur	pyriproxyfen	spinosad	temephos
IRS, ITN re-treatment and larviciding; preparation																				
Mixing; liquid or solid	Inhalation	Worker	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•
Loading, stirring, pouring	Dermal	Worker	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•
Spills	Inhalation, dermal	Worker	Exposures evaluated in a qualitative manner																	
IRS, ITN re-treatment and larviciding; disposal																				
(Groundwater contamination)	Ingestion of contaminated groundwater	Resident	•	•	•	•	•	•	•	•	•	•	•	•		•	•	•	•	•
IRS; spraying																				
Spraying	Inhalation, dermal	Worker	•	•	•	•	•	•	•	•	•	•	•			•	•			
Spraying (residual on indoor walls)	Dermal	Resident	•	•	•	•	•	•	•	•	•	•	•			•	•			

Activity	Exposure Route	Receptor	alpha-	bendiocarb	bifenthrin	chlorfenapyr	cyfluthrin	DDT	deltamethrin	etofenprox	fenitrothion	lambda-	malathion	methoprene	permethrin	pirimiphos-methyl	propoxur	pyriproxyfen	spinosad	temephos
Leaks and spills	Ingestion, dermal	Resident	Exposures evaluated in a qualitative manner																	
LLIN/ITN; use																				
Washing nets	Dermal, ingestion	Resident	•						•			•			•					
Contact with LLIN/ITN during use	Dermal, ingestion (infant)	Resident	Exposures evaluated in a qualitative manner																	
Wall lining; use and installation																				
Contact with treated net during use	Dermal	Resident							•						•					
Installation	Dermal	Worker							•						•					
Larviciding; spraying																				
Spraying	Inhalation, dermal	Worker												•				•	•	•
Spraying (residual)	Ingestion of contaminated water	Resident	Exposures evaluated in a qualitative manner																	

The exposure assessment methodology is consistent with EPA guidance for human health risk assessment, which has largely been developed in support of the Superfund program. Other guidance documents from EPA and international bodies, as well as journal articles, specific to pesticide exposure and risk assessment were also employed. Our intent was to ensure that the approach developed for this risk assessment was consistent with common practices in evaluating pesticide risks as well as the current state-of-the-science in the broader chemical risk assessment community. Examples of these materials include the following:

- Barlow, S.M., F.M. Sullivan, and J. Lines. 2001. Risk assessment of the use of deltamethrin on bed nets for the prevention of malaria. *Food and Chemical Toxicology 39*: 407–422.
- Najera, J.A., and M. Zaim. 2002. *Malaria Vector Control: Decision Making Criteria and Procedures for Judicious Use of Insecticides*. World Health Organization. WHO/CDS/WHOPES/2002.5 Rev 1.
- Machera, K. et al. 2009. Dermal Exposure of Pesticide Applicators as a Measure of Coverall Performance Under Field Conditions. *Ann. Occup. Hyg.*, Vol. 53, No. 6: 573–584.
- USAID (United States Agency for International Development). 2002. *Programmatic Environmental Assessment for Insecticide-Treated Materials in USAID Activities in Sub-Saharan Africa*. Washington, DC: Office of Sustainable Development. January.
- USAID. 2007. *Integrated Vector Management Programs for Malaria Vector Control: Programmatic Environmental Assessment*. Prepared for Bureau for Global Health by RTI International, Research Triangle Park, NC. January.
- U.S. Environmental Protection Agency (U.S. EPA). 1989, *Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)*, Interim Final, Office of Emergency and Remedial Response, U.S. Environmental Protection Agency, Washington, D.C.
- U.S. EPA. 1997a. *Standard Operating* P*rocedures (SOPs) for Residential Exposure Assessments*. Draft. Office of Pesticide Programs. December 19. Available at http://www.epa.gov/pesticides/trac/science/trac6a05.pdf (accessed September 27, 2005).
- U.S. EPA. 2001. *General Principles for Performing Aggregate Exposure and Risk Assessments*. Office of Pesticides. November 28.
- U.S. EPA. 2004. *Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part E, Supplemental Guidance for Dermal Risk Assessment)*. Washington, DC: Office of Superfund Remediation and Technology Innovation. July.
- WHO (World Health Organization). 2004. *A Generic Risk Assessment Model for Insecticide Treatment and Subsequent Use of Mosquito Nets*. Communicable Disease Control, Prevention, and Eradication WHO Pesticide Evaluation Scheme.

5.2.3.2 General Methods for the Calculation of Exposure (Intake)

As described in the 2007 PEA (USAID, 2007), the exposure assessment methodology is largely based on algorithms developed by the EPA Office of Pesticide Programs and referred to as standard operating procedures (SOPs) (U.S. EPA, 1997a). The approach presented in the WHO generic risk assessment (2004) was also employed to estimate individual exposures related to pre-treated materials. Although the SOPs and generic risk assessment were very useful in framing the exposure assessment, they do not address all exposure pathways in this risk assessment nor were they developed to characterize long-term (chronic) exposures. Therefore, these exposure algorithms were supplemented as necessary by

incorporating additional variables and modeling constructs used in chemical exposure assessment. Most obviously, averaging time and exposure duration are now explicitly represented (see, for example, U.S. EPA, 1989). This change enables us to calculate an average daily dose of pesticide over a period of time that can be matched to a health effects benchmark over the length of time that exposure is assumed to occur.

The basic structure of the exposure equations used in this assessment is described in EPA risk assessment guidance (U.S. EPA, 1989). Equation 5-1 shows the general exposure equation for chemicals that serves as the basis for the pathway-specific equations in subsequent subsections:

$$\text{Chemical Intake} = \frac{C_i \times CR \times EF \times ED}{BW \times AT}$$ **Equation 5-1**

where:

Intake = rate of chemical available for uptake at an exchange boundary (mg/kg body weight/day)

C_i = concentration of chemical *i* at exposure point (e.g., mg/kg soil, mg/L water)

CR = contact rate with the environmental medium (e.g., mg soil ingestion per day; L water ingestion per day)

EF = exposure frequency (days/yr)

ED = exposure duration (yr)

BW = body weight (kg)

AT = averaging time for toxicological effects (days).

The term "intake" refers to the rate at which a chemical becomes available for uptake at an exchange boundary, such as the walls of the gastrointestinal tract or the skin surface. Hence, it is not equivalent to an absorbed dose, which is the amount of chemical actually entering the bloodstream across an exchange boundary. The fraction of chemical that may be absorbed into the body is addressed in the more detailed exposure models for each exposure activity below. In particular, the algorithms used to evaluate dermal exposures apply to an absorbed dose—the mass of chemical that crosses skin and is absorbed systemically. This is largely a function of the skin permeability to a particular pesticide and is intended to reflect the ability of the skin to prevent chemicals from entering the bloodstream.

For noncancer endpoints, an average daily dose (ADD) is calculated for each route of exposure for the scenario-specific duration (e.g., seasonal exposure for pesticide workers) and averaged over the time period during which exposure occurs (U.S. EPA, 1989). As described in the general intake equation, the exposure duration represents the actual length of time that a receptor is exposed, and the averaging time represents the period of time over which toxicity is expressed. For example, an individual who is exposed for two days a week for 12 weeks is assumed to have an exposure duration of 24 days (2 days/week x 12 weeks) and a noncancer averaging time of 84 days (7 days/week x 12 weeks).

For cancer endpoints, a lifetime average daily dose (LADD) is calculated that reflects the ADD over a person's entire lifetime. Thus, the LADD is calculated by averaging a dose of any duration over an entire lifetime. Because cancer risk is expressed as a probability averaged over a lifetime, possible resident exposure as a child and as an adult is integrated in intake calculations for carcinogenic effects. Daily doses from different routes of exposure were summed to estimate an aggregate exposure per *Guidance for Performing Aggregate Exposure and Risk Assessments* (U.S. EPA, 2001).

The following subsections provide a concise description of the exposure models supporting the risk calculations for each of the six exposure activities described in Section 5.2.2.2.The exposure algorithms are presented in ***Annex G***, Exposure and Risk Calculations, along with an explanation of each of the input values used in the risk calculations. Information on other input parameter values used in certain exposure calculations, such as pesticide-specific inputs and pesticide application rates, is presented in ***Annex D***, Input Parameter Tables.

5.2.3.3 Estimating Exposure for IRS, ITN re-treatment and Larviciding; Worker Preparation of Pesticide.

As summarized in Figure 5-3, worker exposure is evaluated for preparing (mixing) the insecticide formulation with water, as either a powder or liquid concentrate. Workers may be exposed by inhalation during the mixing process, as through dermal contact while mixing due to splashes or spills.

For the preparation of insecticide for IRS and ITN re-treatment, we looked at potential dermal and inhalation exposures for workers mixing the insecticide formulation (emulsifiable concentrate and/or wettable powder) with water. In the case of pirimiphos-methyl CS, unit exposure estimates for the capsule suspension formulation were unavailable and were protectively assumed to be analogous to those of the emulsifiable concentrate. For larviciding, we also looked at preparation exposures related to granular formulations. The algorithms were adapted from the EPA SOP 2.1 (Handler Inhalation and Dermal Potential Doses from Pesticides Applied to Turf) (U.S. EPA, 1997a), as described in the 2007 PEA (USAID, 2007). These algorithms for worker exposures from mixing insecticide formulation were modified to include the amount of formulation used per tank. For the preparation of insecticide for treating nets, the unit exposure estimates for capsule suspension for lambda-cyhalothrin and wetable powder for deltamethrin were reviewed as analogous to WP.

For this scenario, we assumed that only adult workers are involved in mixing the insecticides Because we did not have any information on the tenure of pesticide workers, the cancer risk was calculated for a single year of exposure. Lifetime cancer risk for additional years would be additive, such that cancer risks for 2 or 3 years of employment would be 2 and 3 times higher, respectively. As described in Section 5.2.3.1, worker risk estimates are provided based on low-end, middle, and high-end exposure parameter values and both with, and without, use of PPE. A summary of the exposure parameter values for worker preparation of pesticide is provided in Table 5-6. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Tables G-1 through G-4 of ***Annex G***.

Table 5-6 Summary of Key Exposure Parameter Values – IRS, ITN Re-Treatment and Larviciding;
Preparation of Pesticide

Parameter	Explanation	Value[1]
Inhalation unit exposure	mg of pesticide inhaled per kg handled during preparation (open mixing, no PPE)	0.0026 (EC and CS) 0.096 (WP) 0.0037 (G)
Dermal unit exposure	mg of pesticide deposited on skin per kg handled during preparation (open mixing, no PPE)	6.4 (EC and CS) 9.7 (WP) 0.066 (G)
Exposure rate	Number of 10-L tanks prepared per day	3.5 / 5.0 / 7.1
Exposure frequency	Number of days per spray cycle	33 / 36 / 44
Exposure duration	For cancer risk, a worker is assumed to	1

Parameter	Explanation	Value[1]
	be employed for one year only	
Spray cycles	Number of spray cycles per year	1.0 / 1.25 / 2.0 [2]
Inhalation PPE	Exposure reduction factor for use of N95 respirator	20
Dermal PPE (liquid splashes/spills)	Exposure reduction factor for use of gloves and coveralls	33
Dermal PPE (powder and granules)	Exposure reduction factor for use of gloves and coveralls	50

[1] Low end / average / high end values are based on survey responses (see ***Annex F***).

[2] For cancer risk calculations, only a single IRS spray cycle per year is assumed for the long-lasting pesticide DDT. Non-cancer effects of pesticides are assessed over the course of exposure for a single spray cycle.

5.2.3.4 Estimating Exposure for IRS, ITN Re-treatment and Larviciding; Resident Groundwater Use Subsequent to Disposal of Surplus.

Rinsing of spray equipment after use or the dumping of left over pesticide after treating a net may result in pesticide contamination of soil. Also, expired pesticide formulation may be disposed of by burying or dumping onto soil. These practices can lead to the contamination of groundwater, and subsequent exposures, as illustrated in Figure 5-4.

A screening of groundwater risks related to pesticide burial was performed in the 2007 PEA (USAID, 2007). With the exception of DDT, the 2007 screening employed a default dilution attenuation factor (DAF) of 20 published by EPA (U.S. EPA, 2002). The default DAF assumes equilibrium conditions between soil and groundwater, and so is suitable for wide-scale and persistent soil contamination. As noted in the 2007 PEA, this DAF presumes that well concentrations of pesticides remain constant for the entire period of exposure, which in turn presumes that there is sufficient pesticide mass in the buried containers to approximate an infinite source.

In this assessment, the use of DAFs has been replaced with the simple transport model SCI-GROW published by EPA's Office of Pesticide Programs (OPP) (http://www.epa.gov/oppefed1/models/water/). SCI-GROW is described by EPA as follows:

> SCI-GROW is a screening model which the OPP frequently uses to estimate pesticide concentrations in vulnerable ground water. The model provides an exposure value which is used to determine the potential risk to the environment and to human health from drinking water contaminated with the pesticide. The SCI-GROW estimate is based on environmental fate properties of the pesticide (aerobic soil degradation half-life and linear adsorption coefficient normalized for soil organic carbon content), the maximum application and existing data from small-scale prospective ground-water monitoring studies at sites with sandy soils and shallow ground water.

The model has only four inputs: application rate, number of annual applications, K_{oc}, and soil metabolism half-life. The output groundwater concentrations are linearly related to both the application rate and number of annual applications. The advantages of this model are that it is based on field observations and is applicable to vulnerable groundwater. A disadvantage is that maximum point concentrations in groundwater related to burial may be underestimated, although the likelihood that a well would be located immediately downgradient of a burial location are probably very small.

Pesticide-specific values for K_{oc}, and aerobic soil metabolism half-life are documented in ***Annex D***-1. A unit value of 1 kg/acre (2.2 lb/acre) was used in the SCI-GROW calculations, with a single annual "application". Because groundwater concentrations are linearly related to these inputs, the annual mass of disposed pesticide necessary to exceed risk threshold criteria can be calculated rate.

The exposure assessment for disposal of pesticides addresses ingestion of contaminated groundwater and dermal exposure by bathing in groundwater for adult and child residents. The water ingestion algorithm is adapted directly from the basic intake equation (Equation 5-1) presented in ***Annex G***. The dermal exposure algorithm was adopted from RAGS (U.S. EPA, 2004) for estimating the absorbed dose from dermal contact with contaminated water.

A summary of the exposure parameter values for resident use of contaminated groundwater is provided in Table 5-7. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Tables G-5 and G-6 of ***Annex G***. As described in Section 5.2.3.1, resident risk estimates are provided based on CTE and RME exposure parameter values.

Table 5-7 Summary of Key Exposure Parameter Values – Disposal of Surplus; Groundwater Use

Parameter	Explanation	Value[1]
Adult water ingestion rate	Liters of water consumed each day; assumes 365 day/year of exposure	1.4 / 2.3
Child water ingestion rate	Liters of water consumed each day; assumes 365 day/year of exposure (child age 1 – 6 yrs)	0.3 / 0.9
Adult whole-body surface area	Area of skin through which dermal absorption can occur, in units of cm^2	18,000
Child whole-body surface area	Area of skin through which dermal absorption can occur, in units of cm^2	6,600
Bathing frequency	Number of baths per year	276 / 300
Bathing time	Length of baths, in hours	0.22 / 0.38
Exposure duration	1 year or longer for chemical hazard; assumes lifetime exposure for cancer risk.	1 year (noncancer) 50 years (cancer)
[1] CTE (average) / RME (high end) values are based on survey responses (see ***Annex F***).		

5.2.3.5 Estimating Exposure for IRS and Larviciding; Worker Application by Spraying.

For IRS and larviciding, we assessed the inhalation exposure of workers during spray application. Some larvicides may also be applied as granules, pellets, tablets, or briquettes. However, as noted in Section 5.2.2.2, worker exposures related to application of these solid forms of larvicide are likely to be negligible. Therefore, worker risks are quantified only for spray applications.

The IRS algorithm was adapted from the EPA SOP 6.1.1 (Inhalation Potential Dose from Painting/Staining in Residential Settings) (U.S. EPA, 1997a). The scenario is based on an application of active ingredient of insecticide per unit area of the house and takes into account total surface area of the walls of an estimated average size house in Africa and the total number of houses sprayed in 1 day by a worker. Thus, this algorithm for indoor spraying was customized to reflect IRS practices in Africa. In lieu of specific information related to the daily area spray-treated during larviciding operations, or the

number of days per year operations are conducted, the values for IRS were used as a surrogate for larviciding. The algorithms used for calculating dose due to spray application of larvicide are analogous to those employed for IRS.

As described in Section 5.2.3.1, worker risk estimates are provided based on low-end, middle, and high-end exposure parameter values and both with, and without, use of PPE. A summary of the exposure parameter values for worker preparation of pesticide is provided in Table 5-8. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Tables G-7 and G-8 (IRS), and Tables G-11 and G-12 (larviciding), of Annex G.

Table 5-8 Summary of Key Exposure Parameter Values – IRS and Larviciding; Worker Spray Application

Parameter	Explanation	Value[1]
Inhalation unit exposure	mg of pesticide inhaled per kg of formulation applied (no PPE)	0.066
Dermal unit exposure	mg of pesticide deposited on per kg of formulation applied (no PPE)	170
IRS area treated	Number of houses per day, (then multiplied by assumed house area of 35.8 m^2)	9 / 11 / 14
Larvicide area treated	Area sprayed per day, in units of m^2	320 / 390 / 500
Exposure frequency	Number of days per spray cycle	33 / 36 / 44
Exposure duration	For cancer risk, a worker is assumed to be employed for one year only	1
Spray cycles	Number of spray cycles per year	1.0 / 1.25 / 2.0
Inhalation PPE	Exposure reduction factor for use of N95 respirator	20
Dermal PPE	Exposure reduction factor for use of gloves and coveralls	43
[1] Low end / average / high end values are based on survey responses (see ***Annex F***).		

5.2.3.6 Estimating Exposure for IRS; Resident Post-IRS Wall Contact.

In the 2007 PEA (USAID, 2007), residential exposures through dermal contact with indoor surfaces was assumed to occur immediately after spraying. Acute exposures and associated health risks were evaluated for a single day for both adults and children based on exposure to insecticide residue that adheres to surfaces other than walls during spraying. In this assessment, a model is developed to evaluate potential chronic risks for exposure to residual pesticide on walls for periods of six months or longer.

This initial application rate of IRS pesticides on indoor walls was estimated in this assessment and in the 2007 PEA based on information in Najera and Zaim (2002). The critical factor in estimating chronic exposure to residual pesticide on wall surfaces is the amount of pesticide on wall surfaces over time that is available for dermal absorption. As noted in the 2007 PEA, typical peri-urban African homes are constructed of earthen materials (e.g., mud or cement) which tend to absorb the insecticide. Therefore,

surface concentrations of applied pesticide may be expected to decrease very quickly due to absorption, followed by a less-rapid decrease as the absorbed pesticide is released from the walls or degrades *in situ*.

An article in the publication *Wing Beats* (Alara et al, 2009) describes bioassay results from Cameroon in which mosquito mortality on mud walls sprayed with 25 mg/m^2 lambda-cyhalothrin declined to approximately 75% in 5 months and was just 10% after 6 months. In reviews of previous bioassays, the authors noted that other researchers have shown effective control with the same application on mud walls for up to 12 months. These results suggest that significant residual concentrations of synthetic pyrethroids may remain on mud wall surfaces for between 5 and 12 months, or longer.

In this assessment, a simple mathematical model was used to estimate the time-integrated surface concentration of IRS pesticide over a one-year period. The application rate concentration (in mg/m^2) is assumed to decrease very quickly to 1/10th of the application rate value due to absorption into the wall surface. A long-term decrease of one-half of the remaining surface concentration is then assumed to occur each month over a period of one year, at which point the concentration is considered negligible. This assumption results in an approximately 60-fold reduction factor applied to the initial application rate. The 60-fold factor is calculated by taking the average concentration over a 12-month period beginning with the effective initial concentration, as shown in this example:

Initial application rate	25 mg/m^2
Effective initial concentration	2.5 mg/m^2
1-month concentration	1.25 mg/m^2
2-month concentration	0.625 mg/m^2 …, until,
12-month concentration	0.0012 mg/m^2.

A summary of the exposure parameter values for resident exposure to post-IRS pesticide on walls is provided in Table 5-9. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Table G-9 of ***Annex G***. Although other resident risk estimates employ both CTE and RME exposure parameter values, only a single (screening) estimate is provided for this risk calculation.

Table 5-9 Summary of Key Exposure Parameter Values – Post-IRS Resident Contact with Walls

Parameter	Explanation	Value
Application attenuation factor	Time-integrated reduction factor applied to initial application rate	60
Adult skin surface area	Area of skin that contacts the wall, in units of cm^2	1040
Child skin surface area	Area of skin that contacts the wall, in units of cm^2	380
Exposure frequency	Number of wall contact events per year	365
Exposure duration	1 year or longer for chemical hazard; assumes lifetime exposure for cancer risk.	1 year (noncancer) 50 years (cancer)

5.2.3.7 Estimating Exposure for LLINs/ITNs; Resident Use.

The pesticides in LLINs are contained within the netting fabric. Testing by the WHO of various brands of LLINs indicates that such nets generally retain a significant fraction of the original pesticide content even after years of use and repeated washings (WHO 2008; WHO, 2009). ITNs are treated when the pesticide is no longer viable, with the new longer lasting treatments, this can vary from 15 to 20 washes. Residents who sleep beneath these nets may potentially be exposed to LLIN/ITN pesticides due to dermal absorption when bare skin contacts the net. Infants sleeping beneath the nets may also potentially be exposed by placing netting in their mouths. However, no estimate of the mass of pesticide transferred from the net to skin or mouth during a contact event is available. Although direct pesticide transfer data are unavailable, there is information on the loss of LLIN/ITN pesticide from repeated washing of nets. This pesticide loss is linear over the course of repeated washings, and may result in overall losses of approximately 2 – 8% of the original quantity per wash (based on deltamethrin; WHOPES 2009; Tables 6 and 12).

As described in Section 5.2.2.2, resident exposure to LLIN/ITN pesticides is evaluated based on dermal absorption of pesticide released into the wash water because data on the rate of pesticide transferred from the net to skin during a contact event is unavailable. The dermal exposure algorithm was adopted from RAGS (U.S. EPA, 2004) and is identical to that used for assessing dermal absorption of pesticide from bathing in contaminated groundwater. 100% of the pesticide lost during washing is protectively assumed to be available for dermal absorption from the wash water. For noncancer endpoints, the acute hazard associated with a washing event is evaluated. For cancer risk, the cumulative exposure of washing LLINs/ITNs over a lifetime is assessed.

A summary of the exposure parameter values for resident washing of LLINs/ITNs is provided in Table 5-10. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Table G-10 of ***Annex G***. As described in Section 5.2.3.1, resident risk estimates are provided based on CTE and RME exposure parameter values. The results of this risk assessment for LLIN/ITN exposures during washing are also used as a basis to discuss the potential significance of exposure due to incidental dermal contact or oral exposures of infants in the risk characterization in Section 5.2.5.

Table 5-10 Summary of Key Exposure Parameter Values – Washing of LLINs/ITNs

Parameter	Explanation	Value[1]
Pesticide loss per wash	Fractional loss of initial pesticide mass in LLIN/ITN	0.05 / 0.08
Adult skin surface area	Area of hands and forearms through which dermal absorption can occur, in units of cm^2	2080
Basin volume	Volume of wash water in which pesticide is dissolved; L	10
Washing frequency	Number of net washings per year	2 / 4
Washing time	Length of washing event, in hours	0.17
Exposure duration	Assumes lifetime exposure for cancer risk.	50 years (cancer)
[1] CTE (average) / RME (high end) values.		

5.2.4. TOXICITY ASSESSMENT

5.2.4.1 Overview of Toxicity Assessment

The ability of a pesticide used in malaria vector control to elicit adverse health effects depends on the route of exposure (i.e., ingestion, inhalation, or dermal), the frequency and duration of exposure (i.e., acute, subchronic, or chronic) the toxicity of the insecticide (which may vary by route and duration of exposure), and the sensitivity of the exposed individual. With the exception of microbial larvicides, insecticides as a class function as neurotoxicants – their efficacy as well as many of their toxic effects in humans relate to their effects on the nervous system. For example, organophosphate pesticides inhibit the action of the nervous system enzyme acetylcholinesterase, and pyrethroid ester insecticides affect the flow of ions across the neuronal cell membrane. Although there may be multiple types of toxic effects associated with a given pesticide, to evaluate the risk related to pesticide exposures we identified pesticide-specific human health benchmarks for each exposure route and duration evaluated in the risk assessment.

The EPA has evaluated available dose-response information for many pesticides s and has published this information in the form of toxicity values and accompanying information. For noncancer endpoints, the health benchmark "reference dose" (RfD) represents a point (in milligrams of pesticide per kilogram body weight per day) on the dose–response continuum below which adverse effects would not be anticipated. That is, a dose below the RfD would not be expected to cause an adverse health effect. For cancer endpoints, the health benchmark "cancer slope factor" (CSF) represents a plausible upper-bound estimate of the lifetime probability of developing cancer associated with exposure to a specific quantity of a potential carcinogen (U.S. EPA, 1989). A CSF is expressed in units of risk per dose ([milligrams of pesticide per kilogram body weight per day]$^{-1}$). The CSF model of carcinogenicity is based on the assumption that *any* exposure is associated with some finite probability of an individual contracting cancer.

Section 5.2.4.2 provides a brief summary of the health effects of concern for each of the pesticides evaluated in this screening assessment. These summaries are based on the more detailed information provided in ***Annex E***, Pesticide Profiles. The methods and references used to identify the health benchmarks used in the risk calculations are described in Section 5.2.4.3. The human health benchmarks used in this risk assessment are summarized in ***Annex D***, Table D-3.

5.2.4.2 Summary of Health Effects for Malaria Vector Control Pesticides

- **Alpha-cypermethrin.** Alpha-cypermethrin is a highly active synthetic pyrethroid used to control mosquitoes. Alpha-cypermethrin affects the way the nerves and brain normally function by interfering with the sodium channels of nerve cells. Typical symptoms for acute exposure include irritation of skin and eyes, and neurological effects such as headaches, dizziness, nausea, vomiting, diarrhea, excessive salivation, and fatigue. Dermal exposure to alpha-cypermethrin has also been shown to cause paresthesia (a burning, tingling, or stinging of the skin). These effects are generally reversible and disappear within a day of ending the exposure. Alpha-cypermethrin is rapidly metabolized and excreted from the body. Limited data are available for chronic low-level exposures to alpha-cypermethrin; however, hypersensitivity pneumonitis has been observed for other pyrethrin-based pesticides. No data are available on the carcinogenic potential of alpha-cypermethrin.

- **Bendiocarb.** Bendiocarb is a broad-spectrum carbamate insecticide. Bendiocarb exhibits its toxic effects through reversible cholinesterase inhibition. In humans, symptoms of bendiocarb toxicity include excessive sweating, salivation, headache, blurred vision, nausea, vomiting, stomach pain, giddiness, slurred speech, tightness in the chest, and muscular twitching. The effects of chronic bendiocarb exposure have not been well documented in humans. Based on animal studies, bendiocarb is not expected to have reproductive effects in humans at environmental exposure levels.

It has not been shown to be mutagenic in animals. EPA has classified bendiocarb as "noncarcinogenic to humans."

- **Bifenthrin.** Bifenthrin is a pyrethroid insecticide used in agricultural and human health applications including mosquito control. As a synthetic pyrethroid, bifenthrin affects the nerves and brain by interfering with nerve cell sodium channels. Symptoms of acute exposure may include skin and eye irritation and neurological effects such as headache, dizziness, nausea, vomiting, diarrhea, excessive salivation, fatigue, irritability, and numbness. Inhalation of pyrethrins may cause a localized reaction of the upper and lower respiratory tracts. In mammals, pyrethroids are generally of low toxicity due to their rapid biotransformation. No toxicity data for chronic bifenthrin exposure are available in humans, but neurological and reproductive effects have been observed in animal studies. EPA has classified bifenthrin as a "possible human carcinogen."

- **Chlorfenapyr.** Chlorfenapyr is a pyrrol insecticide very effective against insects and mites that are resistant to organophosphates, carbamates, pyrethroids, and chitin-synthesis inhibitors. Chlorfenapyr is a pro-insecticide that is metabolized to the active form by mixed function oxidase enzymes in the target pest. The active form inhibits production of adenosine triphosphate, the primary source of cellular energy. Because it is a relatively new product, symptoms of acute and chronic exposure are not well characterized in humans, but chlorfenapyr is moderately to highly toxic in acute oral tests in rodents with non-cancer effects related to neurotoxicity and reproductive toxicity. Chlorfenapyr was characterized as "cannot be determined, suggestive" in EPA carcinogen classification.

- **Cyfluthrin.** Cyfluthrin is a synthetic pyrethroid that can affect the nerves and brain by interfering with nerve cell sodium channels. Typical symptoms for acute human exposure are skin and eye irritation. Dermal exposure to cyfluthrin has been shown to cause paresthesia (a burning, tingling, or stinging of the skin) which may lead to a numbness lasting up to 24 hours. Skin irritation may be immediate or delayed for up to 2 hours. In animals, exposure to high levels of cyfluthrin causes nervous system effects such as irritability, excessive salivation, incoordination, tremors, convulsions, and even death. Cyfluthrin is rapidly metabolized and excreted from the body. Limited data are available for chronic low-level exposures of humans to cyfluthrin. Based on animal studies, it is not expected to be a reproductive or developmental toxicant. No evidence of carcinogenic potential of cyfluthrin has been reported in animals.

- **DDT.** DDT is a broad-range organochlorine insecticide. It was banned in the early 1970s in the United States and in most industrial countries, mainly because of its persistence in the environment and ecological impacts. DDT has been used in large populations for more than 60 years with little evidence of acute toxicity, except from accidental exposures. In these relatively rare instances, DDT acts by impairing the conduction of nerve impulses. Symptoms of acute exposure to high levels of DDT by any route include mild altered sensations, tremors, convulsions, and respiratory depression. Additional effects observed in humans after acute DDT exposure include headaches; nausea and vomiting; diarrhea; numbness; paresthesia (a burning, tingling, or stinging of the skin); increased liver enzyme activity; irritation of the eyes, nose, or throat; altered gait; and malaise or excitability. In addition to potential acute effects, DDT is a liver toxicant, and is associated with various reproductive and developmental effects. Recent data indicate that exposure to DDT in amounts necessary for malaria control may cause preterm birth, decreased birth weight, early weaning, and pregnancy loss. The International Agency for Research on Cancer (IARC) has classified DDT in Group B2, "probable human carcinogen."

- **Deltamethrin.** Deltamethrin is a powerful broad-spectrum synthetic pyrethroid. It is of moderate toxicity to mammals as it is rapidly metabolized and does not accumulate. Deltamethrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the

sodium channels of nerve cells. Typical symptoms of acute exposure are irritation of skin and eyes and neurological effects such as severe headaches, dizziness, nausea, anorexia, vomiting, diarrhea, excessive salivation, and fatigue. Tremors and convulsions have been reported in severe poisonings. Dermal exposure to deltamethrin has been shown to cause reversible cutaneous paresthesia (a burning, tingling, or stinging of the skin). Limited data exist for humans following chronic exposures. Chronic occupational exposure to deltamethrin has resulted in skin and eye irritation. Long-term animal studies have not shown reproductive or mutagenic effects. IARC has classified deltamethrin as "not classifiable as to its carcinogenicity in humans."

- **Etofenprox.** Etofenprox is a nonester pyrethroid-like insecticide. Like other pyrethroids, it acts on the central nervous system by interfering with nerve cell sodium channels. WHO has classified etofenprox as a low risk for acute toxicity in humans under conditions of normal use. Limited chronic human exposure data are available. Etofenprox was not observed to result in developmental or reproductive effects in animal studies, but long-term exposures have been associated with thyroid, kidney, and liver effects. With respect to carcinogenicity, EPA has classified it in Group C, as a "possible human carcinogen."

- **Fenitrothion.** Fenitrothion is an organophosphate insecticide. It can cause overstimulation of the nervous system due to cholinesterase inhibition, which may result in nausea, dizziness, confusion, and at very high exposures, respiratory paralysis and death. Chronic symptoms of toxicity in humans include general malaise, fatigue, headache, loss of memory and ability to concentrate, nausea, thirst, weight loss, cramps, muscular weakness, and tremors. Reproductive and developmental toxicity have been reported in animal studies. EPA has classified fenitrothion as a Group E chemical, with "evidence of noncarcinogenicity for humans."

- **Lambda-cyhalothrin.** Lambda-cyhalothrin is a synthetic pyrethroid that is a more biologically active form than cyhalothrin. It is used to control pests (including mosquitoes) in agricultural, public, and animal health settings. Typical symptoms for acute exposure to lambda-cyhalothrin include tingling, burning, or numbness (particularly at the point of skin contact); dizziness; headache; nausea; tremors; incoordination of movements; paralysis or other disrupted motor functions; convulsions; and loss of consciousness. These effects are generally reversible because lambda-cyhalothrin breaks down rapidly in the body. No toxicity data for chronic lambda-cyhalothrin exposure are available in humans, but neurological effects have been observed in animal studies. Lambda-cyhalothrin was not observed to have teratogenic or fetotoxic effects in animal studies. It has been classified by EPA as a Group D chemical, "not classifiable as to human carcinogenicity."

- **Malathion.** Malathion is a broad-spectrum organophosphate insecticide that is used in a wide variety of applications, including agricultural, veterinary, and public health uses, such as the control of mosquitoes. Malathion causes neurological effects by inhibiting cholinesterase and thereby interfering with nervous system function. Acute exposure to high concentrations of malathion can cause numbness, headaches, sweating, abdominal cramps, blurred vision, difficulty breathing, respiratory distress, and loss of consciousness. Limited data from chronic human exposures indicate that the nervous system is the main target organ of chronic malathion toxicity. Reproductive and developmental toxicity have not been reported in animal studies, but there is indication of immunological effects at doses lower than those resulting in neurotoxicity. EPA has classified malathion as having "suggestive evidence of carcinogenicity."[5]

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[5] Under EPA's new system, group letters (e.g., A, B, C, and D) are no longer used to classify chemicals with respect to potential human carcinogenicity. As this process is being phased in, some chemicals—like malathion—are identified under the new system.

- **Methoprene.** Methoprene is a larvicide and growth regulator that acts by interfering with the life cycle of the insect rather than by direct toxicity. It prevents insects from reaching maturity or reproducing. EPA has classified methoprene as toxicity class IV, slightly to almost nontoxic. It is selective, stable, and potent, though not persistent in the environment or toxic to mammals. It has low potential for acute oral or inhalation toxicity. It is not a skin or eye irritant or skin sensitizer and is of low acute dermal toxicity. Limited data are available for humans following chronic exposures to methoprene; however, increased liver weights were observed in a 90-day rodent feeding study. No reproductive, developmental, or neurotoxic effects have been seen in humans or animals. No evidence of carcinogenic potential was observed in animal studies.

- **Permethrin.** Permethrin is a synthetic pyrethroid used in bed nets and other materials for controlling mosquitoes. Like other pyrethroids, permethrin exhibits toxic effects by interfering with the sodium channels in nerve cell membranes. . Typical symptoms for acute exposure include irritation of skin and eyes, headaches, dizziness, nausea, vomiting, diarrhea, excessive salivation, and fatigue. These effects are generally reversible and disappear within a day of ending the exposure. Low-level, chronic exposures to permethrin do not generally cause neurological effects in humans, because permethrin is rapidly metabolized and excreted from the body. EPA has classified permethrin as "likely to be carcinogenic to humans by the oral route."

- **Pirimiphos-methyl.** Pirimiphos-methyl is organophosphate insecticide and acaricide. Like other organo-phosphates, pirimiphos-methyl acts by inhibiting cholinesterase activity. Symptoms of acute pirimiphos-methyl exposure include excessive sweating, headache, weakness, giddiness, nausea, vomiting, stomach pains, blurred vision, slurred speech, and muscle twitching. Subchronic and chronic exposures in animal studies have indicated cholinesterase inhibition in plasma, erythrocytes, and brain tissues. No evidence of developmental, reproductive, or carcinogenic effects exists based on available animal studies.

- **Propoxur.** Propoxur is a carbamate insecticide that exhibits its toxic effects through reversible cholinesterase inhibition. In humans, symptoms of acute oral poisoning include red blood cell cholinesterase inhibition with mild transient cholinergic symptoms including nausea, vomiting, sweating, blurred vision, and tachycardia. Long-term exposures in humans have resulted in cholinesterase inhibition, headaches, nausea, and vomiting. In addition to cholinesterase inhibition, chronic animal studies have indicated effects on the liver and nervous system. EPA has classified propoxur in Group B2 as a "probable human carcinogen" Based on animal data.

- **Pyriproxyfen.** Pyriproxyfen is a pyridine-based pesticide. This molecule is a juvenile hormone analog and acts as an insect growth regulator that affects the physiology of morphogenesis, reproduction and embryogenesis of insects. The acute toxicity of pyriproxyfen in mammals is relatively low, with transient and minimal signs of toxicity observed only at high oral dosages. It may cause brief and minor irritation to skin. Chronic feeding studies in rodents and dogs suggest that pyriproxyfen is a possible liver toxicant as well as a possible blood toxicant. EPA has not developed a carcinogenicity classification for pyriproxyfen, but neither developmental nor carcinogenic effects have been observed in test animals.

- **Spinosad.** Spinosad is a mixture of two neurotoxins, spinosyn A and D metabolites, produced during fermentation by the bacteria *S. spinosa*. Its mode of action involves triggering of nicotinic acetylcholine receptors. Spinosad exhibits very low acute mammalian toxicity in oral and inhalation tests in rates and dermal tests in rabbits. Chronic exposure at high doses induced lesions in a wide variety of tissues in mice, rats, and dogs. EPA has not developed a carcinogenicity classification for spinosad but no evidence of carcinogenicity has been observed in animal studies.

- **Temephos.** Temephos is annorganophosphate larvicide used in the United States since 1965 to control of mosquito, midge, and black fly larvae. Temephos' activity is caused by inhibiting cholinesterase, which results in overstimulation of the nervous system. Acute effects of exposure may include eye irritation, blurred vision, dizziness, nausea, abdominal cramps, diarrhea, salivation, headaches, loss of muscle coordination, and difficulty breathing. The effects of chronic exposure to temephos have not been well documented in humans. In addition to cholinesterase inhibition, liver effects have been reported in rodent and rabbit studies. No data exist on the carcinogenic effect of temephos in humans, and only very limited data exist for animals. EPA has not classified temephos as a carcinogen.

5.2.4.2 Selection of Toxicity Criteria

The toxicity assessment for this risk assessment is based on the assumptions and methods developed in the 2007 PEA (USAID, 2007). The references for the health benchmark criteria and hierarchy of sources used in this risk assessment are identical to those employed in the 2007 PEA. For pesticides that were evaluated in the 2007 PEA, these references were reviewed to determine whether any benchmarks had been up dated between 2007 and the present day. Updated benchmarks were used when available. For the new pesticides not evaluated in the 2007 PEA (chlorfenapyr, spinosad, and pyriproxyfen) the hierarchy of toxicity criteria described below was used to identify toxicity criteria. Assumptions related to route-to-route extrapolation of toxicity, and the use of benchmarks for longer-duration exposures as surrogates for shorter exposures, are also analogous in this risk assessment and in the 2007 PEA.

Two types of benchmarks were selected for the screening risk assessment. For noncancer hazard, an RfD specific to the duration of exposure was selected for each pesticide. The RfD is defined by EPA as an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime (U.S. EPA, 1989). It can be derived from a no observed adverse effect level (NOAEL), lowest observed adverse effect level (LOAEL), or benchmark dose, with uncertainty factors generally applied to reflect limitations of the data used. The degree of uncertainty and confidence levels in RfDs vary and are based on both scientific (i.e., toxicological studies) and policy (i.e., level of conservatism) considerations. Noncarcinogenic effects are generally assumed to manifest only when exposure exceeds a threshold and not when exposure is less than the threshold or at some time following the exposure. Hence, the averaging time related to these effects is defined as the time period during which exposure takes place.

For cancer risk, a CSF was selected for those pesticides for which EPA has developed such criteria. The CSF is an upper-bound estimate (approximating a 95 percent confidence limit) of the increased human cancer risk from exposure to an agent over the lifetime of the individual (U.S. EPA, 1989). Unlike RfDs, CSFs do not represent "safe" exposure levels; rather, they relate levels of exposure to a probability of developing cancer. Because there may be a decades-long latency period between exposure and effect (U.S. EPA, 2005), carcinogenic effects are averaged over an entire lifetime.

Health benchmarks were identified from several sources in the following order of preference:

a) EPA's Reregistration Eligibility Decision (RED) documents, or risk assessments documented in the Federal Register supporting same

b) EPA's Integrated Risk Information System (IRIS) (U.S. EPA, 2011)

c) EPA's Health Effects Assessment Summary Tables (HEAST) (U.S. EPA, 1997b)

d) ATSDR's Toxicological Profiles.

For noncancer endpoints, the length of time that workers and residents may be exposed to a pesticide varies by activity (e.g., preparation, spraying, treatment). Exposure scenarios for workers are associated with subchronic exposure periods, while those for residents are general associated with chronic exposure periods. An exception to the latter is the evaluation of noncancer effects due to acute exposure of residents washing LLINs. Therefore, benchmarks were identified for three exposure duration categories consistent with the definitions presented in the RED documents:

1) Acute (≤1 day)
2) Intermediate-term, *aka* subchronic (>30 days to ≤6 months)
3) Chronic (>6 months).

If benchmarks were not available from a RED document, we obtained chronic and subchronic benchmarks from IRIS or HEAST (i.e., chronic and subchronic RfDs), and used the subchronic benchmarks to evaluate the intermediate-term exposures. In the absence of data from EPA sources, we relied on ATSDR documents to identify acute MRLs (developed for exposures of 1–14 days) to represent acute exposure durations; intermediate MRLs (developed for exposures of 2 weeks to 1 year) to represent subchronic exposures; and chronic MRLs (developed for exposures longer than 1 year) to represent chronic exposures.

The inhalation benchmarks not presented in units of dose were converted to milligrams of pesticide per kilogram body weight per day (mg/kg-day) based on an assumed inhalation rate of 20 m^3/day and an average adult body weight of 70 kg. However, inhalation benchmarks were not available for some of the pesticides. In those instances, this risk assessment employed the protocol used in the 2007 PEA (USAID, 2007) of applying an oral benchmark to the inhalation exposure route. This simple route-to-route extrapolation implicitly assumes that that there are no portal-of-entry effects and the route of administration is irrelevant to the dose delivered to the target organ. Although EPA's Superfund program no longer routinely applies oral benchmarks as a surrogate for inhalation benchmarks, this protocol established in the 2007 PEA was continued in this PEA.

Similarly, dermal benchmarks were not available for some of the pesticides evaluated in this risk assessment. In those instances, we used the methodology published by EPA for making route-to-route extrapolations for systemic effects via percutaneous absorption (U.S. EPA, 2004). Oral RfDs are generally expressed as the amount of substance *administered* per unit time and body weight, whereas dermal exposure estimates are expressed as *absorbed* dose. EPA recommends that a default value of complete (i.e., 100 percent) oral absorption be assumed in the absence of data indicating poor gastrointestinal absorption, thereby eliminating the need to adjust the oral toxicity value. However, using the oral absorption default value may result in an underestimate of risk at a level that is inversely proportional to the true oral absorption of the chemical in question (U.S. EPA, 2004). EPA does not recommend adjusting for absorption unless gastrointestinal absorption is less than 50 percent. EPA specifically recommends that DDT not be adjusted as oral absorption ranges from 70 to 90 percent (U.S. EPA, 2004). Additional data indicate that malathion oral absorption is about 89 percent (in 60 minutes) in mice (ATSDR, 2003b); permethrin oral absorption is about 60 percent in rats (ATSDR, 2003a); and cyhalothrin oral absorption ranges from 48 to 80 percent in dogs (WHO, 1990). Based on this information, no adjustment was made for any of the pesticides of concern and oral toxicity values were used for the dermal assessment.

The human health benchmarks used in this risk assessment are summarized in ***Annex D***, Table D-3, and toxicological profiles are presented in ***Annex E***.

5.2.5. RISK CHARACTERIZATION

This section of the human health risk assessment describes the interpretation and risk characterization of the screening results for noncancer hazard and cancer risk for the malaria vector control practices, pesticides, exposure scenarios, and receptors that are the focus of this report. The risk characterization is presented in four parts:

Section 5.2.5.1 describes the risk assessment methodologies and thresholds used for characterizing chemical hazard and cancer risk, focusing primarily on the screening phase.

Section 5.2.5.2 provides the noncancer and cancer risk assessment results. For each malaria vector control practice and pesticide-related activity, we interpret the results of the risk calculations with respect to the level of conservatism and the significance of the health endpoints. The strengths and limitations of the risk assessment are summarized, and key uncertainties are identified. A separate risk characterization is provided for each of the exposure scenarios described in Section 5.2.2.2. These risk characterizations are organized as follows:

Section 5.2.5.2.1. IRS, ITN re-treatment and larviciding; worker preparation of pesticide.

Section 5.2.5.2.2. IRS and larviciding; worker application.

Section 5.2.5.2.3. IRS, ITN re-treatment and larviciding; resident exposure to groundwater from disposal of surplus, and to larvicide applied in surface water.

Section 5.2.5.2.4. IRS, resident exposure to residual.

Section 5.2.5.2.5. LLINs/ITNs; resident exposure.

Section 5.2.5.2.6. Wall linings; resident exposure. This subsection provides a qualitative analysis of potential risks based on the results of the LLIN assessment in the previous subsection.

Section 5.2.5.3 presents a separate analysis of potential resident risks related to the use of DDT for IRS based on studies from the malaria vector control program and other sources of information.

Section 5.2.5.4 summarizes the major conclusions and recommendations of the human health risk assessment.

Section 5.2.5.1 Methodology for Calculating Noncancer Hazard and Cancer Risk

The hazard quotient (HQ) is the metric used to express noncancer hazard. As discussed previously, the HQ is simply the ratio between the predicted dose and the health benchmark (both are in units of milligrams of pesticide per kilogram body weight per day). Hazard quotients from different routes of exposure were summed to estimate an aggregate exposure per *Guidance for Performing Aggregate Exposure and Risk Assessments* (U.S. EPA, 2001).

The HQ is calculated as described in Table G-13, as follows:

$$HQ = \frac{ADD}{RfD}$$ **Equation 5-2**

where:

ADD = average daily dose (mg/kg body weight/day)

RfD = reference dose (mg/kg body weight/day)

An HQ greater than 1 (one) is regarded as an indication of potential hazard for any of the three categories of benchmarks identified in Section 5.2.4 (U.S. EPA, 1989), with higher values being related to greater concern for adverse effects. If there is the possibility of simultaneous exposure to two or more pesticides, HQs for each pesticide may be summed to calculate a hazard index (HI) across pesticides for each exposure pathway if target organs and mechanisms of toxicity are similar. However, the level of concern generally does not increase linearly as an HQ or HI of unity is approached or exceeded because RfD values do not necessarily have equal accuracy or precision and the dose-response relationship above the RfD threshold may be very different than at lower doses. The practical consequence is that an HQ or HI is not a measure of risk in the sense that larger values imply a commensurately higher probability of observing an adverse effect.

For cancer endpoints, we use EPA's recommended approach to estimate cancer risk by multiplying the LADD by the CSF obtain the incremental excess lifetime cancer risk (U.S. EPA, 1989). Cancer risks from different routes of exposure were summed to estimate an aggregate exposure per *Guidance for Performing Aggregate Exposure and Risk Assessments* (U.S. EPA, 2001). Cancer risks were calculated as described in Table G-14 as follows:

$$ILCR = LADD \times CSF \qquad \text{Equation 5-3}$$

where:

LADD = lifetime average daily dose

CSF = cancer slope factor $(mg/kg\ body\ weight/day)^{-1}$

The cancer risk estimate represents a person's risk of contracting cancer due to the exposures received over a lifetime. Note that this is a simplification of a very complex process that may depend greatly on the timing of exposure with respect to the life stage of the person. As with the noncancer endpoints, the aggregate cancer risk from exposure to multiple pesticides can be calculated using a simple summation. Although this approach does not distinguish between different types of cancers that may be associated with different chemicals, summation of cancer risks is less problematic in principle than summation of HQs for different chemicals. In environmental assessments in the United States, the acceptability of any calculated incremental cancer risk is generally evaluated relative to the point of departure of 1 × 10-6 and the target risk range of 1 × 10-6 to 1 × 10-4 described in the "National Oil and Hazardous Substances Pollution Contingency Plan" (40 CFR 300.430).

As a point of comparison, national cancer statistics have been developed that provide the background incidence of cancer for the U.S. population. For example, national cancer statistics indicate that each male has approximately a 1 in 2 chance of developing cancer during his lifetime and that each female has approximately a 1 in 3 chance of developing cancer in her lifetime (American Cancer Society 2005, Surveillance Research: Probability of Developing Invasive Cancers Over Selected Age Intervals, by Sex). A U.S. individual with a theoretical incremental lifetime cancer risk of 1-in-100,000 due to pesticide exposure has an approximate total cancer risk of 50,001-in-100,000 (male) or 33,334-in-100,000 (female), where the background levels are 50,000-in-100,000 (male) and 33,333-in-100,000 (female).

5.2.5.2 Noncancer Hazard and Cancer Risk Results

This section summarizes and interprets the results from the risk assessment for each malaria vector control practice and related activity described in the conceptual exposure models. The noncancer HQs and cancer risk estimates are calculated using the exposure parameter values and described in ***Annex G***.

The cancer risk and HQ values that underlie the discussions in the following subsections are presented in ***Annex H***.

5.2.5.2.1 IRS, ITN Re-Treatment and Larviciding; Worker Preparation of Pesticide

Cancer risk and chemical hazard risk assessment results for worker preparation of pesticides are provided in Tables H-1 and H-2 of ***Annex H***, respectively. Because different unit application exposure estimates (see Tables G-1 and G-3 of ***Annex G***) apply to preparation of different pesticide formulations, separate results are provided for emulsifiable concentrate formulations and formulations prepared from wettable powders (some IRS and ITN pesticides) or granules (some larvicides).

For the preparation of insecticide for IRS, ITN re-treatment and larviciding, risks related to potential dermal and inhalation exposures were estimated for workers mixing the insecticide formulation with water. For most pesticides, estimated dermal cancer risks and HQs were higher than estimated inhalation results both with, and without, consideration of the use of PPE.

For etofenprox and propoxur, cancer risks related to preparation of the pesticide were well below the 1×10^{-6} to 1×10^{-4} risk management range described in Section 5.2.5.1 when workers were assumed to use PPE. Even in the absence of PPE, the only risk calculation that exceeds 1×10^{-6} for etofenprox and propoxur are the high-end exposure estimate results of 2×10^{-6} (WP) and 3×10^{-6} (EC), which are still within the lower portion (1×10^{-6} to 1×10^{-5}) of the risk management range. DDT preparation cancer risks for workers using PPE are either below (low-end estimate) are within the lower portion (mid-range and high-end) of the risk management range. If workers are not using PPE, the high-end exposure estimate for wettable powder DDT preparation (1×10^{-4}) is at the upper end of the risk management range.

Mid-range and high-end exposure estimates for preparation of pesticides even without use of PPE are below the chemical hazard threshold of 1.0 for all pesticides with the exception of DDT, pirimiphos-methyl, chlorfenapyr, and fenitrothion. The noncancer assessment results for preparation of DDT and pirimiphos-methyl in particular indicate a potential noncancer hazard above the threshold of 1.0, largely due to dermal exposure. The use of PPE can significantly mitigate the potential hazards related to preparation of these pesticides. Low-end to high-end estimates of HQ values for worker preparation of DDT using PPE range from 2 to 6. For pirimiphos-methyl, the equivalent range is 1 to 4. These values contrast greatly with HQ estimates between 90 and 300 (DDT), and between 40 and 100 (pirimiphos-methyl) for worker preparation of these pesticides without PPE. Chemical hazard results for chlorfenapyr and fenitrothion are below 1.0 for calculations in which workers are assumed to use PPE.

As noted in the 2007 PEA (USAID, 2007), the dermal risk calculations for worker exposure during pesticide preparation may overestimate exposures because the exposure interval may be shorter than the time required to achieve steady-state diffusion across the stratum corneum, as assumed in the dermal exposure model. Additionally, consistent with the methods used in the 2007 PEA, an assumption is made that 100 percent of the pesticide in the highly concentrated preparation is absorbed through the skin. This may overestimate actual exposure. This latter assumption may be particularly problematic for pirimiphos-methyl CS, where encapsulation may inhibit dermal absorption.

In addition to routine exposures from pesticide preparation, workers may also be exposed due to accidental releases from spills occurring in a pesticide storage facility or during pesticide preparation. If spills in the vicinity of homes being sprayed for IRS are not properly cleaned up, subsequent resident exposures may also be of concern. Chapter 8 of the BMP Manual (USAID, 2010) addresses proper protocols to minimize exposures related to occasional spill events. Consideration should be given to the location where pesticide formulations are prepared to minimize possible resident exposures related to spills. For example, pesticide preparation in a location outside the home and away from gardens and livestock would reduce the likelihood of resident exposures in the event that a pesticide spill occurred and was inadequately remediated. Tanks and nozzles must also be properly maintained to avoid leaks and drips during the application process itself.

Recommendations

The relatively low HQ values of between 2 and 6 for DDT and 1 and 4 for pirimiphos-methyl are not necessarily indicative of expected noncancer hazards to workers using PPE. For example, a recent article in the South African Medical Journal (Bismenya et al, 2010) did not find evidence of impaired liver function in IRS sprayers in northern Uganda who presumably also prepared the pesticide formulations used in the spraying. This finding was based on comparison of liver enzyme concentrations that are biomarkers of liver function to population reference levels. This finding is particularly relevant insofar as worker risks due to subchronic exposures from pesticide preparation and spraying are likely to be additive.

In keeping with the recommendations of the 2007 PEA (USAID, 2007), this assessment also recommends that workers be adequately trained and provided with PPE to ensure the appropriate handling of pesticides during preparation. As stated in the 2007 PEA (USAID, 2007), given current deficiencies in the available data and modeling approaches for dermal effects from exposures to highly concentrated pesticide solutions, it is highly likely that a probabilistic modeling approach would produce similar results to the range of values presented here, unless we consider the uncertainty inherent in the benchmarks selected for this analysis. Therefore, as noted in the 2007 PEA (USAID, 2007), improving the relevance of the risk assessment results to decision making should involve a more extensive evaluation of the underlying toxicological studies and subchronic reference dose values, particularly for DDT. For instance, the studies on which the EPA's noncancer benchmark for DDT is based are very old (around 1950). It was noted in the 2007 PEA (USAID, 2007) that the literature on human exposures does not indicate that the effects threshold in humans is anywhere near 0.0005 mg/kg-day RfD used in these risk calculations. This observation is consistent with the results of Bismenya et al (2010).

Worker and resident exposures to pesticides due to spill events during preparation can be minimized by following best management practices described in USAID (2010). Preparation of pesticides in a location outside of the homes being sprayed, and proper maintenance of tanks, lines, and nozzles to minimize dripping during application, are appropriate precautions for reducing exposures due to leaks and spills.

5.2.5.2.2 IRS AND LARVICIDING; WORKER APPLICATION

Cancer risk and chemical hazard risk assessment results for worker application of pesticides are provided in Tables H-3 and H-4 of ***Annex H***, respectively. For the spray application of insecticide for IRS and larviciding, risks related to potential dermal and inhalation exposures were estimated for workers. For the majority of pesticides, estimated dermal cancer risks and HQs were higher than estimated inhalation results both with, and without, consideration of the use of PPE.

In the absence of PPE, dermal exposures were assumed to occur on the head, neck, arms, chest, back, thigh, lower legs, and arms (U.S.EPA, 1997a; airless sprayer application). Low-end to high-end exposure cancer risk results for etofenprox and propoxur were within the 1×10^{-6} to 1×10^{-4} risk management range. However, calculated DDT cancer risks for workers without PPE were all above this range, with a high-end exposure result of 2×10^{-3}. These results are almost wholly associated with the dermal exposure pathway. Risk calculations based on the assumed use of PPE were significantly lower, with only DDT results reaching the risk management range. Low-end to high-end DDT cancer risk results for IRS applicators using PPE ranged from 1×10^{-5} to 5×10^{-5}.

Because the tenure of IRS applicators is uncertain, cancer risk calculations for these workers was performed for a single year of exposure. The high-end exposure cancer risk estimate for DDT of 5×10^{-5} indicates that a cumulative exposure of six years as an applicator would be necessary to exceed 1×10^{-4}. For the low-end exposure estimate, a 10-year exposure duration would be required for an IRS applicator of DDT to reach a cancer risk of 1×10^{-4}.

For IRS and larvicide applicators, mid-range exposure estimates of noncancer hazard in the absence of PPE were above 1.0 for several pesticides. Mid-range results for these pesticides both with, and without, PPE use are summarized in Table 5-11.

Table 5-11 Summary of Spray Application Mid-Range HQs for Pesticides with HQ > 1 without PPE Use

IRS Pesticide	HQ (no PPE)	HQ (with PPE)
chlorfenapyr	100	3
DDT	3,000	70
fenitrothion	200	4
malathion	2	0.07
pirimiphos-methyl	200	4
Larvicide	**HQ (no PPE)**	**HQ (with PPE)**
temephos	3	0.06

Of the IRS pesticides summarized in Table 5-11, only DDT had an HQ estimate well above the effects threshold of 1.0 even assuming worker use of PPE. In both cases, the dermal absorption exposure route was almost wholly responsible for the calculated HQ values. Similar to worker pesticide preparation risks above, in the absence of pesticide-specific information 100% dermal absorption of pesticide reaching the skin was also assumed in the spray application risk calculations. Only for pirimiphos-methyl was such information available; as detailed in Annex G a dermally absorbed dose fraction of 8% was applied to pirimiphos-methyl based on *in vitro* data for concentrations used in IRS. Because the *in vitro* data pertain to an emulsifiable concentrate formulation, the value of 8% may overestimate dermal exposure for the capsule suspension form of pirimiphos-methyl.

As discussed in the 2007 PEA (USAID, 2007), a significant source of uncertainty in the calculation of worker risks related to spray application is the quantification of exposure concentrations to which workers are exposed. Both inhalation and dermal exposures are estimated based on "unit exposure" values published by the EPA (U.S. EPA, 1997a). The inhalation unit exposure value used pertains to residential backpack spraying of low to mid-level shrubs, and may underestimate exposures for applications above the waist, such as spraying of walls and eaves. The dermal unit exposure value pertains to residential users of airless sprayers. As noted in U.S. EPA (1997a), airless sprayers are typically rented by homeowners who therefore may not be skilled in their use. It is possible that homeowner dermal exposures will overestimate those of IRS applicators who are trained and practiced in the use of spray equipment.

The unit exposure approach does not characterize the air concentrations and particle sizes to which workers are exposed, nor does it address the amount of time spent during spraying under which inhalation and dermal exposure can occur. It is likely that the daily exposure time of IRS applicators may exceed that of the homeowners evaluated in U.S. EPA (1997a).

As discussed in Section 5.2.5.2.1, relatively low HQ values between 1 and 7 are not necessarily indicative of expected noncancer hazards to workers using PPE. However, an HQ values of 70 (DDT) suggests the possibility of observable adverse effects. The research of Bismenya et al (2010), which failed to find evidence of impaired liver function in IRS DDT sprayers in northern Uganda, suggests that such activity may not result in subchronic DDT exposures above the noncancer effects threshold. This finding was

based on comparison of four enzyme concentrations that are biomarkers of liver function to population reference levels.

Although Bismenya et al (2010) concluded that their results overall indicated no deleterious effect on liver function, 25% of 119 plasma samples tested for GGT enzyme activity were stated to be above the reference range. Bismenya et al (2010) also cited other researchers who did observe elevated liver enzyme concentrations in IRS DDT sprayers. Because the reference dose values developed by EPA and used in the risk assessment are intended to protect potentially sensitive individuals[6] and may not pertain to a general population, the conclusions of Bismenya et al (2010) and the results of the HQ calculations are not necessarily contradictory.

Recommendations

The findings of Bismenya et al (2010) confirm the conclusion of the 2007 PEA (USAID, 2007) that, even when using PPE, worker exposures during spraying activities are not completely preventable. As recommended in the 2007 PEA, the spray application exposure model used in this PEA represents a refinement of the 2007 model. Specifically, this PEA incorporates a dermal exposure pathway to supplement the inhalation pathway evaluated in the 2007 PEA, provides risk estimates for a range of possible exposure intensities, and references a recent publication on IRS applicator DDT exposures in a country (Uganda) where the malaria vector control program is active.

The risk assessment presented in this PEA for spray applicators suggests that potentially significant risks are associated only with DDT. The use of dermal and respiratory PPE can effectively mitigate potential worker exposures if this equipment is used under an appropriate protocol, such as that described in the President's Malaria Initiative BMP Manual (USAID, 2010). Use of PPE in accordance with this protocol is essential to protect worker health during spray application of pesticides. However, the degree of mitigation afforded by N95 respirators, protective overalls, and gloves may be inadequate for DDT. Risk management recommendations related to worker protection are provided in Section 5.2.5.4. Recommendations regarding refinement of the toxicological basis of the benchmarks for DDT (see Section 5.2.5.2.1) are also pertinent to this IRS applicator exposure scenario.

5.2.5.2.3 IRS, ITN re-treatment and larviciding; resident exposure to groundwater from disposal of surplus, and to larvicide applied in surface water

The cancer risk and chemical hazard risk assessment results for adult and child resident exposure via groundwater to disposed IRS and ITN pesticides and larvicides are provided in Tables H-5 and H-6 of Annex H, respectively. As shown in Figure 5-4, residents may be exposed to pesticides in contaminated groundwater due to ingestion or by dermal uptake during bathing. In addition to the risk calculation for groundwater exposure, this assessment includes a semi-quantitative evaluation of potential human health risks related to surface water exposures subsequent to larviciding.

Among the potentially carcinogenic insecticides evaluated in this PEA, only DDT had a calculated cancer risk above 1×10^{-6}. The CTE (2×10^{-6}) and RME (3×10^{-6}) results for DDT are both within the lower portion (1×10^{-6} to 1×10^{-5}) of the risk management range. No chemical hazard results exceeded 1.0 for any pesticide evaluated in this IRS scenario.

As described in Section 5.2.3.4, a unit value of 1 kg/acre per year was used in the groundwater modeling calculations in lieu of specific information on the quantity of pesticide that might be disposed in an area by burial or rinsing of spray equipment. The quantities of disposed pesticide resulting in a child HQ of

[6] For example, pregnant or nursing women, or individuals whose genetic make-up renders them particularly susceptible to the toxic effects of pesticide exposure.

1.0 or (for DDT, etofenprox, and propoxur) a cancer risk of 1×10^{-5} based on RME exposure assumptions, are shown in Table 5-12.

Table 5-12 Annual Quantity of Disposed Pesticide Related to a Groundwater Risk Estimate at Threshold Values

IRS Pesticide	Disposal Amount (kg)
alpha-cypermethrin	85,000
bendiocarb	3,300
bifenthrin	16,000
chlorfenapyr	2,800
cyfluthrin	13,000
DDT	3.6
deltamethrin	14,000
etofenprox	90
fenitrothion	340
lambda-cyhalothrin	5,800
malathion	1,100
permethrin	Not applicable; LLIN and wall linings only
pirimiphos-methyl	100
propoxur	8.9
Larvicide	**Disposal Amount (kg)**
methoprene	270,000
spinosad	5,500
temephos	2,900
pyriproxyfen	160,000

For the majority of IRS and larviciding pesticides, disposed quantities in excess of 1,000 kg are required to reach groundwater concentrations associated with the cancer risk and chemical hazard thresholds described above. Quantities of DDT and propoxur, however, are below 10 kg, and quantities of pirimiphos-methyl, etofenprox, and fenitrothion are between 90 and 340 kg.

The SCI-GROW screening model developed by U.S.EPA that was used to calculate groundwater concentrations for each pesticide is discussed in Section 5.2.3.4. There are uncertainties associated with the modeling that may result in either over- or underestimation of pesticide groundwater concentrations

at a particular location. The SCI-GROW model is based on pesticide migration to groundwater in susceptible environments where sandy soils and shallow groundwater facilitate leaching. In areas of clayey soil or deeper groundwater, leaching would be expected to be overestimated. In addition, the modeling assumes that annual disposals continue to contaminate the groundwater throughout the residents' lifetimes.

However, the SCI-GROW model applies to field application of pesticides rather than disposal / burial of concentrated amounts at a specific location. The aerobic soil degradation half-life used in the modeling may not be applicable to deeper subsurface soils nor to concentrated pesticides. In a worst-case situation, where a shallow groundwater well is immediately down gradient from a location where pesticides have been buried, the quantities of disposed pesticides necessary to result in risks above threshold criteria are likely smaller than those estimated here.

Surface Water

Resident risks from exposure to surface water treated with larvicides are inherently difficult to quantify. The application concentration of the larvicides is shown in Table G-15 and ranges from 7.1 mg/L (pyriproxyfen) to 140 mg/L (spinosad) for high-end application rates. One approach to screening potential risks related to such concentrations is to estimate the dilution factor necessary to achieve the hazard quotient threshold of 1.0 given a protective exposure scenario. The RME scenario for groundwater ingestion (see Table G-5) was evaluated using the high-end application concentration of the larvicides shown in Table G-15. Chemical hazards for chronic exposure involving 2.3 L/day for each larvicide application concentration were calculated. Because HQs are proportional to exposure concentrations, the dilution factors to achieve an HQ of 1.0 are equivalent to these HQs. These dilution factors are shown in Table 5-13.

Table 5-13 Larvicide Dilution Factors Related to a Drinking Water HQ of 1.0

Larvicide	Dilution Factor
methoprene	2.7
spinosad	200
temephos	150
pyriproxyfen	0.77

These results indicate that very little dilution of the applied larvicide concentration is required to result in surface water concentrations below levels of potential concern even for long-term drinking water exposures. Human health risks are likely to be negligible from use of these larvicides to control mosquito larvae in natural water bodies from which people may obtain drinking water.

Recommendations

The land disposal of most pesticides is unlikely to result in groundwater contamination affecting human health risks unless a groundwater well is located immediately down gradient of a burial location. Potential exceptions include DDT and propoxur, where disposal of less than 10 kg/year may result in cancer risks above 1×10^{-5}. Therefore, for these two insecticides, it is important to ensure that wastewater disposal practices adhere to BMPs for effluent disposal, which includes the use of progressive rinsing , and soak pits or evaporation tanks, and that signs of effluent overflow (resulting from insufficient absorptive capacity of evaporation tanks or soak pits) are immediately reported. PMI should consider sampling soak pits to confirm that they are effective. Because of the possibility of localized groundwater contamination

from the land disposal of large quantities of pesticides, this practice cannot be generally recommended. The use of larvicides is unlikely to present significant risks to residents from use of surface waters as a domestic water supply.

5.2.5.2.4 IRS; resident exposure to IRS residual

Cancer risk and chemical hazard risk assessment results for adult and child resident exposures to IRS pesticides subsequent to application are provided in Tables H-7 and H-8 of ***Annex H***, respectively. Resident risk was quantified for potential dermal exposures to sprayed wall surfaces. Because DDT is a persistent environmental pollutant that may contribute risks via a number of exposure pathways, a separate multi-pathway DDT assessment is presented in Section 5.2.5.3. In addition to the risk calculation for dermal exposure, this evaluation includes a discussion of potential acute exposures related to foods inadvertently sprayed during IRS and possible re-use of IRS pesticide containers.

The potentially carcinogenic insecticides etofenprox and propoxur had calculated cancer risks within the 1×10^{-6} to 1×10^{-4} risk management range based on a 50-year exposure duration. The only IRS pesticide with a calculated child or adult chemical HQ above the threshold of 1.0 was pirimiphos-methyl. These values were 8 (child) and 6 (adult).

The most uncertain exposure variable in this assessment is the attenuation factor applied to the initial surface area application of pesticide. As described in Section 5.2.3.6, a simple mathematical model was used to estimate the time-integrated surface concentration of IRS pesticide over a one-year period. This model produced an approximately 60-fold reduction factor applied to the initial application rate. This factor may reasonably be expected to vary based on the characteristics of the wall surface and the pesticide class. Other uncertainties include the frequency and intensity of dermal contact events with wall surfaces and the extent to which other surfaces such as the floor become contaminated due to sloughing of wall material.

As discussed in previous subsections of the risk characterization, relatively low HQ values such as 6 and 8 are not necessarily indicative of expected noncancer hazards. The noncancer reference dose values are designed to provide protectively biased estimates of effects thresholds. But the magnitude of potential dermal exposures to residents, as well as the contributions of other pathways such as inadvertent soil ingestion of wall and floor materials, is sufficiently uncertain that it is impossible to conclude that the risk assessment results are protective.

Acute exposures; food, spills, and re-use of IRS insecticide containers. Evaluation of acute exposures related to these exposure pathways was conducted in the 2007 PEA (USAID, 2007). Potentially unacceptable acute exposures from foods left uncovered during spraying were calculated for DDT, as well as fenitrothion, malathion, and pirimiphos-methyl. Acute exposures related to the use of IRS pesticide containers were also found to be potentially unacceptable for the majority of pesticides. Risks to IRS workers due to spills were evaluated in the 2007 PEA. The 2007 PEA concluded that such risk "does not appear to warrant further consideration."

Infant exposures; breast milk. Infants are a potentially important subpopulation of individuals for exposure to pesticides with the potential to accumulate in body tissues. Among WHO-recommended insecticides for use in IRS, LLINs and ITN re-treatment, Bouwman and Kylin (2009) determined that breast milk concentrations of DDT (see Section 5.2.5.3) and certain pyrethroids (cyfluthrin, deltamethrin, and permethrin) exceeded WHO maximum residue limits in food (MRLs) in some individuals residing in areas of KwaZulu-Natal Province, South Africa, where these insecticides are employed. Among the pyrethroids, only the maximum measured concentration exceeded the MRL for deltamethrin and permethrin, whereas mean breast milk concentrations exceeded MRLs for cyfluthrin. With respect to pyrethroid exposures and breast milk concentrations, Bouwman and Kylin (2009) note that there is wide variation in measured breast milk concentrations and indicate that occupational pyrethroid exposures

from agricultural uses may be a significant source in addition to, or instead of, malaria vector control-related exposures.

Recommendations

The post-IRS dermal exposure risk calculation used in this PEA represents a refinement of the dermal exposure model used in the 2007 PEA (USAID, 2007). Specifically, this PEA employs a dermal exposure model based on chronic exposure rather than the screening-level acute exposure model used in the 2007 PEA. The magnitude of the cancer risk estimates for etofenprox (3×10^{-6}) and propoxur (2×10^{-5}), and the child chemical hazard for pirimiphos-methyl (8), would not necessarily suggest unacceptable levels of risk if the exposure assessment were demonstrably biased in a protective manner. In this assessment, however, there is considerable uncertainty in the chronic dermal exposure model and conservatism cannot be demonstrated.

The collection of samples of surface material from sprayed walls at intervals following IRS is recommended to refine the results the post-IRS resident exposure risk assessment. Specifically, collection of samples of wall scrapings similar to that described in the DDT transfer study conducted by RTI (RTI, 2011c) are recommended to establish the time course of exposure concentrations for the synthetic pyrethroids, organophosphates, and carbamates. Sampling of floor sweepings to determine whether incidental ingestion and/or dermal absorption of IRS pesticides from residual pesticide on floors may be a significant contributor to overall post-IRS resident exposure should also be considered.

The recommendations of the 2007 PEA (USAID, 2007) with respect to potential exposures related to sprayed foods are still relevant and are repeated here:

> Given that (the food ingestion) pathway can be eliminated by simply removing or covering the food prior to spraying, we do not recommend additional modeling of this scenario: the risks for this scenario could be reduced to essentially zero if aerosol contact with food is prevented. Residents should be educated to take appropriate steps to prevent food from being sprayed (and spray teams should be instructed to remove any exposed food). In addition, it is strongly recommended that surfaces other than walls be covered during spraying and/or cleaned immediately after spraying activities are completed.

Analogous recommendations may be offered with regard to exposures from re-use of pesticide containers. Again, risks may be reduced to zero by preventing re-use of containers. Education of residents regarding the toxicity of the IRS pesticides, as well as appropriate protocols for spray teams to account for all pesticide containers and inventory (per BMP Manual; USAID, 2010), will minimize possible exposures by this pathway.

Recommendations related to control of exposures subsequent to spills or leaks associated with IRS are described in Section 5.2.5.2.1.

5.2.5.2.5 LLINs/ITNs; resident exposure

Cancer risk and chemical hazard risk assessment results for adult resident exposures to LLIN/ITN pesticides are provided in Tables H-9 and H-10 of ***Annex H***, respectively. Resident risk was quantified for potential dermal exposures to during periodic washing of LLINs/ITNs. Because individual washings of LLINs/ITNs are likely to occur only a few times per year, noncancer hazards were calculated using benchmarks for acute exposure (1 day or less). Cancer risk estimates for permethrin, the only LLIN pesticide for which EPA publishes a CSF, were calculated based on a 50-year exposure duration. Risk calculations were based on pesticide concentrations reported for specific LLIN products, as described in footnotes to Table G-15 in ***Annex G***.

The CTE and RME cancer risk estimates for exposure to permethrin over a 50-year period of washing LLINs/ITNs were 8×10^{-5} and 2×10^{-4}. CTE and RME chemical hazard results for alpha-cypermethrin, deltamethrin, lambda-cyhalothrin, and permethrin, and piperonyl butoxide were all below the threshold of 1.0.

As described in Section 5.2.3.7, pesticide loss was assumed to occur in a linear manner over the course of repeated washings. Five percent (CTE) and 8% (RME) of the original pesticide mass was assumed to be lost at each wash based on information for deltamethrin (WHOPES 2009; Tables 6 and 12). For the CTE calculation, where two washes per year are assumed, this indicates that 100% of the original pesticide mass will occur within 10 years. For the RME calculation, where four washes per year are assumed, approximately 100% of the original pesticide mass is lost by the end of the third year. Because individual LLINs/ITNs are commonly used for up to three years before replacement (see Section 3.2.2), the RME exposure calculation is at the mass balance limit for this scenario. Additionally, dermal absorption was likely overestimated because the exposure interval assumed for washing nets (10 minutes) is shorter than the time required to achieve steady-state diffusion across the stratum corneum, as assumed in the dermal exposure model.

Because dermal absorption of permethrin in each wash was probably overestimated to a significant degree, and because use and washing of a permethrin-impregnated net for 50 years may also be unrealistically high, it is unlikely that permethrin exposures from washing LLINs/ITNs will result in cancer risks above the 1×10^{-6} to 1×10^{-4} risk management range.

Residents who sleep beneath LLINs/ITNs may also be exposed to LLIN/ITN pesticides due to dermal absorption when bare skin contacts the net. Infants sleeping beneath the nets may potentially be exposed by placing netting in their mouths. It is possible, but unlikely, that continuous exposures of this sort could result in chemical hazard above a chronic effects threshold. The acute reference dose criteria for LLIN/ITN pesticides used in this assessment are either identical or numerically close to the chronic criteria. Therefore, risk calculations with effects averaged over one day, or over one year of daily exposures, will be identical for the same dose rate. A conclusion that LLIN/ITN exposures are unlikely to result in significant health risks is consistent with the findings presented in an independent LLIN/ITN safety assessment (WHOPES, 2009; Section 3.1).

Recommendations

No additional assessment of resident risks for use of LLINs/ITNs containing the pesticides concentrations evaluated in this risk assessment is recommended. It is recommended that IEC/BCC materials incorporate messaging designed to discourage disposing of LLIN/ITN wash water in proximity of water bodies used by communities or in sensitive ecosystems (i.e., water bodies with significant aquatic populations; see Section 5.3).

5.2.5.2.6 Wall linings; resident exposure

Pesticides that are currently used in wall linings include deltamethrin and permethrin. As shown in Figure 5-2, the exposure pathways related to use of wall linings in a residence are similar to the incidental contact pathways for LLINs. Dermal contact with the pesticide-impregnated cloth hanging on walls is expected to be the dominant exposure pathway for both residents and workers installing the lining. In order to quantify pesticide exposure by dermal contact, an estimate of the mass of pesticide transferred from lining to skin during a contact event is necessary. Unfortunately, no information was discovered to support such estimation. Potential risks related to exposures to deltamethrin and permethrin in wall linings may be judged by evaluating the results of the risk calculations for LLINs containing these materials. As discussed above, in the RME calculation for washing of LLINs approximately 100% of the original pesticide mass is lost by the end of the third year. This equates to a calculated lifetime cancer risk for LLIN permethrin exposure near 1×10^{-4}. The surface area of an LLIN is approximately 15 m^2, so

assuming approximately equivalent pesticide concentrations (mass pesticide per unit area) between LLINs and wall linings a resident would need to absorb 100% of the permethrin in 15 m^2 of wall lining every three years over 50 years to reach the equivalent cancer risk. Because permethrin and deltamethrin dermal reference dose values are identical for acute and chronic exposures, this equivalence also holds true for chemical hazard.

Chemical hazard results for deltamethrin are approximately 300 times below those for permethrin. Permethrin is also a potential carcinogen, with calculated lifetime cancer risks for LLIN exposures from washing near 1×10^{-4}. Of these two pesticides, these calculations indicate potential human health risks are significantly less likely for deltamethrin. However, based on analogy to LLIN exposures, neither pesticide would be expected to present cancer risk or chemical hazard above threshold levels.

5.2.5.3 Migration and Potential Resident Risks from DDT Indoor Residual Spraying

5.2.5.3.1 DDT Migration Subsequent to Indoor Residual Spraying

The conceptual model for residential exposure to DDT subsequent to IRS (see Figure 5-9) includes a number of potential exposure pathways that collectively indicate a complex environmental fate and transport model. Unlike some pesticides which have a relatively short environmental half-life, DDT may persist in environmental media for long periods of time (see Table D-1, ***Annex D***). This characteristic has led to the well-known environmental persistence of DDT and is responsible for its occurrence in the Stockholm Convention on Persistent Organic Pollutants, as discussed elsewhere in this PEA.

To assess the migration of DDT subsequent to IRS, a routine monitoring program has been developed for sampling in Ethiopia and Mozambique. The results of sampling in Ethiopia in July 2008 before PMI IRS spraying with DDT (pre-IRS sampling), and sampling after one round of IRS DDT spraying in the Fall of 2008, is described for samples of stored crops and of soil in RTI (2011a). Approximately 40 pre-IRS DDT samples from crops stored in homes, 50 samples of soil at home entrances, and 30 in nearby gardens, were collected across five districts. Approximately 50 post-IRS samples from such locations, plus soils in runoff channels near the homes, were also collected. A summary of the Ethiopia DDT sampling results is provided in Table 5-14.

Table 5-14 Summary of DDT Routine Monitoring Data in Ethiopia

Sample type	Pre-IRS Samples (mg/kg)			Post-IRS Samples (mg/kg)		
statistic	median	mean	90th percentile	median	mean	90th percentile
Crops, stored in home	0.033	0.30	0.18	0.043 (a)	0.12 (a)	0.32 (a)
Soil, home entrance	0.14	0.65	1.5	0.26	1.04	1.84
Soil, garden	0.017	0.13	0.25	0.22	1.08	3.22
Soil, runoff channel	NA	NA	NA	0.41	1.38	3.67

NA: not available
(a) Statistic does not include a single outlier result of 148 mg/kg.

A similar report to that described above for Ethiopia provides the results of DDT routine monitoring sampling in Mozambique (RTI, 2011b). This report includes samples of stored crops and of soil from home entrances, gardens, and runoff channels from three districts in Mozambique. Once again, both pre-IRS (September 2008) and post-IRS sample results (Fall 2008) are reported, as well as post-IRS results from a separate district collected in Fall 2009. Sample numbers ranged from approximately 30 to 70.

A summary of the Mozambique DDT sampling results is provided in Table 5-15.

Table 5-15 Summary of DDT Routine Monitoring Data in Mozambique

Sample type	Pre-IRS Samples (mg/kg)			Post-IRS Samples (a) (mg/kg)		
statistic	median	mean	90th percentile	median	mean	90th percentile
Crops, stored in home	0.036	0.35	0.98	0.13	0.40	0.91
Soil, home entrance	0.091	0.32	0.78	0.39	1.1	2.7
Soil, garden	0.0075	0.022	0.055	0.0075	1.3	0.41
Soil, runoff channel	NA	NA	NA	0.20	0.69	1.0

NA: not available
(a) Results include only the three districts sampled for baseline to ensure comparability.

A further investigation into DDT transfer from sprayed walls to air, floors, and stored crops in Mozambique is described in RTI (2011c). The objectives of this study were to evaluate transfer rates of DDT to stored crops in homes where IRS with DDT occurs, as well as more general transfer rates from sprayed walls to other locations and media. Six homesteads, including two controls, in Zambezia Province were included in the study. Sampling occurred one day, three months, and eight months after crops (dried beans and maize) were introduced into the homes for the study. A summary of the results for the various sampled media is provided in Table 5-16.

Table 5-16 Summary of DDT Transfer Study Results in Mozambique

Sample type	Day 1 (mg/kg or µg/m³ air)		Month 3 (mg/kg or µg/m³ air)		Month 8 (mg/kg or µg/m³ air)	
statistic	median	mean	median	mean	median	mean
beans, IRS homes (a)	0.14	0.14	0.34	0.54	0.54	0.64
beans, control homes (a)	0.038	0.054	0.11	0.11	0.094	0.13
maize, IRS homes (a)	0.22	2.25	0.37	0.70	0.59	7.71
maize, control homes (a)	0.23	0.26	0.22	0.20	0.09	0.16
wall scraping, IRS homes	2688	2619	705	735	386	432
wall scraping, control homes	<0.01		<0.01 / 0.19		1.1 / 0.19	
floor sweeping, IRS homes	164	569	201	231	216	275
floor sweeping, control homes	0.033 / 0.10		0.028 / 1.7		0.14 / 0.26	
air, IRS homes	3.6/1.2/1.3/0.97 µg/m³		0.083/6.1/6.0/11 µg/m³		5.6/2.0/3.6/1.9 µg/m³	
air, control homes	0.062/0.034 µg/m³		0.14/0.044 µg/m³		0.064/0.047 µg/m³	

__ / __ : Statistics not provided in RTI (2011c) summary tables. These are the individual results from the two control or four IRS homes.

(a) Data are pooled across all container types used in the study (open basket, woven plastic sack, metal can).

The results of the routine monitoring sampling of crops stored indoors (Tables 5-14 and 5-15) do not indicate that DDT has obviously contaminated these crops. The transfer study crop data, however, suggest increasing transfer of DDT into stored crops over time. This is particularly evident with beans, which the authors suggest may be due to their higher lipid content relative to maize (RTI, 2011c). Migration of DDT into soils is evident in all three of the studies. Interestingly, the difference in DDT soil concentrations between IRS and control group homes in Tables 5-14 and 5-15 is higher for garden

soils than soil at the entrance to the homes. This, and the relatively high DDT concentrations observed in runoff channel samples, may indicate that DDT is migrating into the environment from sprayed homes. The persistently high DDT concentrations in floor sweepings and indoor air in sprayed homes over an 8-month period provide an indication that sprayed homes may remain a source of DDT for migration into the surrounding environment long after IRS is performed.

5.2.5.3.2 Potential Resident Health Risks Related to Indoor Residual Spraying of DDT

The complex nature of DDT fate and transport in the environment renders predictive modeling of potential human exposures based on the data summarized in RTI (2011a; 2011b, 2011c) difficult and beyond the scope of this risk assessment. However, a recent publication (Van Dyk et al, 2010) has presented data of DDT body burdens of residents in areas of South Africa where IRS with DDT occurs. The affected village evaluated in Van Dyk et al (2010) is sprayed annually with DDT. The control village is approximately 23 km distant and has never had DDT spraying. Twelve homesteads consisting of several, round thatch-roof huts with mud/cement walls comprise the study village. Nine homesteads of similar characteristics comprise the control village. Vegetable crops are located adjacent to the huts and livestock (chickens and goats) roam freely. Table 5-17 summarizes the DDT results from this study for comparison with the statistics shown in Tables 5-14 through 5-16.

Table 5-17 Summary of Van Dyk et al (2011) DDT Concentrations

Sample type	IRS Village (a)		Control Village (a)	
statistic	median	mean	median	mean
floor dust; mg/m^2	0.91	1.2	0.0013	0.0018
outside soil; mg/kg	0.02	0.025	0.0055	0.021
indoor air; µg/m^3	2.7	3.9	0.013	0.01
vegetables; mg/kg	0.025	0.043	<0.01	<0.01
chicken muscle; mg/kg	0.29	0.5	0.29	0.7
chicken fat; mg/kg	150	240	0.17	0.54
human serum; µg/g lipid	5.1 (b)	7.3 (b)	< 5 µg/ L blood	< 5 µg/ L blood

(a) DDT concentrations are the sum of DDT and DDE isomers.
(b) Equivalent to approximately 51 (median) and 73 (mean) µg/ L blood, assuming 10 g lipid/ L blood (blood lipid levels not reported in study).

Concentrations of DDT in outside soil summarized in Table 5-17 are not greatly different in the sprayed and control villages, and these concentrations are well below the post-spray soil sample results from

home entrances and gardens shown in Tables 5-14 and 5-15. Tables 5-16 and 5-17 are in accord in showing that DDT concentrations in floor and indoor air samples are much higher in homes with DDT IRS than in control homes. The indoor air samples, which are the most analogous for comparison of Van Dyk et al (2010) and RTI (2011a, 2011b, 2011c) indoor DDT concentrations, show very similar levels. Van Dyk et al (2010) indicates clearly elevated blood levels of DDT in individuals in the sprayed village, which is consistent with the findings of other researchers summarized in that paper.

A simple, multi-pathway chronic risk assessment calculation was performed for residents exposed to DDT via incidental soil ingestion, inhalation of indoor air, skin contact with wall surfaces, and ingestion of home-raised vegetables and chicken. In the absence of locally derived parameters, standard U.S. EPA assumptions were employed to characterize soil and food ingestion rates. Vegetable and chicken ingestion rates were based on U.S. home-produced values.

A summary of the exposure parameter values for resident exposure to post-IRS pesticide on walls is provided in Table 5-18. A complete listing of input parameter values, including references, and the equations for calculating ADD and LADD, are provided in Tables G-16 through G-19 of Annex G. Although some resident risk estimates employ both CTE and RME exposure parameter values, only a single (screening) estimate is provided for this risk calculation.

Table 5-18 Summary of Key Exposure Parameter Values – Multi-Pathway Resident Risk Assessment for DDT

Parameter	Explanation	Value
Adult soil ingestion rate	Daily average; units of mg/day	100
Child soil ingestion rate	Daily average; units of mg/day	200
Adult skin surface area	Area of skin that contacts the wall, in units of cm2	1040
Child skin surface area	Area of skin that contacts the wall, in units of cm2	380
Child skin adherence factor	Mass of material from wall contact that adheres to skin; units of mg/cm2-event	0.2
Adult skin adherence factor	Mass of material from wall contact that adheres to skin; units of mg/cm2-event	0.07
Vegetable ingestion rate	Daily average for home-grown produce, in units of g/day	70
Chicken ingestion rate	Daily average for home-raised poultry, in units of g/day	40
Exposure frequency	Applies to all exposure pathways	365
Exposure duration	1 year or longer for chemical hazard; assumes lifetime exposure for cancer risk.	1 year (noncancer) 50 years (cancer)

The results of the multi-pathway DDT risk assessment are summarized in Table 5-19. With the exception of ingestion of home-raised chicken, chemical hazard values for each pathway are near or below the threshold of 1.0. The cancer risk results are within the 1 × 10-6 to 1 × 10-4 risk management range for dermal contact with walls and vegetable ingestion, and between two and four times above the upper end of this range for soil ingestion and inhalation pathways. Because additional dermal exposures over a larger area of skin may also pertain to contact with floors, the dermal results may be underestimated.

Table 5-19 Summary of Multi-Pathway DDT Risk Assessment Results

Pathway	Cancer Risk	Adult HQ	Child HQ
Soil ingestion	4E-04	0.002	0.01
Inhalation	2E-04	0.9	2
Dermal absorption	2E-05	0.09	0.3
Vegetable ingestion	2E-05	0.1	
Chicken ingestion	1E-02	60	
SUM	1E-02	60	60

Of potentially greatest significance are the high cancer risk and HQ results for DDT exposure due to ingestion of home-raised chicken. These results are based on mean DDT measurements in muscle tissue and fat from 12 chicken samples obtained in the impacted village. Because patterns of DDT contamination in the Ethiopia and Mozambique monitoring programs (RTI, 2011a; RTI, 2011b) and Mozambique transfer study (RTI, 2011c) are similar to those described in Van Dyk et al (2010) these chicken ingestion risk calculations may be pertinent to the malaria vector control program.

Infants are a potentially important subpopulation of individuals for exposure to pesticides such as DDT which can biomagnify in the food chain. For an infant, the largest source of DDT exposure is likely to be via breast milk (Bouwman and Kylin, 2009). Data published by other researchers and summarized in Table 2 of Bouwman and Kylin (2009) indicate mean DDT levels in breast milk of approximately 300 μg/L in individuals residing in impacted areas of KwaZulu-Natal Province, South Africa. This value was associated with an infant daily intake from breast milk of approximately 50 μg/ kg body weight, which was stated to exceed by a factor of five a health-based acceptable daily intake (ADI) of 10 μg/ kg body weight-day (Bouwman and Kylin, 2009).

Recommendations

The high potential for human DDT exposure by ingestion of home-raised poultry products indicated in the Van Dyk et al (2010) data should be evaluated for significance to conditions where the malaria vector control programs are active. If chickens are raised in a free-ranging manner with access to the indoor environment of areas proximal to sprayed homes consideration should be given to sampling of meat and eggs to determine if potentially unacceptable exposures may be occurring via this pathway. PMI should monitor/sample DDT levels in chickens in one country during the next spray round, and subsequent spray rounds if necessary; results of the sampling will be used to refine the cancer and non-cancer risk assessments. Risk management recommendations related to infant exposure to DDT via breast milk are provided in Section 5.2.5.2.4.

5.2.5.4 Conclusions and Risk Management Recommendations

This worker and resident risk assessment for pesticides used in vector control provides a great deal of information about potential risks associated with pesticide use in malaria vector control and allows for the comparison of different pesticides and management strategies. These comparisons should be integrated into decision making on malaria vector control strategies and selection of pesticides, as described in Section 6.

In addition, the assessment results are useful in identifying the drivers for exposure scenarios with risk levels of concern. For these "risky" scenarios, data development and/or more refined modeling can be used to more accurately characterize the potential health risks. For example, the level of conservatism and/or uncertainty in the risk estimates can be decreased in some cases by obtaining empirical data to replace modeled estimates of exposure concentrations. Additional research may not only enhance our ability to characterize pesticide risks, but also increase the value of information that we provide to the decision maker. Thus, the focus of this section is to,

- Summarize the major conclusions from the risk assessment, and
- Identify where additional research could be valuable and provide risk management recommendations for next steps.

<u>IRS, ITN Re-Treatment and Larviciding Worker Cancer Risk and Chemical Hazard</u>

Preparation of pesticide

1) HQ results for preparation of pesticides without the use of PPE are below the threshold of 1.0 for all pesticides with the exception of DDT, pirimiphos-methyl, chlorfenapyr, and fenitrothion. Cancer risks without PPE use are below or within the 1×10^{-6} to 1×10^{-4} risk management range except for DDT.
2) With PPE use, all high-end exposure results were within or below the 1×10^{-6} to 1×10^{-4} risk management range.
3) With PPE use, only DDT (HQs of 2 to 6) and pirimiphos-methyl (HQs of 1 to 4) had pesticide preparation HQ values above 1.0.
4) The relatively low HQ values of between 1 and 6 are not necessarily indicative of expected noncancer effects for workers using PPE.
5) Workers should be adequately trained and provided with PPE during pesticide preparation, particularly if handling the pesticides described above.
6) Worker and resident exposures due to spills during preparation can be minimized by following best management practices described in USAID (2010) and preparing pesticides in a location outside of the homes being sprayed.

Application of pesticide

1) Exposure by dermal absorption resulted in much higher risks than inhalation exposures for pesticides with HQ or cancer risk results above thresholds.
2) With PPE use, only DDT cancer risk results reached 1×10^{-6}. The low-end to high-end DDT cancer risk results for spray applicators ranged from 1×10^{-5} to 5×10^{-5}.
3) With PPE use, only DDT (mid-range HQ = 70) had an HQ estimate well above the effects threshold of 1.0.

4) A recent study in Uganda (Bismenya et al, 2010) failed to find evidence of noncancer effects in a group of DDT sprayers.

5) Use of PPE in accordance with this protocol is essential to protect worker health during spray application of pesticides, particularly for sensitive individuals.

6) The degree of protection afforded sprayers by use of respirators, protective overalls, and gloves may be inadequate for sensitive individuals[7] applying DDT. The use of chemically impermeable coveralls will reduce dermal exposure.

7) PMI should employ biomonitoring of workers for all organophosphate pesticides; a protocol for such monitoring and interpretation of findings should be developed on a country-specific basis and the IRS Best Management Practices related to environmental measures should be amended.

Resident Cancer Risk and Chemical Hazard

Groundwater and Surface Water Exposures

2) For IRS, ITN re-treatment and larviciding pesticides other than those described below, annual land-disposed quantities in excess of 1,000 kg are required to reach groundwater concentrations associated with cancer risk > 1×10^{-5} or HQ > 1.0.

3) Between 90 and 340 kg of annual disposal of pirimiphos-methyl, etofenprox, and fenitrothion are required to reach the thresholds noted above.

4) For DDT and propoxur, annual disposed quantities below 10 kg are required to reach the thresholds noted above.

5) Very little dilution of applied larvicide concentrations (between 3-fold [methoprene] and 200-fold [spinosad]) is required to result in surface water concentrations resulting in an HQ of 1.0 for long-term drinking water exposures.

6) The land disposal of pesticides is unlikely to result in groundwater contamination affecting human health risks unless a groundwater well is located immediately down gradient of a burial location; the risk of groundwater contamination is highest for DDT and propoxur.

7) The use of larvicides is unlikely to present significant risks to residents from use of surface waters as a domestic water supply.

Exposure to Residual Pesticide Following Indoor Residual Spraying

8) Etofenprox and propoxur had calculated cancer risks within the 1×10^{-6} to 1×10^{-4} risk management range based on a 50-year exposure duration and dermal exposure to wall surfaces. (DDT evaluated separately)

9) The only IRS pesticide with a calculated child (HQ = 8) or adult (HQ = 6) hazard above 1.0 for dermal exposure to wall surfaces was pirimiphos-methyl.

10) Potentially unacceptable acute exposures from foods left uncovered during spraying were calculated for DDT, fenitrothion, malathion, and pirimiphos-methyl in the 2007 PEA (USAID, 2007).

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[7] For example, pregnant or nursing women, or individuals whose genetic make-up renders them particularly susceptible to the toxic effects of pesticide exposure.

11) Acute exposures related to the re-use of IRS pesticide containers were found to be potentially unacceptable in the 2007 PEA (USAID, 2007) for the majority of pesticides.

12) The collection and analysis of samples of surface material from sprayed walls, and sampling of floor sweepings, at intervals following IRS is recommended to refine the dermal exposure risk assessment.

13) Resident exposures due to foods left exposed during spraying, or due to re-use of pesticide containers, can be avoided by a combination of appropriate spray team protocols and resident education outreach.

14) Worker and resident exposures due to spills during preparation can be minimized by following best management practices described in USAID (2010) and preparing pesticides in a location outside of the homes being sprayed.

Exposures to Pesticides Contained in Long-Lasting Insecticidal Nets and Treated ITNs

15) Central-tendency and reasonable-maximum cancer risk estimates for permethrin over a 50-year period of washing LLINs/ITNs were 8×10^{-5} and 2×10^{-4}.

16) HQ results for all LLIN/ITN pesticides were below the threshold of 1.0.

17) Reasonable-maximum calculations assume exposures at the mass balance limit for the amount of pesticide released from LLIN/ITNs during washings.

18) We conclude that LLIN/ITNs exposures are unlikely to result in significant health risks, which is consistent with the findings presented in an independent LLIN/ITNs safety assessment (WHOPES, 2009; Section 3.1).

19) PMI should develop IEC/BCC materials that discourage washing or fishing with LLINs/ITNs in sensitive ecosystems, and should distribute such materials to communities in close proximity to such water bodies.

Exposures to Pesticides Contained in Wall Linings

20) Potential risks were judged by evaluation of LLIN risk results for deltamethrin and permethrin.

21) The relative risk for deltamethrin is approximately 300 times below that for permethrin.

22) By analogy to the reasonable-maximum LLIN assessment, assuming equivalent pesticide mass per unit area, a resident would need to have intake of 100% of the pesticide in 15 m^2 of wall lining every three years for a comparable degree of exposure.

23) By analogy to LLIN results, and expected contact with wall lining, neither deltamethrin nor permethrin is likely to present cancer risk or chemical hazard above threshold levels.

Exposures to DDT Used in Indoor Residual Spraying

24) Studies by RTI in Ethiopia and Mozambique suggest that DDT is migrating into the environment from sprayed homes and that sprayed homes may remain a source of DDT for migration into the surrounding environment long after IRS is performed.

25) RTI studies and Van Dyk et al (2010) indicate that DDT concentrations in floor and indoor air samples are much higher in homes with DDT IRS than in control homes.

26) Van Dyk et al (2010) and other researchers have found that blood levels of DDT are higher in sprayed villages than in unsprayed ones, indicating resident exposure to DDT used in IRS.

27) A risk calculation evaluating incidental soil ingestion, soil dermal absorption, inhalation, and vegetable and chicken ingestion pathways indicates that potential exposures by chicken ingestion are by far the most significant and may result in a lifetime cancer risk of approximately 1×10^{-2} and an HQ of 60. DDT exposures of infants via breast milk may also be significant.

28) In areas where chickens have access to the area in and around sprayed homes, sampling of DDT in chicken meat and eggs should be considered to determine the possible relevance of this pathway for the malaria vector control program.

Note: There was a concern about the results of the Human Health Risk Assessment for fenitrothion, malathion and pirimiphos-methyl, therefore approaches for biomonitoring organophosphates were reviewed (please see Annex N). PMI will evaluate various approaches for monitoring sprayer exposure to OPs, and will develop protocols based on these evaluations. PMI will use these protocols to guide the implementation of the OP monitoring program.

5.2.6. HHRA REFERENCES

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5.3. ENVIRONMENTAL CONSEQUENCES

Eliminating unnecessary human exposure to pesticides is the primary concern of the PEA; however, domestic livestock (particularly chickens) and organisms in the environment (nontarget aquatic species) may also be harmed if malaria vector control interventions are not conducted according to best practices. The methods employed to assess environmental consequences related to these interventions are described in Section 5.3.1. The Environmental Consequences section of the 2007 PEA (USAID, 2007) provided a qualitative ecotoxicological review and ranking of the effects of pesticides of concern on wildlife for the IRS and larviciding intervention scenarios. This revision of the 2007 PEA provides updated ecotoxicological information in Section 5.3.2 and also provides additional information regarding key environmental exposure and effects pathways. Sections 5.3.3, 5.3.4, and 5.3.5 each address a specific ecological risk question identified based on the findings of 2007 PEA. Section 5.3.3 addresses the question of what degree of risk does exposure to post spray IRS DDT residues on crops and soils in village homesteads have on domestic livestock (chickens). Section 5.3.4 addresses the question of what degree of risk does exposure to larvicides used in surface water bodies have on nontarget aquatic species. Section 5.3.5 addresses the question of what degree of risk does exposure to pesticides and the physical disturbance of LLINs when used for fishing/washing by villagers have on nontarget aquatic species.

5.3.1. METHODS

The environmental consequences methods consist of "Problem Formulation and Ecological Effects Evaluation" and "Preliminary Exposure Estimate and Risk Calculations" as outlined in the EPA

Ecological Risk Assessment Guidance for Superfund or ERAGS (U.S. EPA, 1997). These components of an ecological risk assessment are also consistent with the Guidelines for Ecological Risk (U.S. EPA, 1998) that considers prospective as well as retrospective evaluations of risk for a broad array of stressors. ERAGS provides an appropriate set of tools for assessing the environmental consequences of IRS, Larviciding, and LLIN (and wall lining), and ITN Re-treatment) malaria vector control scenarios. Figure 5-10 depicts the ecological risk assessment process. The evaluation presented here is a screening level ecological risk assessment (SLERA) that is meant to be used to identify priorities and data needs for a baseline assessment that may include a biomonitoring component. The results of this evaluation will provide simplified representations of key site activities, receptors and site characteristics, as well as the link between activities and ecological impacts and provide the foundation for effects assessment.. This evaluation is intended to be protective and not necessarily predictive of the actual risks at the site of concern because the parameters used are very conservative and represent the worst case scenario. Figure 5-11 depicts the screening assessment strategy.

Figure 5-10 Ecological Risk Assessment Process

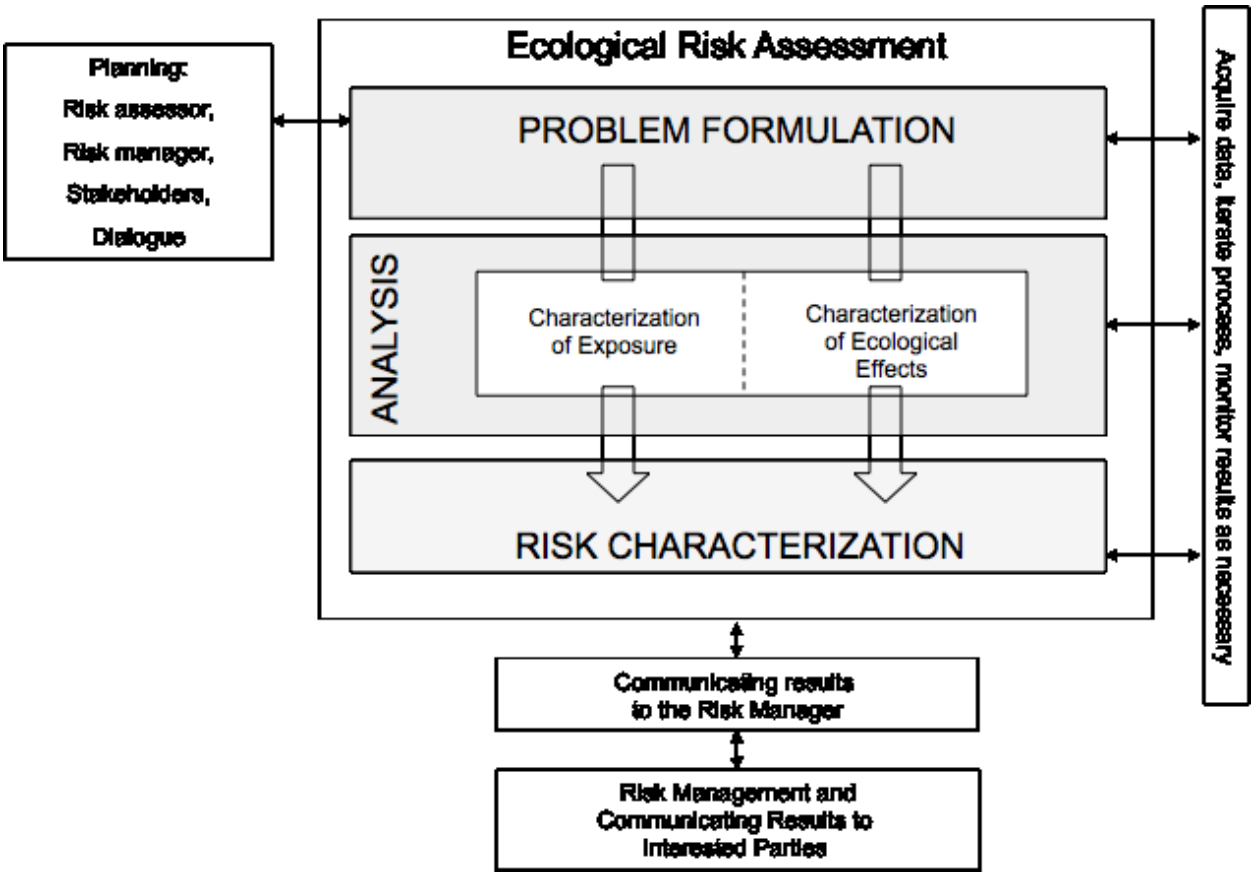
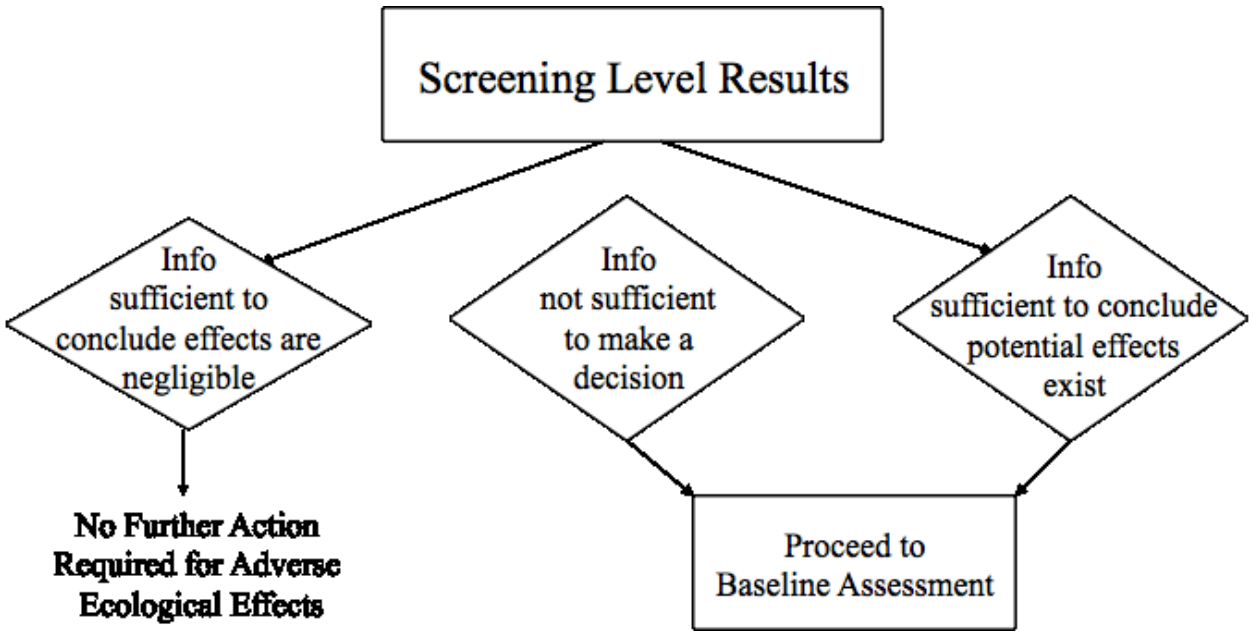


Figure 5-11 Screening Assessment Strategy



Problem Formulation and Ecological Effects Evaluation. This evaluation consists of seven parts including the identification/description of:

1) the environmental setting including habitat types, observed species and species likely to be present based on habitat types documented, as well as any threatened, rare, and endangered species;

2) chemical and physical stressors of potential ecological concern, which describes the pesticides and physical stressors, if any, that are associated with the malaria vector control intervention of concern along with the concentrations of pesticides present in each medium and degree of physical stress, if known;

3) fate and transport mechanisms that may exist along with conceptual site model;

4) chemical/physical properties affecting environmental behavior;

5) ecotoxicity synopsis describing the mechanisms associated with each pesticide and the categories of wildlife receptors that may be affected;

6) complete exposure pathways; and

7) ecological screening levels (ESLs) taken from the peer reviewed literature.

The environmental setting is scenario specific, but emphasizes areas near human habitation. Specific assumptions made for each scenario evaluated are included in the subsection for each scenario. In

general, the environmental setting will vary depending on the location of the country. Section 4 (Affected Environment) of this PEA should be consulted when applying the results of this assessment to specific locations.

The hierarchy of data sources used for the selection of ecological screening levels was as follows:

1) U.S. Environmental Protection Agency or other nationally recognized organizations such as the National Oceanic and Atmospheric Administration

2) Los Alamos National Laboratory ECORISK Database or other compendium of peer-reviewed values such as EXTOXNET, a cooperative effort of University of California-Davis, Oregon State University, Michigan State University, Cornell University, and the University of Idaho.

3) Primary peer-reviewed literature toxicity values (i.e., LC_{50}s for aquatic organisms)

4) **Preliminary Exposure Estimate and Risk Calculations**. This section consists of two parts 1) risk calculations, which estimates risk by comparing exposure concentrations with the ecological screening values; and 2) risk characterization, which discusses the results to provide input to risk managers to decide either that the SLERA is adequate to determine that ecological threats are negligible or provide risk management options.

5.3.2. ECOTOXICOLOGICAL REVIEW

The ecotoxicological review addresses two aspects of problem formulation: chemical/physical properties affecting environmental behavior; and ecotoxicity synopsis describing the mechanisms associated with each pesticide and the categories of the of wildlife receptors that may be affected. General descriptions of the pesticides are found in section 3.0. Table 5-20 provides a summary of the pesticides of potential concern.

Table 5-20 List of Pesticides of Potential Concern by Malaria Vector Control Intervention

Malaria IVM Intervention	Pesticide
IRS	Alpha-cypermethrin WP Bendiocarb WP Bifenthrin WP Cyfluthrin WP DDT WP Deltamethrin WP Etofenprox WP Fenitrothion WP Lambda-cyhalothrin WP Malathion WP Pirimiphos-methyl EC Pirimiphos-methyl CS OP[1] Propoxur WP and EC Chlorfenapyr pyrroles[1] EC
Larviciding	Methoprene GC Temephos G and ECPyriproxyfen G and EC Bacillus thuringiensis israelensis (Bti) Bacillus sphaericus (Bs) Spinosad[1] G, T and CG Monomolecular films or oils
LLINs (insecticide is either coated on polyester or incorporated into polyethylene)	Alpha-cypermethrin Deltamethrin Etofenprox Lambda-cyhalothrin Permethrin Piperonil Butoxide (PBO), synergist
Re-treating ITNs	Deltamethrin WT Lambda-cyhalothrin CS

[1] New pesticide for 2012.

5.3.2.1 Insecticides

The ecotoxicological review was excerpted from the pesticide information profiles (PIPS) provided by the EXTOXNET database (EXTOXNET, 2011) except where noted otherwise. The 2007 report also provided a qualitative ranking of the IRS insecticides based on persistence and bioaccumulation potential. The update to the 2007 Environmental Consequences section adds information for one insecticide – Chlorfenapyr (Table 5-21).

Detailed information on each insecticide is presented below.

- **Alpha-cypermethrin**

In the air, alpha-cypermethrin exists in both vapor and particulate phases. As a vapor, it is broken down by reactions with hydroxyl radicals and ozone. The half-life for these reactions is estimated at 18 hours to 49 days. As a particulate, alpha-cypermethrin is removed from the atmosphere by wet and dry deposition.

Once in the terrestrial environment, alpha-cypermethrin binds tightly to soil. Volatilization is the major fate process in moist soils; however, the tight bond of alpha-cypermethrin to soil attenuates the volatilization. In nonsterile soil, alpha-cypermethrin is biodegraded by environmental organisms and sunlight. It does not build up in surface soils nor leach to subsurface soils.

In aquatic environments, alpha-cypermethrin bonds tightly to suspended solids and sediments. Volatilization of alpha-cypermethrin from water is expected; however, this is lessened by its bond with soil. Photodecomposition is also expected. Based on its bioconcentration factor, alpha-cypermethrin has a high potential to bioaccumulate in aquatic organisms. However, the ability of aquatic organisms to rapidly metabolize alpha-cypermethrin suggests that actual bioaccumulation may be lower than the potential.

Effects on birds: Alpha-cypermethrin is practically nontoxic to birds. Its acute oral LD50 in mallard ducks is more than 4,640 mg/kg. No adverse reproductive effects occurred in mallards or bobwhite quail given 50 ppp, the highest dose tested.

Effects on aquatic organisms: Alpha-cypermethrin is very highly toxic to fish and aquatic invertebrates. The LC50 (96-hour) for alpha-cypermethrin in rainbow trout is 0.0082 mg/L, and in bluegill sunfish is 0.0018 mg/L. Its acute LC50 in Daphnia magna, a small freshwater crustacean, is 0.0002 mg/L. Alpha-cypermethrin is metabolized and eliminated significantly more slowly by fish than by mammals or birds, which may explain this compound's higher toxicity in fish compared with other organisms. The half-lives for elimination of several pyrethroids by trout are all more than 48 hours, while elimination half-lives in birds and mammals range from 6 to 12 hours. The bioconcentration factor for alpha-cypermethrin in rainbow trout was 1,200 times the ambient water concentration, indicating that there is a moderate potential to accumulate in aquatic organisms.

Effects on other organisms: Alpha-cypermethrin is highly toxic to bees.

- **Bendiocarb**

When applied to plants, bendiocarb enters the soil both directly and indirectly. In soil, bendiocarb is moderately to very highly mobile. The major fate processes are hydrolysis (in moist soils) and biodegradation. Volatilization is not an important fate process in either moist or dry soils. Biodegradation of bendiocarb is expected to be rapid. Photolysis is important in the photodegradation of bendiocarb in soil. Bendiocarb degrades prior to leaching through soil and its degradation products remain in the upper layers of soil in low concentrations. It is unlikely that bendiocarb will move through soil to groundwater or to surface water through runoff. Bendiocarb is of low persistence in soil.

Water is an important factor in the transport of bendiocarb. However, bendiocarb is of limited hazard in water due to its rapid decomposition under aqueous conditions. In water, bendiocarb is not expected to adsorb to suspended soils and sediments. The major fate processes in water are hydrolysis and biodegradation; volatilization is unimportant. Additionally, direct photolysis is not a major degradative pathway in water and is dependent on the turbidity of the water. In alkaline and neutral environments, hydrolysis is expected to be a major fate process. Bendiocarb does not accumulate in water and, based on

soil studies, biodegradation in water is expected to be rapid. Because bendiocarb degrades rapidly in water, bioconcentration in fish is unlikely.

Effects on birds: Bendiocarb is moderately toxic to birds.

Effects on aquatic organisms: Bendiocarb is moderately to highly toxic to fish.

Effects on other organisms: Earthworm populations under turf are severely affected by bendiocarb. It is toxic to bees; the LD_{50} is 0.0001 mg per bee.

- **Bifenthrin**

In the terrestrial environment, bifenthrin has a low mobility in soils with large amounts of clay, silt, or organic matter and in sandy soils without much organic matter. In moist soils, volatilization is a major fate process, though this is lessened by absorption in the soil. Depending on the soil type and the amount of air in the soil, the half-life of bifenthrin ranges from 7 days to 8 months. Bifenthrin is expected to biodegrade readily and it is not absorbed by, or translocated, in plants.

Bifenthrin is fairly insoluble in water, so there is little concern about groundwater contamination through leaching. Volatilization is a major fate process from surface water; however, volatilization is attenuated by bifenthrin's tendency to adsorb to suspended soils and sediments. Based on its bioconcentration factor, bifenthrin has a high potential to accumulate in aquatic organisms. However, the actual bioconcentration may be lower than the potential due to the ability of aquatic organisms to metabolize bifenthrin.

Effects on Birds: Bifenthrin is moderately toxic to many species of birds. There is concern about possible bioaccumulation in birds.

Effects on Aquatic Organisms: Bifenthrin is very highly toxic to fish, crustaceans, and aquatic animals. Because of its low water solubility and high affinity for soil, bifenthrin is not likely to be found in aquatic systems.

Effects on Other Animals (Non-target species): Bifenthrin is toxic to bees.

- **Cyfluthrin**

In the air, cyfluthrin exists predominantly in the particulate phase. As a particulate, cyfluthrin is removed from the atmosphere by wet and dry deposition.

Once in the terrestrial environment, cyfluthrin is highly immobile in soil. Therefore, it does not leach easily into groundwater. Cyfluthrin is one of the more persistent pyrethroids, and its persistence is not significantly affected by soil moisture. The major fate processes in soil are biodegradation and photolysis. Volatilization is not expected to be a major fate process in either moist or dry soils.

In aquatic environments, cyfluthrin binds tightly to soil, is practically insoluble in water, and is less dense than water, which allows it to float on the surface of natural water. Cyfluthrin is stable in water under acidic conditions, but hydrolyzes rapidly under basic conditions. Photolysis is expected to occur in surface waters but volatilization is not. Aqueous hydrolysis is not an important environmental fate process. Cyfluthrin has a high potential to bioaccumulate in aquatic organisms.

Effects on Birds: Cyfluthrin is of low toxicity to upland game birds and waterfowl. Little information was found concerning the toxicity of cyfluthrin to songbirds. LD_{50} values for canaries range from 250 to 1,000 mg/kg.

Effects on Aquatic Organisms: Cyfluthrin is highly toxic to marine and freshwater organisms. Cyfluthrin is exceptionally toxic to the freshwater invertebrate *D. magna*. Marine and estuarine invertebrates are also extremely sensitive to cyfluthrin.

Effects on Other Animals (Nontarget species): Cyfluthrin is highly toxic to bees with an LD_{50} of 0.037 mg/bee (70). Pyrethroids are known to be highly toxic to other beneficial insects.

- **DDT**

Once DDT enters the terrestrial environment, it has a strong affinity for soil and generally remains in the surface layers. As a result of this strong affinity for soil, DDT is quite persistent. The half-life of DDT ranges from 2 to 17 years, depending on soil composition (the warmer and wetter the soil, the shorter the half-life). Therefore, DDT is less persistent in the tropics, where it evaporates and microorganisms degrade it more quickly. The strong affinity for soil also reduces the potential for DDT to leach into groundwater. DDT can be absorbed by some plants and the animals that eat them.

DDT can enter the aquatic environment in several ways, including direct contact (pouring it into a water body), deposition from the atmosphere, and overland transport via erosion and runoff. In surface water, DDT will bind to sediment in the water, settle, and be deposited on the bottom. DDT has some potential to bioaccumulate in marine life because it is absorbed by small organisms, such as plankton and fish. It can accumulate to high levels in fish and marine mammals (such as seals and whales), reaching levels thousands of times higher than in water. In these animals, the highest levels of DDT are found in their adipose tissue (ATSDR, 2002).

DDT is listed in Annex B (Restriction) of the Stockholm Convention on Persistent Organic Pollutants. It is allowed to be used for disease vector control in accordance with Part II of the annex. Parties must register with the Secretariat to use DDT for disease vector control and comply with specific information collection requirements on the production and use of DDT.

Effects on Birds: DDT may be slightly toxic to practically nontoxic to birds. In birds, exposure to DDT occurs mainly through the food web through predation on aquatic and/or terrestrial species having body burdens of DDT, such as fish, earthworms, and other birds. There has been much concern over chronic exposure of bird species to DDT and its effects on reproduction, especially eggshell thinning and embryo deaths. The mechanisms of eggshell thinning are not fully understood. It is thought that this may occur from the major metabolite, DDE (1,1-dichloro-2,2-bis[*p*-chlorophenyl]ethylene), and that predator species of birds are the most sensitive to these effects. Laboratory studies on bird reproduction have demonstrated the potential of DDT and DDE to cause subtle effects on courtship behavior, delays in pairing and egg laying, and decreases in egg weight in ring doves and Bengalese finches. The implications of these for long-term survival and reproduction of wild bird species is unclear. There is evidence that synergism may be possible between DDT's metabolites and organophosphate (cholinesterase-inhibiting) pesticides to produce greater toxicity to the nervous system and higher mortality. Aroclor (polychlorinated biphenyls, or PCBs) may result in additive effects on eggshell thinning.

Effects on Aquatic Species: DDT is very highly toxic to many aquatic invertebrate species. Early developmental stages are more susceptible than adults to DDT's effects. The reversibility of some effects, as well as the development of some resistance, may be possible in some aquatic invertebrates. DDT is very highly toxic to fish species as well. DDT may be moderately toxic to some amphibian species and larval stages are probably more susceptible than adults. In addition to acute toxic effects, DDT may bioaccumulate significantly in fish and other aquatic species, leading to long-term exposure. This occurs mainly through uptake from sediment and water into aquatic flora and fauna, and also fish. Fish uptake of DDT from the water will be size dependent, with smaller fish taking up relatively more than larger fish. The reported bioconcentration factor for DDT is 1,000–1,000,000 in various aquatic species, and bioaccumulation may occur in some species at very low environmental concentrations. Bioaccumulation may also result in exposure to species which prey on fish or other aquatic organisms (e.g., birds of prey).

Effects on Other Animals (Nontarget species): Earthworms are not susceptible to the acute effects of DDT and its metabolites at levels higher than those likely to be found in the environment, but they may serve as an exposure source to species that feed on them. DDT is nontoxic to bees; the reported topical LD_{50} for DDT in honeybees is 27 μg/bee. Laboratory studies indicate that bats may be affected by DDT released from stored body fat during long migratory periods.

- **Deltamethrin**

Deltamethrin is a broad-spectrum synthetic pyrethroid insecticide that was first marketed in 1977 for use in agricultural and public health applications. It is considered the most powerful synthetic pyrethroid. For mosquito control, bed nets and other materials are treated with deltamethrin to protect the user. Deltamethrin is typically formulated as ECs, WPs, ultra-low volume and flowable formulations, and granules (either alone or combined with other pesticides). A dispersible tablet is also used to treat mosquito nets.

In terrestrial environments, deltamethrin is not expected to be mobile, because it binds tightly to soil particles. It is insoluble in water, and recommended application rates are low. Volatilization from moist soils and biodegradation are major fate processes. However, volatilization is lessened by deltamethrin's tendency to adsorb to soil particles. As with other synthetic pyrethroids, deltamethrin degrades rapidly in soil and plants. It does not bioaccumulate in terrestrial systems.

Very little leaching to groundwater is expected, because deltamethrin binds tightly to soil and is practically insoluble in water. 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 2–4 hours. It has a high potential to bioconcentrate in aquatic organisms.

Effects on Birds: The reported 8-day LC_{50} for ducks was more than 4,640 mg/kg diet; and more than 10,000 mg/kg diet for quail.

Effects on Aquatic Organisms: As is common with many pyrethroids, deltamethrin has a high toxicity to fish under laboratory conditions. However, in field conditions under normal conditions of use, fish are not harmed. Deltamethrin had an impact on aquatic herbivorous insects. This impact led to an increase of algae. Although the fish (fathead minnows) accumulated the deltamethrin, no mortality could be observed. In laboratory trials, the LC_{50} for fish was 1–10 μg/L. Aquatic fauna, particularly crustacea, may be affected, but fish are not harmed under normal conditions of use.

Effects on Other Animals (Nontarget species): Deltamethrin is considered toxic to bees. The 24-hour oral LD_{50} for technical deltamethrin fed to bees was 0.079 micrograms ai/bee; and the 24-hour oral LD_{50} for the EC formulation of deltamethrin was equal to or greater than 0.4 micrograms ai/bee. The reported contact LD_{50} for bees is 0.05 micrograms ai/bee. Deltamethrin is very toxic over long periods to the predatory mite *Typhodromum pyri*. The parasitic wasp *Encarsia formosa*, released in greenhouses to combat whitefly, is too sensitive to allow a treatment with deltamethrin against excessive outbreaks of whiteflies. Deltamethrin had little or no effect on adults or cocoons of *Apanteles plutellae*, a parasite of the diamond back moth in India. Spiders were also indicated to be strongly affected in field investigations.

- **Etofenprox**

In soil, studies of adsorption and leaching revealed low translocation. Degradation occurs by oxidation in nonsterile soil. Photodegradation may be an important fate process for degradation of etofenprox from plant surfaces.

In aquatic environments, the stability of etofenprox is dependent on the conditions. Under laboratory conditions, etofenprox is stable in aqueous solutions. An estimated half-life of more than 1 year is seen

at 25°C in neutral and acidic environments in the dark. Under field conditions, etofenprox breaks down more rapidly due to the presence of sunlight.

Etofenprox is slightly to moderately acutely toxic to fish, and affects their behavior, biochemistry, mortality, and physiology. Other organisms are relatively unaffected. No chronic environmental toxicological risks are listed.

- **Fenitrothion**

In the terrestrial environment, fenitrothion degrades rapidly in most soils with a half-life ranging from 3 to 25 days. Fenitrothion is mostly found in the top 6 inches of soil and is not very mobile and only slightly persistent in soil. Fenitrothion leaches very slowly into groundwater from most soils; however, some runoff can occur.

Fenitrothion can enter the aquatic environment from aerial spraying. It is unstable in water in the presence of sunlight or microbial contamination. Fenitrothion accumulates rapidly in fish, but at low concentrations.

Effects on Birds: Negative results were observed in studies on delayed neurotoxicity in hens. The oral LD_{50} for chickens was reported as 28 mg/kg. Fenitrothion was found to be highly toxic to upland game birds and slightly toxic to waterfowl.

Effects on Aquatic Organisms: The time for achieving the highest levels of uptake and the extent of retention of organophosphate residues by fish was directly related to the extent of persistence of a compound in water. Motsugo fish exposed to 0.6-1.2 mg/L of fenitrothion attained the highest body concentrations (162 mg/kg) after 3 days. Fenitrothion (4.9 mg/kg) persisted longer than 4 weeks in fish (153). Fenitrothion is considered somewhat toxic to fish. The chronic toxicity of fenitrothion to fish is considered low. The sublethal effects of fenitrothion exposure on fish include:

- **Morpho Anatomical Changes:** Swelling of the abdomen of fathead minnows occurred. Young Atlantic salmon exposed to 1 mg/L swam with distended fins.

- **Behavioral Changes:** There was a pronounced decline in various agonistic behaviors (chasing, vacating, nipping, etc.) within 2 hours of exposure to several concentrations of fenitrothion. Comfort behaviors (flicks, thrusts, etc.) increased with increasing concentration of the toxicant, but declined at higher concentrations. Altered station selection occurred. At higher concentrations, some fish were unable to maintain position and were swept downstream. After a 5-hour exposure, fish swam near the surface with bloated stomachs and heads pointing downward. Movement was slowed so much that Atlantic salmon did not attempt to avoid capture with a dipnet. Salmon parr exposed to 1 mg/L fenitrothion were more vulnerable to predation by brook trout.

- **Biochemical Changes:** Acetylcholinesterase activity was inhibited 13 percent to 25 percent after various sublethal concentrations of fenitrothion. Cholinesterase activity in the erythrocytes, gills, heart, and serum of rainbow trout was reduced within 1 hour after exposure to fenitrothion.

- **Respiratory Effects:** Oxygen consumption of *Labeo rohita* exposed to fenitrothion progressively decreased with increasing concentrations of insecticide. Exposure caused increased ventilation rate and buccal amplitude at concentrations slightly higher than the 48-hour LC_{50}.

- **Effect on Growth:** Orally administrated fenitrothion had no effect on the growth of rainbow trout.

The compound is considered very toxic to crustaceans and aquatic insects and has a medium toxicity to aquatic worms. A freshwater invertebrate toxicity study reported fenitrothion to be very highly toxic to aquatic invertebrates.

Effects on Other Animals (Nontarget species): There is sufficient information to characterize fenitrothion as highly toxic to honeybees (acute toxicity value = 0.383 μg/bee) when bees are exposed to direct treatment or to dried residues on foliage. Fenitrothion is considered toxic to spider mites with long residual action. The long-term effects of fenitrothion and phosphamidon were evaluated on predaceous carabid beetles and lycosid spiders 1 year after treatment of Northwestern Ontario forests at 6 oz/A and 4 oz/A, respectively. The populations of these predators were clearly suppressed in the treated area. The results "did not imply a 1 year persistence of the insecticides, but rather a persistent disturbance of the ecosystem." The acute oral toxicity of fenitrothion to mule deer was reported to be 727 mg/kg.

- **Lambda-cyhalothrin**

Once in the atmosphere, lambda-cyhalothrin, like all pyrethroids, is broken down and degraded rapidly by sunlight and other compounds found in the atmosphere. Often, lambda-cyhalothrin lasts only 1 or 2 days in the atmosphere before being degraded. Any remaining lambda-cyhalothrin will be removed by precipitation and deposited in terrestrial and aquatic environments.

Lambda-cyhalothrin has a strong affinity for soil and is not easily taken up by the roots of plants and vegetation. It is moderately persistent in the environment, taking a few months to completely degrade (the average half-life ranges from 4 to 12 weeks, depending on soil composition). Also, as a result of its strong affinity for soil, lambda-cyhalothrin is not very mobile in the soil and does not usually leach into groundwater.

Lambda-cyhalothrin enters the aquatic environment either through direct application or in runoff. Lambda-cyhalothrin is not very soluble in water, so once in a water body, it is absorbed strongly by suspended solids and sediments and not expected to be prevalent in the water column. Lambda-cyhalothrin volatilizes slowly from water and soil due to its low vapor pressure and Henry's law constant (ATSDR, 2003a).

Effects on Birds: Lambda-cyhalothrin's toxicity to birds ranges from slightly toxic to practically nontoxic. There is evidence that it does not accumulate in the eggs or tissues of birds.

Effects on Aquatic Organisms: Lambda-cyhalothrin is very highly toxic to many fish and aquatic invertebrate species. Bioconcentration is possible in aquatic species, but bioaccumulation is not likely. Bioconcentration in channel catfish has been reported as minimal, with rapid depuration (elimination). A bioconcentration factor of 858 has been reported in fish, but concentration was confined to nonedible tissues and rapid depuration was observed.

Effects on Other Animals (Nontarget species): Lambda-cyhalothrin is highly toxic to bees, with a reported oral LD_{50} of 38 ng/bee and reported contact LD_{50} of 909 ng/bee (0.9 μg/bee).

- **Malathion**

Once malathion is released in the atmosphere, it can be transported back to surface water and soil by wet and dry deposition. Malathion enters territorial environments either through direct application or by deposition from the atmosphere. Once in the soil, it degrades rapidly and very little of it appears to volatilize from soil, as indicated by its low Henry's law constant. Although malathion is moderately to highly mobile in soils, it is unlikely to leach through soil and into groundwater due to its low persistence and rapid degradation in the environment.

Once in water, malathion is not expected to absorb to sediment particles, and it usually biodegrades within a few weeks. There is also little potential for malathion to bioaccumulate in marine life. The rate of its breakdown water is dependent on the temperature and pH (ATSDR, 2003b).

Effects on birds: Malathion is moderately toxic to birds.

Effects on aquatic organisms: Malathion has a wide range of toxicities in fish, extending from very highly toxic in the walleye (96-hour LC_{50} of 0.06 mg/L) to highly toxic in brown trout (0.1 mg/L) and the cutthroat trout (0.28 mg/L), moderately toxic in fathead minnows (8.6 mg/L) and slightly toxic in goldfish (10.7 mg/L). Various aquatic invertebrates are extremely sensitive. Malathion is highly toxic to aquatic invertebrates and to the aquatic stages of amphibians. Because of its very short half-life, malathion is not expected to bioconcentrate in aquatic organisms. However, brown shrimp showed an average concentration of 869 and 959 times the ambient water concentration in two separate samples, respectively.

Effects on other organisms: The compound is highly toxic to honeybees.

- **Pirimiphos-methyl**

Pirimiphos-methyl has limited mobility and limited persistence in soil. For a variety of soil types, pirimiphos-methyl has a half-life of less than 1 month. It hydrolyzes rapidly in acidic soils and is stable in neutral and alkaline environments. It also decomposes in sunlight. Because its use is limited outdoors, pirimiphos-methyl is not expected to have a significant impact on aquatic environments. It degrades in water, mainly by hydrolysis, which is attenuated by sunlight. It also volatilizes from still water; however, volatilization is not as significant a fate process as hydrolysis for pirimiphos-methyl.

Pirimiphos-methyl is very highly acutely toxic to zooplankton and aquatic insects, moderately acutely toxic to nematodes/flatworms, annelids and fish.

- **Propoxur**

In the terrestrial environment, propoxur is expected to be moderately to very highly mobile and moderately persistent in soil. The mobility depends on the soil type and previous exposures to propoxur. In many soil types, propoxur is highly mobile because of its low affinity for soil binding. Hydrolysis and biodegradation in moist soils appear to be the primary modes of degradation. Biodegradation in soil occurs more rapidly in previously exposed soils. Volatilization is not expected to be a major fate process from moist soil surfaces. Propoxur evaporates from soil, with the amount of evaporation increasing with the moisture content of the soil. The half-life ranges from 6 to 8 weeks depending on the soil type. Also, in soil, propoxur shows no or little susceptibility to photolysis. Propoxur moves rapidly through all soil profiles below a 12-inch sampling depth. Its fate and transport characteristics are similar to chemicals that are known to leach into groundwater.

Propoxur is highly soluble in water and there is a high likelihood of groundwater penetration because it doesn't adsorb strongly to soil. It is relatively stable in water under neutral or acidic conditions, but hydrolyzes rapidly under alkaline conditions. Reported field half-lives for propoxur range from 14 to 50 days. Volatilization from water is not expected to be a major fate process; however, propoxur is susceptible to photolysis in water. Because propoxur degrades rapidly in water, bioconcentration in fish is unlikely.

Effects on birds: Propoxur is very highly to highly toxic to many bird species, but its toxicity varies by the species. Acute symptoms of propoxur poisoning in birds include eye tearing, salivation, muscle incoordination, diarrhea, and trembling. Depending on the type of bird, poisoning signs can appear

within 5 minutes of exposure, with deaths occurring between 5 and 45 minutes, or overnight. Symptoms in survivors disappeared from 90 minutes to several days after treatment.

Effects on aquatic organisms: Propoxur is moderately to slightly toxic to fish and other aquatic species. The reported 96-hour LC_{50} values are 3.7 mg/L in rainbow trout, and 6.6 mg/L in bluegill sunfish. The oral LD_{50} for propoxur in bullfrogs is 595 mg/kg. The compound is not expected to accumulate significantly in aquatic organisms. The calculated accumulation factor for propoxur is nine times the ambient water concentration.

Effects on other organisms: Propoxur is highly toxic to honeybees. The oral LD_{50} for propoxur in mule deer is 100–350 mg/kg.

- **Chlorphenapyr**

Chlorfenapyr is the first commercial pesticide to be derived from a class of microbially-produced compounds known as halogenated pyrroles. Synthesized in 1988 from a naturally-produced chlorinated pyrrole, chlorfenapyr (AC 303,630 Technical: 4-bromo-2-(4-chlorophenyl)-1-(ethosymethyl)-5-(trifluoromethyl)-1H-pyrrole-3-carbonitrile) is being used in at least 32 countries, including the United States. Chlorfenapyr is a "proinsecticide," i.e., it requires activation through metabolism. The parent compound is converted to a metabolite, which functions as an uncoupler of oxidative phosphorylation at mitochondria. The primary, and most toxic, metabolite is the N-dealkylated compound AC 303,268.Chlorfenapyr has low volatility and water solubility; is lipophilic; binds strongly to soil particles; and degrades slowly in soil (avg. half-life of 1 yr), sediment (avg. half-life of 1.1 yr), and water (avg. half-life of 0.8 yr). Biological evidence presented by the manufacturer indicates that chlorfenapyr is rapidly metabolized and excreted by mammals, birds, and fish; hence, unlikely to bioaccumulate in individual organisms or biomagnify between trophic levels. (USGS, 2011)

Effects on birds: Chlorfenapyr has high acute, sub-acute, and chronic (reproductive) toxicity in birds (USGS, 2011). The acute toxicity of chlorfenapyr to birds is high to very high. The subchronic toxicity to birds is also very high (e.g., in mallard ducks, chlorfenapyr at 2.5 ppm in the diet reduced adult body weights and decreased egg-laying and hatch rates by about 40 to 60%) ... Although /lab/ results suggest that there is a considerable potential for the use of chlorfenapyr to cause acute and reproductive toxicity in wild birds, there appear to be no reports of detectable impacts on birds or other wildlife when these have been closely monitored in areas where chlorfenapyr has been used. The mallard duck reproduction NOEL of 0.5 mg/kg-diet serves as the reproduction toxicity endpoint for avian long-term exposure risk calculations. (TOXNET, 2011).

Effects on aquatic organisms: Chlorphenayr poses an acute poisoning hazard to aquatic organisms (definitive data are lacking for chronic effects). (USGS, 2011). The 96 hour LC_{50} for the minnow is 60.2 ug/L. The 96 hour EC50 for growth for mollusks (oyster) is 9.29 ug/L. (PAN, 2011)

Effects on other organisms: Chlorphenapyr is very toxic to honeybees (LC_{50} < 2 ug/bee), and very highly toxic to mosquitoes (LC_{50} < 100 ug/L). (PAN, 2011)

Table 5-21 Qualitative Ranking of the Toxicity and Environmental Behavior of IRS Insecticides to Non-target Organisms

IRS Insecticide	Mammal	Bird	Fish	Other Aquatic	Bee	Persistence	Bioaccumulate[1]
Alpha-cypermethrin							
Bendiocarb							
Bifenthrin							
Cyfluthrin							
DDT		[2]					
Deltamethrin							
Etofenprox							
Fenitrothion							
Lambda-cyhalothrin							
Malathion							
Pirimiphos-methyl							
Propoxur							
Chlorfenapyr[3]							

[1] Potential to bioaccumulate in the environment, but note some pesticides may be detoxified in some vertebrates.
[2] Low toxicity, but high chronic or bioaccumulation effect on raptors, pelicans.
[3] New chemical for 2012

Key	
High	
Medium to High	
Medium	
Low to Medium	
Low	
Data Not Found	

5.3.2.2 Larvicides

The ecotoxicological review was excerpted from the pesticide information profiles (PIPS) provided by EXTOXNET database (EXTOXNET, 2011), except where noted otherwise. The larvicides are also ranked based on persistence and bioaccumulation potential (Table 5-22). The update to the 2007 Environmental Consequences section adds information for two larvicides – Spinosad and Pyriproxyfen. The 2007 report did not provide a qualitative ranking of the larvicides based on persistence and bioaccumulation potential. The update to the 2007 Environmental Consequences section provides such a ranking in Table 5-22.

Detailed information on each larvicide is presented below.

- **Methoprene**

Breakdown in soil and groundwater: Methoprene is of low persistence in the soil environment; reported field half-lives are up to 10 days. In sandy loam, its half-life was calculated to be about 10 days. When Altosid was applied at an extremely high application rate of 1 pound per acre, its half-life was less than 10 days. In soil, microbial degradation is rapid and appears to be the major route of its disappearance from soil. Methoprene also readily undergoes degradation by sunlight. Methoprene is rapidly and tightly absorbed to most soils. It is slightly soluble in water. These properties, along with its low environmental persistence make it unlikely to be significantly mobile. In field leaching studies, it was observed only in the top few inches of the soil, even after repeated washings with water.

Breakdown in water: Methoprene degrades rapidly in water. Studies have demonstrated half-lives in pond water of about 30 and 40 hours at initial concentrations of 0.001 mg/L and 0.01 mg/L, respectively. At normal temperatures and levels of sunlight, technical Altosid is rapidly degraded, mainly by aquatic microorganisms and sunlight.

Breakdown in vegetation: Altosid is biodegradable and nonpersistent, even in plants treated at very high rates. It has a half-life of less than 2 days in alfalfa when applied at a rate of 1 pound per acre. In rice, the half-life is less than 1 day. In wheat, its half-life was estimated to be 3 to 7 weeks, depending on the level of moisture in the plant. Plants grown in treated soil are not expected to contain methoprene residues.

Effects on birds: Methoprene is slightly toxic to birds. The reported 5- to 8-day LC50 values for Altosid, a methoprene formulation, are greater than 10,000 ppm in mallard ducks and bobwhite quail, and the acute oral LD50 for Altosid is greater than 4640 ppm in chickens. In mallards an acute oral LD50 of greater than 2000 mg/kg was determined. Nonlethal effects that may affect survival of the birds did appear at acute oral doses of 500 mg/kg. These effects appeared as soon as 2 hours after treatment and persisted for up to 2 days and included slowness, reluctance to move, sitting, withdrawal, and incoordination. These effects may decrease bird survival by making them temporarily more susceptible to predation. No effects were observed in the reproduction of bobwhite quail and mallard ducks at 30 ppm constant feeding of Altosid.

Effects on aquatic organisms: Methoprene is slightly to moderately toxic to fish. The reported 96-hour LC50 values for the methoprene formulation Altosid were 4.6 mg/L in bluegill sunfish, 4.4 mg/L in trout, and greater than 100 mg/L in channel catfish and largemouth bass. Methoprene residues may have a slight potential for bioconcentration in bluegill sunfish and crayfish. Methoprene is very highly toxic to some species of freshwater, estuarine, and marine invertebrates, while the acute LC50 values are greater than 100 mg/L in freshwater shrimp, and it is greater than 0.1 mg/L in estuarine mud crabs. Altosid had very little effect, if any, on exposed non-target aquatic organisms including water fleas, damselflies, snails, tadpoles, and mosquito fish. Methoprene has been found to be moderately toxic to cold water and freshwater fish, but is virtually nontoxic to warm water fish.

Effects on other organisms: Tests with earthworms showed little if any toxic effects on contact. It is nontoxic to bees.

- **Temephos**

Breakdown in soil and groundwater: There is little information available about the fate and behavior of temephos in the environment. Based on its very low solubility in water, it would probably have a high affinity for soil. Based on this, a half-life of 30 days has been estimated, indicating a low to moderate persistence.

Breakdown in water: Weekly application of temephos at twice the normal application rates on pond water resulted in the rapid disappearance of the compound from the water and from the sediments. At even higher application rates to pond water there were still only traces of the compound detected 1 week after application. Temephos will be photolyzed in water. Temephos was sprayed over an intertidal mangrove community in Florida. Between 15% and 70% of the sprayed amount reaching the leaf surface entered the water below the trees. Additional amounts were washed into the water during rainfall. Pesticide residues were detected in the water 2 hours but not 4 hours after application, indicating a very short persistence in the water. However, in simulated tide pools the compound persisted for up to 4 days. It also persisted in oysters for 2 days after application. Temephos has low persistence in water.

Breakdown in vegetation: Breakdown in plants is very slow.

Effects on birds: Tests with various wildlife species indicate that the compound is highly toxic to some bird species and moderately toxic to others. The LD50 of temephos ranges from 18.9 mg/kg in the California quail to 240 mg/kg in the chukar partridge. The LD50 values in other bird species studied (Japanese quail, pheasant, and rock dove) were between 35 mg/kg and 85 mg/kg. Mallards fed diets containing moderate amounts of temephos showed no changes in reproduction except in the frequency of egg-laying.

Effects on aquatic organisms: Temephos shows a wide range of toxicity to aquatic organisms, depending on the formulation. Generally, the technical grade compound (tech) is moderately toxic and the emulsifiable concentrate (ec) and wettable powder (wp) formulations are highly to very highly toxic. The most sensitive species of fish is the rainbow trout with a temephos LD50 ranging from 0.16 mg/L (ec) to 3.49 mg/L (tech). Other 96-hour LD50 values are reported as: coho salmon 0.35 mg/L (ec), largemouth bass 1.44 mg/L (ec), channel catfish 3.23 mg/L (ec) to >10 mg/L (tech), bluegill sunfish 1.14 mg/L (ec) to 21.8 mg/L (tech), and Atlantic salmon 6.7 mg/L (ec) to 21 mg/L (tech). Freshwater aquatic invertebrates such as amphipods are very highly susceptible to temephos, as are some marine invertebrates such as mysids. The 96-hour LD50 of temephos in Gammarus lacustris is 0.08 mg/kg, and in stoneflies is 0.01 to 0.03 mg/kg. Because the compound is an insecticide and is used effectively to control the aquatic larval stages of mosquitoes, black flies, and midges, its high toxicity to these organisms is not surprising. The product Abate 4E (46% emulsifiable concentrate) is very highly toxic to saltwater species such as the pink shrimp (LC50=0.005 mg/L) and the Eastern oyster (LC50=0.019 mg/L). The compound is nearly nontoxic to the bull frog with an LD50 of greater than 2000 mg/kg. Temephos has the potential to accumulate in aquatic organisms. The bluegill sunfish accumulated 2300 times the concentration present in the water. Nearly 75% of the compound was eliminated from the fish after exposure ended.

Effects on other organisms: The compound is highly toxic to bees, with a direct contact LC50 of 1.55 ug/bee.

- **Pyriproxyfen**

Bioaccumulation: The BCF in whole fish for pyriproxyfen was determined as 660 and 501 for the pyridinyl and phenoxyphenyl labeled substance, respectively. Of the pyridinyl-labeled substance 10.4% was detected as residues in the whole fish after 14 days of depuration. The DT90 was determined to be approximately 100 days in sediment and the risk from bioaccumulation therefore needs to be considered. The risk assessment for fish was based on an early life stage study and the Annex VI trigger was met indicating a low long-term risk to fish. Furthermore, the risk to fish-eating birds and mammals was considered to be low. Therefore, bioaccumulation was considered to be of low concern. (EFSA, 2009)

Pyriproxyfen was proposed to be classified as very toxic to aquatic organisms based on LC/EC50 values of >0.27, 0.40 and 0.094 mg a.s./L obtained for fish, daphnids and algae, respectively. The NOEC for reproduction was determined as 0.015 μg/L for Daphnia magna in a laboratory study, while the NOAEC from an available microcosm study was determined to 5.0 μg/L, based on class 2 effects and no assessment factor. It was noted in the expert meeting that insects were missing in the microcosm study, and a data gap was agreed to address the risk to aquatic insects, given the fact that it is an insect growth regulator. The formulation 'S-71639 10EC' has an acute toxicity in the same order of magnitude as expected from the content of technical pyriproxyfen but since the LC/EC50 values were somewhat lower these were used in the acute risk assessment. Since pyriproxyfen was not readily biodegradable it could be classified as R53 (May cause long term adverse effects in the aquatic environment). (EFSA, 2009)

Risk to sediment-dwelling organisms - Pyriproxyfen partitions to sediment. However, the risk to sediment dwelling organisms was considered to be low based on TER values for C. riparius. (EFSA, 2009)

- **Bacillus thuringiensis israelensis (Bti) and Bacillus sphaericus (Bs)**

In addition to chemical insecticides, the larvicides Bacillus thuringiensis (Bt) and Bacillus sphaericus (Bs) were described in Section 3.2.3. The mechanism of action for these larvicides relates to the binding of bacterial toxins on unique receptor cells present in the gut of mosquito larvae (Poopathi and Abidha, 2010). These receptors are not present in the tissues of humans or other animals (U.S. EPA, 1998b). Because of this unique mechanism of action, toxicity to nontarget organisms related to the active component of these microbial larvicides has not been observed (U.S. EPA, 1998b). However, EPA notes that other bacterial toxins may be produced as impurities during industrial fermentation and therefore requires quality control testing and manufacturing standardization during commercial production of Bt (U.S. EPA, 1998b). Because the nature and quantity of such potential impurities is variable and batch-specific, and because controls have been put in place to mitigate their inclusion in commercial Bt, they are not evaluated in this risk assessment.

A Reregistration Eligibility Document for Bs has not been developed by EPA, but based on common mechanism of action (Poopathi and Abidha, 2010) a presumption of no toxicity to nontarget avian, freshwater fish, freshwater aquatic invertebrates, estuarine and marine animals, arthropod predators/parasites, honey bees, annelids and mammalian wildlife may also be made for Bs.

- **Spinosad**

In Soil: Spinosad degrades readily in the soil environment and is nonpersistent. Primary mechanisms of degradation are sunlight photolysis and microbial breakdown. Under field conditions, spinosad breaks down rapidly in the soil with observed halflives of less than one day, degrading into carbon dioxide and water by the soil microbial community. It is moderately to strongly absorbed by soil particles and is considered to be "relatively immobile to immobile" with regard to leaching. In Water: In natural water systems, spinosad degrades rapidly in sunlight. A water column half-life of less than one day has been observed in artificial pond systems in outdoor conditions (Natular brochure).

The active ingredient in Natular™ larvicides, spinosad, is a highly selective insect control product with high potency for target insects but low toxicity toward mammals and other non-target organisms. In Animals: Because of its unique mode of action, spinosad is highly selective to insects. In mammals, spinosad is not readily absorbed through the skin; any minute amounts that are absorbed or ingested are rapidly metabolized to inactive by-products, which are excreted. As a result, it has very low acute toxicity. In long term studies, no evidence of carcinogenicity, mutagenicity, or neurotoxicity has been observed. Reported LC50s include: Bluegill Sunfish 96-hour LC 50 5.9 mg/L, Rainbow Trout 96-hour LC 50 30 mg/L, Sheepshead Minnow 96-hour LC 50 7.9 mg/L, Common Carp 96-hour LC 50 5.0 mg/L, Water Flea 48-hour EC 50 1.5—14.0 mg/L, Grass Shrimp 48-hour LC 50 >9.7 mg/L, and Midge 25-day NOEC 0.002 mg/L.

- **Monomolecular films**

Monomolecular films can be toxic to fish and crustaceans, and animals that require the use of water surface tension for survival. However, used according to label directions for larva and pupa control, they pose minimal risks to the environment and will not be evaluated further in this risk assessment because they do not last very long in the environment, and are usually applied only to standing water, such as roadside ditches, woodland pools, or containers that contain few nontarget organisms (USAID, 2007).

- **Monomolecular oils**

Oils, if misapplied, may be toxic to fish and other aquatic organisms. For that reason, the EPA has established specific precautions on the label to reduce such risks. When used according to label directions for larva and pupa control, oils do not pose a risk to non-target organisms (USAID, 2007).

Table 5-22 Qualitative Ranking of the Toxicity and Environmental Behavior of Larvicides to Non-target Organisms

IRS Insecticide	Mammalian Toxicity	Avian Toxicity	Fish Toxicity	Other Aquatic Organism Toxicity	Bee Toxicity	Persistence in Environment	Bioaccumulation in Organisms
Methoprene							Aquatic
Temephos							
Pyriproxyfen[1]							
Spinosad[1]							

[1] New chemical for 2012

Key	
High	
Medium to High	
Medium	
Low to Medium	
Low	
Data Not Found	

5.3.2.3. LLINs, Re-Treating ITNs (and wall lining)

The ecotoxicological review was excerpted from the pesticide information profiles (PIPS) provided by EXTOXNET database (EXTOXNET, 2011), except where noted otherwise.

- Alpha-cypermethrin (see Section 5.3.2.1)
- Deltamethrin (see Section 5.3.2.1)
- Lambda-cyhalothrin (see Section 5.3.2.1)
- Permethrin (see the following)

Breakdown in soil and groundwater: Permethrin is of low to moderate persistence in the soil environment, with reported half-lives of 30 to 38 days. Permethrin is readily broken down, or degraded, in most soils except organic types. Soil microorganisms play a large role in the degradation of permethrin in the soil. The addition of nutrients to soil may increase the degradation of permethrin. It has been observed that the availability of sodium and phosphorous decreases when permethrin is added to the soil. Permethrin is tightly bound by soils, especially by organic matter. Very little leaching of permethrin has been reported. It is not very mobile in a wide range of soil types. Because permethrin binds very strongly to soil particles and is nearly insoluble in water, it is not expected to leach or to contaminate groundwater.

Breakdown in water: The results of one study near estuarine areas showed that permethrin had a half-life of less than 2.5 days. When exposed to sunlight, the half-life was 4.6 days. Permethrin degrades rapidly in water, although it can persist in sediments. There was a gradual loss of toxicity after permethrin aged for 48 hours in sunlight at 0.05 mg/L in water.

Breakdown in vegetation: Permethrin is not phytotoxic, or poisonous, to most plants when it is used as directed. Some injury has occurred on certain ornamental plants. No incompatibility has been observed with permethrin on cultivated plants. Treated apples, grapes, and cereal grains contain less than one mg/kg of permethrin at harvest time.

Effects on birds: Permethrin is practically non-toxic to birds. The oral LD50 for the permethrin formulation, Pramex, is greater than 9900 mg/kg in mallard ducks, greater than 13,500 mg/kg in pheasants, and greater than 15,500 mg/kg in Japanese quail.

Effects on aquatic organisms: Aquatic ecosystems are particularly vulnerable to the impact of permethrin. A fragile balance exists between the quality and quantity of insects and other invertebrates that serve as fish food. The 48-hour LC50 for rainbow trout is 0.0125 mg/L for 24 hours, and 0.0054 mg/L for 48 hours. The 48-hour LC50 in bluegill sunfish and salmon is 0.0018 mg/L. As a group, synthetic pyrethroids were toxic to all estuarine species tested. They had a 96-hour LC50 of less than or equal to 0.0078 mg/L for these species. The bioconcentration factor for permethrin in bluefish is 715 times the concentrations in water and is 703 in catfish. This indicates that the compound has a low to moderate potential to accumulate in these organisms.

Effects on other organisms: Permethrin is extremely toxic to bees. Severe losses may be expected if bees are present at treatment time, or within a day thereafter. Permethrin is also toxic to wildlife. It should not be applied, or allowed to drift, to crops or weeds in which active foraging takes place.

- **Piperonil butoxide (PBO)**

PBO degrades rapidly (8.4-hour half-life) in the environment by photolysis in water, and is metabolized by soil microorganisms. Other tested routes of degradation, such as hydrolysis, aerobic and anaerobic aqueous metabolism, are very slow or have questionable rates due to experimental difficulties, as in the case of soil photodegradation. The estimated atmospheric half-life of PBO is 3.4 hours, based on the estimated reaction rate with hydroxyl radicals. PBO is moderately mobile in soil-water systems (Koc = 399 - 830). Little volatilization from soil or water is expected, but PBO may enter the atmosphere as an aerosol when applied by spraying. The major degradates PBO-alcohol, PBO-aldehyde, and PBO-acid are expected to be more soluble in water than the parent and therefore more mobile in soil-water systems. Exposure to both parent PBO and its major degradates (PBO-alcohol, PBO-aldehyde, and PBO-acid) were considered in the assessment. The toxicity of the degradates was considered to be equivalent to that of the parent in the absence of data (USEPA, 2006).

Freshwater Fish

PBO is moderately toxic to freshwater fish on an acute basis (LC50 = 1.9 ppm).

A no observed effect concentration (NOEC) of 0.04 ppm was estimated from a chronic early life stage of fish study with fathead minnow in which embryo survival at hatch and length and weight of larvae was observed at the lowest observed effect concentration (LOEC) of 0.11 ppm.

Freshwater invertebrates

PBO ranges from moderately toxic (LC50 = 12.0 ppm) to highly toxic (LC50 = 0.51 ppm) to freshwater invertebrates on an acute basis. The species selected for RQ calculation was *Daphnia magna* with an LC50 of 0.51 ppm.

A NOEC of 0.030 ppm was estimated from a chronic life cycle study where *Daphnia magna* exhibited reproduction affects at the lowest observed effect concentration (LOEC) of 0.047 ppm.

Estuarine fish

PBO is moderately toxic (LC50 = 3.94 ppm) to estuarine/marine fish based on observed effects to sheepshead minnow on an acute basis.

There are no chronic data available for estuarine fish.

Estuarine/Marine invertebrates

PBO is highly toxic to estuarine invertebrates (LC50 = 0.49 ppm). There are no chronic data available for estuarine/marine invertebrates.

Amphibians

PBO is highly toxic to amphibians on an acute basis (LC50 = 0.21 ppm).

Birds

PBO is practically nontoxic to birds on an acute basis. There were no mortalities observed at the highest concentration tested for acute oral (2250 mg/kg bw) or for the sub-acute dietary studies (5620 ppm). EPA did not calculate RQs from the acute toxicity data because no mortality was seen at very high concentrations indicting minimal adverse acute effects to birds.

From chronic avian toxicity data, a NOEC of 300 ppm was estimated from an avian reproduction study in which adult and hatchling body weight and food consumption, number of eggs laid, number of eggs cracked, and eggshell thickness effects were observed at the lowest observed effect concentration (LOEC) of 1200 ppm.

Mammals

PBO is practically nontoxic to mammals on an acute basis. At higher concentrations mortalities were observed; therefore, RQs were calculated based on the LD50 of 4570 mg/kg bw.

From chronic mammal toxicity data, a NOAEC of 1,000 ppm (89 mg/kg bw) was estimated from a 2-generation rat reproductive study in which decreased body weight gain in the maternal rats and offspring was observed at the LOAEC of 5,000 ppm (469 mg/kg bw).

Beneficial insects

PBO is practically nontoxic to honey bees on an acute oral basis (LD50 > 25 μg/bee).

5.3.3. ENVIRONMENTAL CONSEQUENCES – DOMESTIC LIVESTOCK

This section addresses the question of what degree of risk does exposure to post spray IRS DDT residues on crops and soils in village homesteads have on domestic livestock (chickens)..

5.3.3.1 Environmental Setting

The environmental setting is a rural village/homestead. Domestic livestock, particularly chickens in small villages, were identified to be of special concern in the 2007 PEA because: (1) they have high socioeconomic value; and, (2) the occurrence of wildlife species is low due to the disturbed nature of the environment as a result of human habitation.

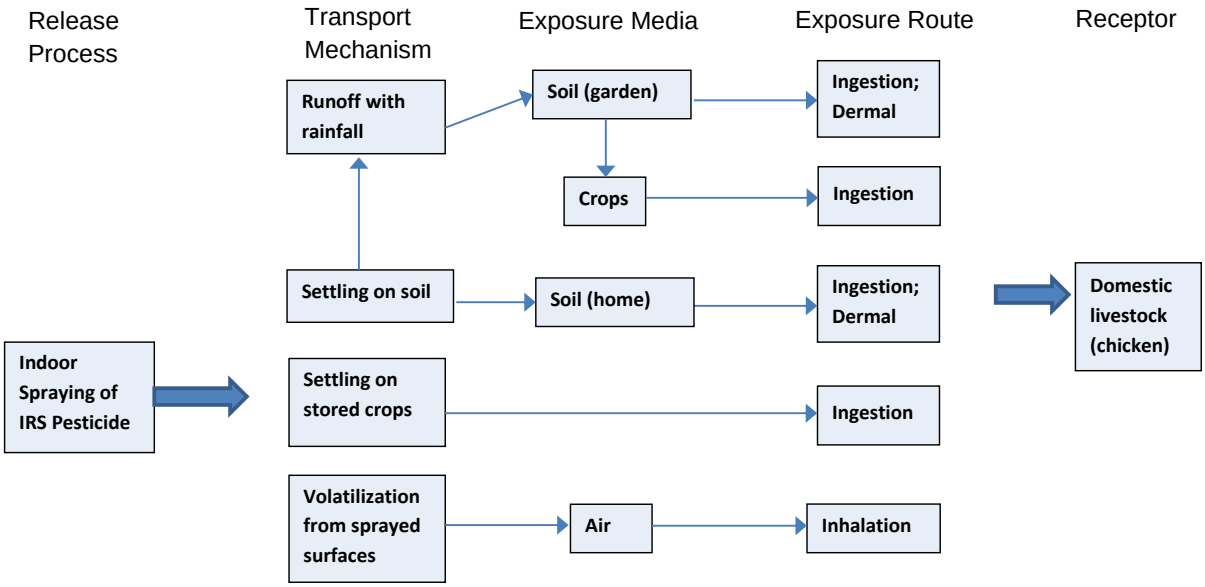
5.3.3.2 Chemical and Physical Stressors of Potential Ecological Concern

The pesticides of potential ecological concern are those pesticides that are used in IRS interventions (Table 5-20). The concentrations of pesticides in soil and crops in villages have not been empirically measured, except for DDT (IRG, 2011a, b and c). There are no physical stressors of potential ecological concern associated with IRS intervention.

5.3.3.3 Fate and Transport Mechanisms

The general conceptual site model for the fate and transport of residues of pesticides used in an IRS intervention (Figure 5-12 Conceptual Model for IRS Pesticides) indicates that residues may settle on stored crops that may then be ingested by chickens, settle on soil around the home that may be incidentally ingested by chickens or that may make its way into gardens and crops with runoff from rainfall. The chickens may then eat the contaminated crops or soil. Pesticide residues may also volatilize from sprayed surfaces and be inhaled by chickens.

Figure 5-12 Conceptual Site Model for IRS Pesticides



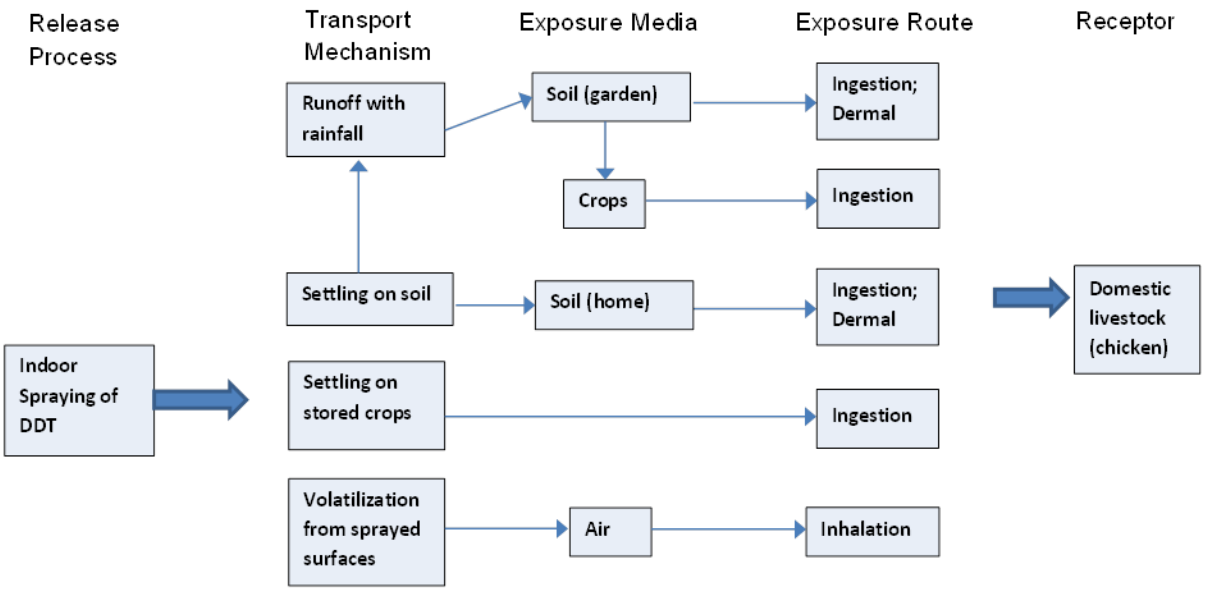
5.3.3.4 Complete Exposure Pathways

The completeness of exposure pathways presented in Figure 5-12 was determined by considering the environmental behavior of each pesticide along with its ecotoxicity profile. Table 5-21 provides a summary of this information.

The primary chemical of concern for IRS was determined to be DDT because of its persistence in the environment and its bioaccumulation in organisms, with chronic reproductive effects to birds (USAID, 2007). Also, a study of post spray IRS DDT residues in a Mozambique village confirms that DDT residues are in chicken muscle (Van Dyk et al., 2010). The other pesticides used in IRS are not evaluated further because they are not expected to be exposure concerns for birds (chickens) due to their behavior in the environment, which is to not persist long enough after spraying to be an exposure concern to foraging chickens; and/or due to their toxicity to birds being primarily acute with a low likelihood for exposure to chickens at acutely toxic concentrations due to degradation and/ or dilution in soil or foodstuffs. Figure 5-13, shows the potential exposure pathways for DDT and the chicken. The primary

or most complete route of exposure of chickens to DDT is expected to be ingestion of foodstuffs and soil contaminated with DDT residues; therefore the inhalation pathway is not evaluated because the exposure is expected to be less than and can be represented by ingestion.

Figure 5-13 Conceptual Model for DDT Exposure to Domestic Livestock (Chickens)



5.3.3.5 Screening Levels

Wild bird screening levels were selected as a surrogate for the chicken and to also screen for any sensitive wild bird species that may be at a site. These values represent trophic level (food chain) transfer exposure. An U.S. EPA ecological soil screening level (Eco-SSL) for DDT and metabolites for birds (woodcock; primarily eats earthworms) was selected and is equal to 0.093 mg/kg soil (EPA, 2007). The No Observable Adverse Effect (NOAEL)-based Toxicity Reference Value (TRV) is equal to 0.227 mg/kg/d and is equal to the highest bounded NOAEL lower than the lowest bounded Lowest Observable Adverse Effect (LOAEL) for reproduction, growth and survival results. The accompanying LOAEL is 2.27 mg/kg/d. This value was selected because it is a nationally recognized soil screening value for birds and it also provides the most conservative estimate of risk because insectivorous birds tend to have the highest risk of adverse effects from DDT (LANL, 2010). However, because the woodcock eats primarily worms, it does not represent the expected omnivorous dietary habits of the chicken, so an ecological screening level (ESL) for soil for an omnivorous wild bird species, the (American Robin), was also selected from the ECORISK Database. This value was selected because it represents a bird that eats both plants and invertebrates, which is more representative of the chicken diet. The NOAEL-based screening level for soil for the American Robin (omnivore) is 0.72 mg/kg soil and is bounded by a LOAEL-based ESL of 2.1 mg/kg soil (LANL, 2010). The NOAEL-based TRV is 2.01 mg/kg/d and is bounded by a LOAEL of 5.96 mg/kg/d. Both the NOAEL- and LOAEL-based TRVs are both based on the geometric mean of toxicity values taken from studies on quail, duck, pheasant, dove and finch and include measurements on reproduction/development and survival.

5.3.3.6 RISK CALCULATIONS

A hazard quotient (HQ) greater than 1 would indicate a potential for ecological risk, where the hazard quotient is equal to the concentration in the exposure medium divided by an appropriate ecological screening level (U.S. EPA, 1998).

The soil concentration data selected for this risk calculation/estimate was post spray, soil DDT residue results reported in studies in villages of two African countries (IRG, 2011a and b). The maximum soil concentrations post spray for both countries are summarized in Table 5-23. This data was selected for the purpose of providing the most protective/conservative risk estimate. Crop data were also available; however, the soil data was preferred because of the uncertainty of what crops the chickens would actually ingest, furthermore, the soil ESLs already incorporates the food ingestion pathway using an uptake factor to account for the transfer of DDT from soil into food.

In Ethiopian villages, the average maximum reported soil concentration was 9.28 mg/kg soil at entrance of home and 22 mg/kg soil in garden, and 11.6 mg/kg soil in runoff channels near homes (RTI, 2011a). In Mozambique villages, the maximum reported soil concentration was 2.3 mg/kg soil at entrance of home, 10 mg/kg soil in garden, and 2.4 mg/kg soil in runoff channels close to homes (RTI, 2011b).

The Ethiopian village soil samples from the entrance of the home had the highest average maximum soil concentration reported and this data will be used for the screening assessment because it represents the maximum exposure scenario for ingestion of DDT residues by a bird receptor (Table 5-23).

Two avian ESLs were selected to estimate risk from DDT exposure to birds eating plant and/or invertebrates (Section 5.2.3.7). One ESL represents a model for an omnivorous bird (robin) exposed to DDT and the other represents a model for an insectivore (woodcock, primarily eats earthworms) exposed to DDT and metabolites (Table 5-23). These receptors were selected to represent birds that forage close to the ground similar to what a chicken would do and to determine the difference in risk to an insectivorous versus a omnivorous bird.

Table 5-23 presents the avian HQs for DDT in soil with the data sorted from lowest to highest HQ.

Table 5-23 Avian Hazard Quotients for DDT in Soil

Scenario (soil concentration, ESL type, receptor)	DDT Soil Concentration (mg/kg)[1]	Ecological Screening Level for Soil (mg/kg)	Hazard Quotient (Concentration/Screening Level)
Mean, LOAEL, Robin	1.08	2.1	0.5
Mean, NOAEL, Robin	1.08	0.72	1.5
Maximum, LOAEL, Robin	22	2.1	10
Mean, NOAEL, Woodcock	1.08	0.093	12
Maximum, NOAEL, Robin	22	0.72	31
Maximum, NOAEL, Woodcock	22	0.093	237

[1] Average soil concentration for home entrance from all Ethiopian villages sampled.

All, except one of the avian HQs were greater than 1. The exception was a scenario for the mean soil concentration at the site compared to the LOAEL-based ESL for the omnivorous bird. Because the comparison to ESLs for the maximum soil concentrations at the site had HQs greater than 1, a closer look at the toxicity data set was deemed appropriate, and a chicken specific NOAEL-based TRV was derived using the available chicken toxicity data in the woodcock ESL data set (EPA, 2007). The woodcock data set was selected because it represents a nationally recognized source for screening level data. The calculated chicken TRV is equal to 0.88 mg/kg/d, which is 2.3 times less than the American robin TRV (2.01 mg/kg/d) and 3.8 times greater than the woodcock TRV (0.227 mg/kg/d). The chicken TRV is an estimate of toxicity to the organism based on laboratory studies. It is not known what type of food was consumed. However, the chicken TRV refines the risk estimate for the chicken, which is the primary receptor of concern for village/homestead scenarios with IRS intervention (USAID, 2007), because the toxicity data is only from chicken studies. An exposure estimate (mg/kg/d) for ingestion of soil only, ingestion of crops only, and ingestion of both soil and crops was calculated using maximum (22 mg/kg) and mean (1.08 mg/kg) soil concentration (Table 5-23), maximum (4.5 mg/kg) and mean (0.4 mg/kg) crop (in home) concentrations (RTI, 2011a and b), a laying hen food intake rate of 0.1 kg/d (Ng et al., 1968), an average chicken (leghorn hen) body weight of 2.1 kg (PoultryPedia, 2011), and a soil ingestion fraction of 0.1 (EPA, 2005). The HQ results are reported in Table 5-24.

Table 5-24 Chicken Hazard Quotients for DDT in Soil

Scenario	DDT Dose (mg/kg/d)	Chicken TRV[6] (mg/kg/d)	Hazard Quotient (Dose/TRV)
Mean, NOAEL, Food[1]	0.019[3]	0.88	0.022
Mean, NOAEL, Soil[2] only	0.005[4]	0.88	0.006
Mean, NOAEL, Food and Soil	0.025[5]	0.88	0.028
Maximum, NOAEL, Soil[2] only	0.107[4]	0.88	0.12
Maximum, NOAEL, Food[1]	0.22[3]	0.88	0.25
Maximum, NOAEL, Food and Soil	0.33[5]	0.88	0.37

[1]Data for crops from Mozambique villages, includes data only from the 3 distracts that were also sampled for baseline.

[2]Data for soil from Ethiopian villages.

[3] Food only dose (mg/kg/d) = DDT Crop Concentration (mg/kg) *soil intake (kg/d)/ bw (kg), where soil intake is 0.01 kg/d and bw is 2.05 kg.

[4] Soil only dose (mg/kg/d) = DDT Soil Concentration (mg/kg) *soil intake (kg/d)/ bw (kg), where soil intake is 0.01 kg/d and bw is 2.05 kg.

[5] Food and Soil dose (mg/kg/d) = DDT Soil Dose + Food Dose

[6] TRV is equal to the geometric mean of 49 toxicity values reported in the woodcock ecological soil screening level data set (EPA, 2007). Uncertainty Factors of 10 were applied as necessary for subchronic-chronic exposure duration and LOAEL to NOAEL effect level.

5.3.3.9 Risk Characterization

The risk calculations suggest that ingestion of DDT by wild birds eating primarily worms or both plants and invertebrates is a potential ecological risk because all, except 1 HQ are greater than 1 (Table 5-23). The ecological screening levels used were based on conservative assumptions. To address the uncertainty of using a surrogate species to evaluate the risk to chickens, a chicken specific ecological screening level (TRV) was developed, and all HQs calculated for soil and or crop ingestion by the chicken were less than 1 (Table 5-24), suggesting there is no ecological risk to chickens ingesting soil or crops. However, the chicken HQ does not evaluate exposure to invertebrates as do the ESL models for the American robin and the woodcock, and of the wild bird ESL exposure models evaluated here the woodcock eating primarily earthworms was at highest risk of adverse effects. A chicken ESL exposure model would address trophic transfer from soil to invertebrates, if invertebrate data is not available at a site. The number of samples (soil 51, crops 33) and the percent detection (soil 88%, crops 87%) were adequate to support the results used in this analysis. Data were also collected in a separate study (IRG, 2011c, data summarized in Table 5-c of this report) to show the transfer of DDT from air, walls and floors after IRS to in home crops. The results of this study indicate that DDT is increasing in soils and crops over time. The mean concentrations observed by 8 months post spray in beans and maize were 0.64 and 7.71 mg/kg, respectively. The concentration in maize exceeded the crop concentration used in the chicken HQ analysis, however, the resulting HQ (data not shown) for the maize concentration (HQ = 0.43 for maize only ingestion) is still below the chicken TRV. Considering this data along with the Van Dyk study (Van Dyk et al., 2010) that shows that chicken fat is accumulating DDT in IRS villages suggests that even though there is transfer of DDT into the food supply and into the chicken, it is not at a high enough concentration to pose an ecological risk to chickens in the villages, if they are exposed via ingestion of soil and crops. The human health implications are discussed in Section 5.2.

The data gap identified for assessing the risk of DDT exposure to chickens, specifically, remains in having actual data on the types of food ingested and the concentrations of DDT in those food types. With regard to types of food ingested, the ingestion of invertebrates is of greatest concern.

In conclusion, based on the results reported here, the domestic chicken does not appear to be at risk for adverse effects from DDT exposures through ingestion of soil or crops.

5.3.4. AQUATIC TOXICITY OF LARVICIDES

Environmental Setting

The environmental setting is a fresh surface water body near rural villages/homesteads. Saltwater is not of concern because mosquitoes do not breed in saltwater, so larvicides would not be applied to them. Ecological species of concern include fish and nontarget invertebrate species that live in the surface water. However, the occurrence of wildlife species is expected to be low in most village areas due to the disturbed nature of the environment as a result of human habitation.

Chemical and Physical Stressors of Potential Ecological Concern

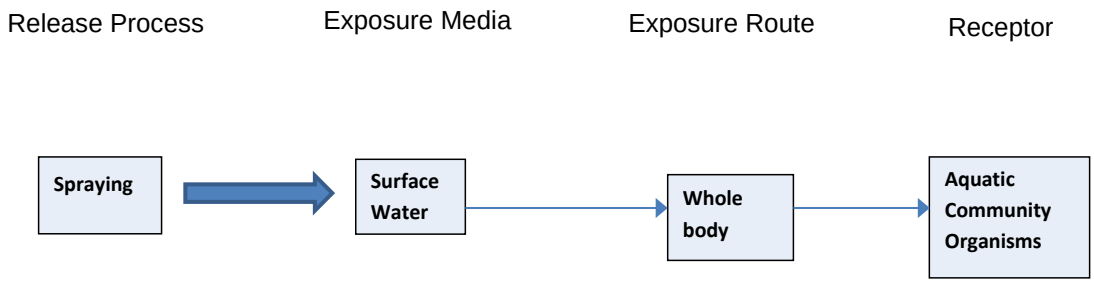
The pesticides of potential ecological concern are those pesticides (methoprene, temephos, pyriproxyfen, spinosad) that are used in larviciding (Table 5-20) and are indicated as posing adverse effects to nontarget organisms. Concentrations of pesticides in surface water after larviciding are modeled based on a simplistic static water model using application concentration to a known amount of water (Table G-15).

There are no physical stressors of potential ecological concern associated with the larviciding intervention.

Fate and Transport Mechanisms

Figure 5-14 shows the conceptual site model for larvicide exposure to aquatic species in surface water bodies. It is assumed that larvicide is sprayed onto a surface water body sufficient in size to support nontarget aquatic life. The aquatic species would be exposed directly and primarily acutely to the larvicides. Longer-term exposure may occur for those insecticides that have moderate to high persistence and/or bioaccumulation potential.

Figure 5-14 Conceptual Model for Exposure of Aquatic Community Organisms to Larvicides



Complete Exposure Pathways

The completeness of exposure pathway presented in Figure 5-14 was determined by considering the environmental behavior of each pesticide along with its ecotoxicity profile. Table 5-22 provides a summary of this information.

In general, the larvicides have low persistence and bioaccumulation potential. They are, in general, very toxic to nontarget aquatic species, except for spinosad, which has generally low toxicity. The exposure scenario of concern is expected to be an acute exposure, toxicity seen right after spraying of a surface water body containing aquatic species. The typical size of surface water body that is sprayed is an unknown. For the purposes of this risk estimate, it is assumed to be sufficiently large enough to support aquatic life. This risk estimate is not concerned with evaluating small bodies of water that do not support non-target aquatic life. This evaluation is concerned with the environmental consequences to actual established aquatic habitat. Smaller surface water bodies could be sprayed with potential to leach or runoff into larger bodies. Due to the relatively short life of these larvicides, the exposure is not expected to occur at concentrations high enough to elicit an acute toxic effect on aquatic species.

Screening Levels

Screening values are not reported specifically for larvicides for aquatic species. In lieu of such data, LC_{50}s for various aquatic species can be used as an estimate of the acute toxicity that may occur. The LC_{50} represents the median lethal dose or the concentration of chemical in exposure medium that kills 50% of the test population in a specified period of time. LC_{50}s represent acute exposure durations. Table 5-25 presents the minimum LC_{50} available for the most applicable freshwater and marine/estuarine fish and invertebrate species based on the ecotoxicological review presented in this report (Section 5.3.2). Because published screening values are not available, a risk ratio is calculated instead of a hazard quotient. A risk ratio has more uncertainty associated with it because the toxicity data has not been peer reviewed and approved for use specifically for screening assessments. However, the risk ratio does provide information about the potential magnitude of toxicity of a certain concentration of larvicide dissolved in water to aquatic species.

Table 5-25 Aquatic LC_{50}s (mg/L)[1] for Larvicides

Larvicide	Fish LC_{50} (freshwater)	Aquatic invertebrate LC_{50} (freshwater)
Methoprene	4.4 mg/L (96 hour, trout)	100 mg/L (acute, shrimp)
Temephos	0.16 mg/L (ec[2]) to 3.49 mg/L (tech[3]) (rainbow trout)	-
Spinosad	-	>9.7 mg/L (48 hour, grass shrimp; some species live in brackish water)
Pyriproxyfen[4]	0.27 mg/L (bluegill)	-

[1] LC50s taken from section 5.3.2, EXTOXNET, 2001, except where noted.

[2]ec = emulsifiable concentrate

[3]tech = technical grade

[4]LC50 data from EPA's ECOTOX database (http://cfpub.epa.gov/ecotox/)

Risk Calculations

The concentration of the larvicide in a 10 L applicator tank (Table G-15) was used in this risk estimate. First it a risk ratio was calculated, which compared larvicide concentration in the 10 L tank to the minimum LC_{50} for each larvicide from Table 5-25. The risk ratio provides a very conservative estimate of risk because the 10 L tank concentration is expected to be diluted by the body of water to which it is applied to at a site. Because of the volume of water mixed with the tank contents is unknown, another metric was calculated and represents, the amount of water needed to mix with the amount of larvicide in the applicator tank to equal the LC_{50} for aquatic species, **Minimum Volume of Water Required for Application to Equal LC_{50}** (Table 5.26). This approach was taken because this is a generic screening level assessment and the exposure concentration after applying the larvicide using a 10 L applicator tank to a body of water at a specific site of concern will vary considerably depending on the size of the body of water. For this reason, a volume of water metric was selected, so that the environmental assessor performing the SEA prior to application of the larvicide can use best professional judgment to determine if the body of water at the site will experience severe adverse effects. Simplistically, the volume of water at a site can be determined by using average measurements length, width and depth of the body of water. Alternatively, the environmental assessor could calculate the expected concentration in the water after larvicide application and compare to the minimum LC_{50}s reported in Table 5-25. The volume of water metric saves the environmental assessor the step of having to calculate the site exposure concentration. Both the LC_{50} and the **Minimum Volume of Water Required for Application to Equal LC_{50}** represent a severe adverse effect level (lethality to 50% of exposed population), and is not being used as a safe level in this evaluation, but rather as a red flag warning for adverse effects to non-target aquatic

species. Further literature review is required to determine an acceptable risk level such as an EC_{20}, concentration affecting 20% of the population, and this is beyond the scope of this screening assessment.

Table 5-26 Risk Ratios and Minimum Volume of Water to be Acutely Toxic to Aquatic Species for Larvicides Applied to Surface Water

Larvicide	Maximum Larvicide Concentration in Applicator Tank[1](mg/L)	Aquatic LC_{50} (mg/L)[2]	Risk Ratio (Maximum Larvicide Concentration in Applicator Tank/ LC_{50})	Minimum Volume of Water Required for Application to Equal LC_{50} (10 * Maximum Larvicide Concentration in Applicator Tank/ LC_{50})
Methoprene	28	4.4	6	64
Spinosad	140	9.7	14	144
Temephos	78	0.16 ec[3], 3.49 tech[4]	487 ec, 22 tech	4875 ec, 223 tech
Pyriproxyfen	7.1	0.27	26	263

[1]Based on mixing the application rate in 10 L of water from Table G-15.

[2] Minimum Freshwater LC_{50}

[3]ec = emulsifiable concentrate

[4]tech = technical grade

Risk Characterization

All risk ratios are greater than 1, indicating these larvicides are acutely toxic to nontarget aquatic species in 10 L of water. This result is not surprising. The more relevant question is how this information applies to a specific-site, and in this assessment the **Minimum Volume of Water Required for Application to Equal LC_{50}** is the metric used to answer this question.

In order for a larvicide not to be acutely toxic to the most sensitive freshwater aquatic species, the minimum volume of water to which it may be applied is larvicide specific. Methoprene is the least potent with a risk ratio of 6 and a minimum volume of water required for application to equal the LC_{50} of 64 L. Temephos (emulsifiable concentrate) is the most potent with a risk ratio of 487 and a minimum volume of water required for application to equal the LC50 of 4875 L. The **Minimum Volume of Water Required for Application to Equal LC_{50}** metric is an indicator of potential lethal acute effects to nontarget aquatic species. If the volume of water being treated with a larvicide is larger than the **Minimum Volume of Water Required for Application to Equal LC_{50}**, severe lethal effects are not expected. For example, for temephos not to be severely lethal to aquatic species the contents of a 10 L tank of temephos at application rate needs to be greater than 4875 L or 4.875 m^3. However, this metric does not indicate what level of adverse effects, lethal or other, may still occur at volumes greater than the minimum water volume required for application to equal LC_{50}. Further evaluation of the toxicological literature is required to set a low or no effect level, and this is beyond the scope of this initial screening assessment.

The data gaps identified in this screening assessment for assessing the acute toxicological risk of larvicide exposure to aquatic species include: data on the actual species present in the surface water, the type of surface water (fresh or saltwater), the volume of surface water; the flow rate of water, if not a closed system, and low or no effect levels.

In conclusion, if larvicides are applied to surface water bodies that are static in nature, less than or equal to the **Minimum Volume of Water Required for Application to Equal LC_{50}** for the applied larvicide(s) and are observed to provide ecological habitat for non-target aquatic species, the results reported here indicate that there is a potential for severe lethality to non-target aquatic species. Further review of the toxicological literature is required to set low and no effect levels, and or a baseline assessment is required.

5.3.5. AQUATIC TOXICITY OF INSECTICIDES

Environmental Setting

The environmental setting is fresh or saltwater bodies used for fishing or washing. Ecological species of concern include fish and invertebrate species that live in the surface water. However, the occurrence of wildlife species is expected to be low in most village areas due to the disturbed nature of the environment as a result of human habitation.

Chemical and Physical Stressors of Potential Ecological Concern

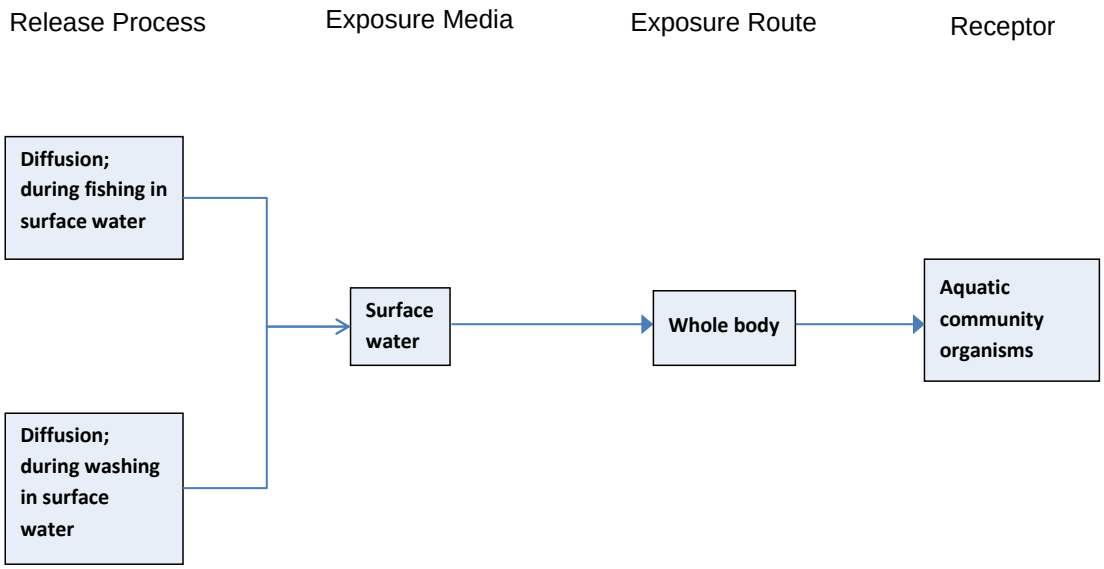
The pesticides of potential ecological concern are those pesticides that are used in LLINs/ITNs (Table 5-20). Concentrations of pesticides in surface water after washing/fishing with LLINs/ITNs are modeled based on a simplistic static water model mixing a known application concentration into a known amount of water (Table G-15).

The physical stressors of potential ecological concern associated with washing/fishing with LLINs/ITNs include turbidity and sedimentation caused by the movement of the nets through the water, as well as the physical presence of the net causing physical damage to or removal of aquatic species.

Fate and Transport Mechanisms of Insecticides

Figure 5-15 shows the conceptual site model for the exposure of aquatic species to pesticides that have diffused from LLINs/ITNs used for washing or fishing into surface water bodies. It is assumed that surface water body used for washing or fishing is of sufficient in size to support aquatic life. The aquatic species would be exposed directly and primarily acutely to the pesticides. Longer-term exposure may occur for those insecticides that moderate to high persistence and/or bioaccumulation potential.

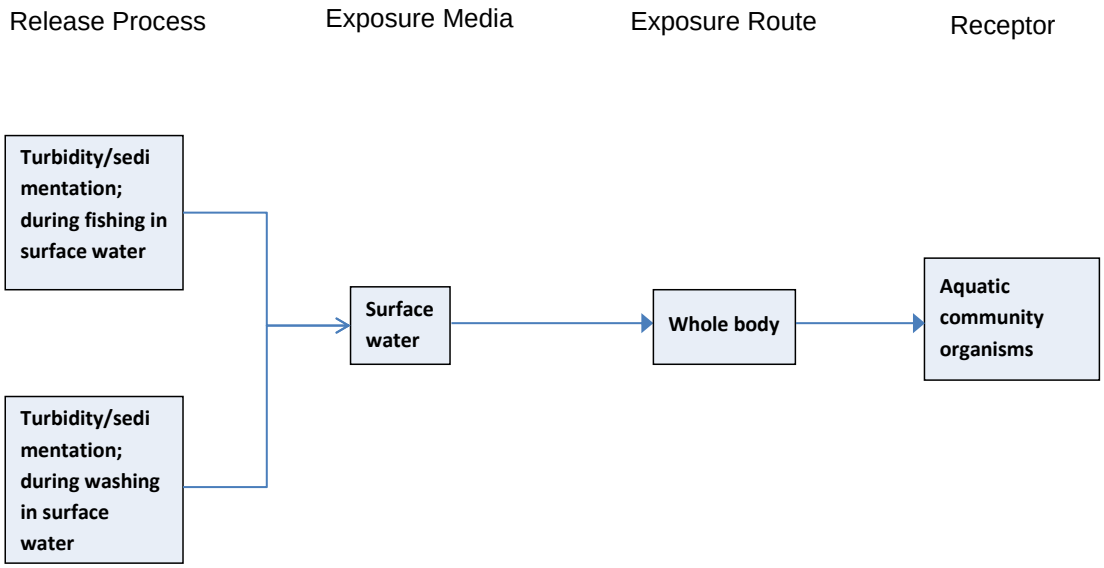
Figure 5-15 Conceptual Model for Exposure of Aquatic Community Organisms to Pesticides on LLINs/ITNs Used for Fishing/Washing



Fate and Transport Mechanisms of Physical Stressors

Figure 5-16 shows the conceptual site model for exposure of aquatic species to physical stressors (turbidity, sedimentation) caused by the use of LLINs/ITNs for fishing/washing in surface water bodies. Direct physical contact with the LLINs/ITNs is also a physical stressor for aquatic species (not shown in conceptual model) as is removal of species as a result of overfishing.

Figure 5-16 Conceptual Model for Exposure of Aquatic Community Organisms to Physical Stress (Turbidity/Sedimentation) Caused by LLINs/ITNs Used for Fishing/Washing



Complete Exposure Pathways Insecticides

The completeness of exposure pathways presented in Figure 5.15 was determined by considering the environmental behavior of each pesticide along with its ecotoxicity profile.

In general, the LLIN/ITN insecticides have low persistence and bioaccumulation potential. In general, they are very acutely toxic to aquatic species. The exposure scenario of concern is expected to be an acute exposure, toxicity seen right after washing/fishing with LLINs/ITNs in a surface water body containing aquatic species. The typical size of surface water body that is used for fishing/washing with LLINs/ITNs is an unknown. Here we assume it is sufficiently large enough to support aquatic life. For those insecticides reported as having moderate to high environmental persistence and bioaccumulation potential, the exposure may be longer term, however, the surface water body is expected to be large enough that the concentrations will be diluted sufficiently to not be toxic.

Complete Exposure Pathways Physical Stressors

The completeness of the exposure pathways presented in Figure 5.16 is assumed to be complete if the nets used are large enough to make contact with the sediment at the bottom of the body of surface water (bottom trawling). The completeness of the exposure pathway for physical damage due to direct contact with the net and of overfishing assumes there are sufficient fish in the body of water to warrant use by fishermen.

Screening Levels –Insecticides

Screening values are not reported specifically for insecticides for aquatic species. In lieu of such data, LC_{50}s for various aquatic species can be used as an estimate of the acute toxicity that may occur. The LC_{50} represents the median lethal dose or the concentration of chemical in exposure medium that kills 50% of the test population in a specified period of time. LC_{50}s represent acute exposure durations. Table 5-27 presents the minimum LC_{50} available for the most applicable freshwater and marine/estuarine fish and invertebrate species based on the ecotoxicological review presented in this report (Section 5.3.2). Because published screening values are not available, a risk ratio is calculated instead of a hazard quotient. A risk ratio has more uncertainty associated with it because the toxicity data has not been peer reviewed and approved for use specifically for screening assessment.. However, the risk ratio does provide information about the magnitude of toxicity of a certain concentration of insecticide dissolved in water.

Table 5-27. Aquatic LC_{50}s (mg/L) for LLIN/ITN Insecticides

Insecticide	Fish LC_{50} (freshwater)	Fish LC_{50} (estuarine/marine)	Aquatic invertebrate LC_{50} (freshwater)	Aquatic invertebrate LC_{50} (estuarine/marine)
Alpha-cypermethrin	0.0018 mg/L (96 hour, bluegill sunfish)	-	0.0002 mg/L (acute, Daphnia)	-
Deltamethrin	-	-	-	-
Lambda-cyhalothrin	-	-	-	-

Permethrin	0.0018 mg/L (48 hour, bluegill sunfish and salmon)	-	-	-
Insecticide	Fish LC_{50} (freshwater)	Fish LC_{50} (estuarine/marine)	Aquatic invertebrate LC_{50} (freshwater)	Aquatic invertebrate LC_{50} (estuarine/marine)
Piperonil butoxide (PBO)	1.9 mg/L	0.51 mg/L (Daphnia magna)	3.94 mg/L	0.49 mg/L

Screening Levels – Physical Stressors

Turbidity is a key test of water quality and the EPA publishes water quality criteria for turbidity, which is measured in units of NTUs. In general, a rule of thumb is background plus 10% depending on the surface water body type. Washington State has the most conservative published values using 5 NTU over background or 10% over background when background is over 50 NTU. (EPA, 1986; LDEQ, 2007; VWRB, 2006, and WDE, 1997.)

There are no screening levels for physical contact or overfishing. Site observations would have to be made to determine the health of the ecosystem.

Risk Calculations - Insecticides

First a risk ratio was calculated, which compared the insecticide concentration in 10L of water after fishing/washing with an LLIN/ITN to the minimum LC_{50} for each LLIN/ITN insecticide from Table 5-25. The risk ratio provides a very conservative estimate of risk because the 10L tank concentration is expected to be diluted by the body of water to which it is applied to at a site. Because of the volume of water mixed with the tank contents is unknown, another metric was calculated and represents, the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** (Table 5.29). This approach was taken because this is a generic screening level assessment and the exposure concentration after fishing or washing with an LLIN/ITN in a body of water at a specific site of concern will vary considerably depending on the actual size of the body of water. For this reason, a volume of water metric was selected, so that the environmental assessor performing the SEA prior to distributing LLINs/ITNs can use best professional judgment to determine if there are bodies of water at the site that could experience severe adverse effects from washing or fishing with LLINs/ITNs. Simplistically, the volume of water a t a site can be determined by using average measurements length, width and depth of the body of water. Alternatively, the environmental assessor could calculate the expected concentration in the water after washing and fishing with an LLIN/ITN and compare to the minimum LC_{50}s reported in Table 5-29. The volume of water metric saves the environmental assessor the step of having to calculate the site exposure concentration. Both the LC_{50} and the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** represent a severe adverse effect level (lethality to 50% of exposed population), and is not being used as a safe level in this evaluation, but rather as a red flag warning for adverse effects to non-target aquatic species. Further literature review is required to determine an acceptable risk level such as an EC_{20}, concentration affecting 20% of the population, and this is beyond the scope of this screening assessment. A risk ratio is calculated using an exposure estimate in surface water to the minimum LC_{50} data available for insecticides to aquatic species). The equation for calculating the Insecticide Concentration in Water After a Fishing or Washing Event is

Insecticide Concentration in Water After a Fishing or Washing Event = Initial LLIN/ITN concentration (mg/m²) * surface area of bed net (m²) * fractional loss of pesticide/ water volume for fishing or washing with net (L).

Table 5-28 shows the parameters used for the water exposure estimate calculation for each LLIN/ITN insecticide. Table 5-29 shows the $LC50_s$ and the risk ratio results.

Table 5-28. Summary of Key Exposure Parameter Values – Fishing or Washing with LLINs/ITNs

Pesticide	Fractional loss of initial pesticide mass in LLIN	Water volume for fishing or washing with net	Surface Area of Bed Net	Initial LLIN Concentration
Alpha-cypermethrin	0.05[1]	10 (L) [2]	15 (m^2)[3]	5500 (mg/kg)[5]
Deltamethrin				99 (mg/m^2)
Lambda-cyhalothrin				50 (mg/m^2)
Permethrin				20000 (mg/kg)[6]
Piperonil butoxide (PBO)				200 (mg/m^2)

[1] CTE (average), Table G-10..

[2] Assumption. Represents a very conservative/protective starting water volume for evaluating toxicity where a larger water volume is expected to result in less toxicity less toxicity due to dilution of the initial insecticide concentration

[3] Najera & Zaim 2002

[4] From Table G-10

[5] Convert to mg/m^2 with factor of 0.045 kg/m^2 (http://duranetmosquitonet.com/closer.cfmhttp://duranetmosquitonet.com/closer.cfm)

[6] Convert to mg/m^2 with factor of 0.05 kg/m^2 (http://www.spartanrelief.com/olyset-mosquito-net.php)

[7] First value represents concentration in LLINs, second value represents concentration used in re-treatment of ITNs

Table 5-29 Aquatic Species Risk Ratios for Insecticides Diffused into Surface Water after Single Washing or Fishing Event with LLINs/ITNs

Insecticides	Insecticide Concentration in Water After Single Washing or Fishing Event[1](mg/L)	Aquatic LC_{50} (mg/L)[3]	Risk Ratio (Insecticide Concentration in Water after Single Washing or Fishing Event/ LC_{50})	Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50} (10 * Insecticide Concentration in Water after Washing/Fishing with LLIN/ LC_{50})
Alpha-cypermethrin	19	0.0002	95000	950,000
Deltamethrin	7.4/1.1-1.9	-	-	
Lambda-cyhalothrin	3.8	-	-	
Permethrin	75	0.0018	41667	416,666
Piperonil butoxide (PBO)	15	0.51 (0.49)[2]	29.4 (30.6)	294 (306)

[1] Concentration in Water After a Fishing or Washing Event is the Initial LLIN/ITN concentration (mg/m^2) * surface area of bed net (m^2) * fractional loss of pesticide/ water volume for fishing or washing with net (L). Based on a single wash in 10 L of water with 5% loss per wash. See Table 5-29 for key parameters.

[2] Freshwater LC_{50} with estuarine/marine LC_{50} in parenthesis

[3] Minimum LC50s

[4] First value represents concentration from LLINs, second value represents concentration from re-treatment of ITNs

All the risk ratios in Table 5-29 are greater than 1 for aquatic species living in a static 10 L volume of water to which a LLIN has been used for washing or fishing.

Risk Calculations – Physical Stressors

No risk calculations could be performed for turbidity/sedimentation or physical damage from net use or overfishing because no site data is available on these parameters.

Risk Characterization - Insecticides

All risk ratios are greater than 1, indicating these insecticides are acutely toxic to nontarget aquatic species in 10 L of water. In order to apply this information the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** was calculated as the relevant metric.

In order for an insecticide diffused from a LLIN/ITN used for washing or fishing not to be acutely toxic to the most sensitive freshwater and saltwater aquatic species, the minimum volume of water to which it may be applied was calculated. Piperonil butoxide being the least potent with a risk ratio ranging between 29.4-30.6 for freshwater and saltwater habitat, respectively, and minimum volume of water required for washing or fishing to equal the LC_{50} ranging between 294 -306 L for freshwater and saltwater habitat, respectively. Alpha-cypermethrin being the most potent with a risk ratio of 95,000 and a minimum volume of water required for washing or fishing to equal the LC_{50} of 950,000 L. The **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** metric is an indicator of potential lethal, acute effects to non-target aquatic species. If the volume of water used for washing is larger than the minimum volume of water required to equal the LC_{50}, severe lethal effects are not expected. For example, for alpha-cypermethrin not to be severely lethal to aquatic species the contents of a 10 L tank of this insecticide at stated application rate needs to be greater than 950,000 L. However, this metric does not indicate what level of adverse effects, lethal or other, may still occur at volumes greater than the minimum water volume required for fishing or washing to equal LC_{50}. Further evaluation of the toxicological literature is required to set a low or no effect level, and this is beyond the scope of this initial screening assessment.

The data gaps identified in this screening assessment of the acute toxicological risk of insecticides diffused from a LLIN/ITN used for washing or fishing exposure to aquatic species include: data on the actual species present in the surface water, the type of surface water (fresh or saltwater), the volume of surface water; the flow rate of water, if not a closed system, and the number of LLINs/ITNs used at the same time and the number of times a net is used, and low or no effect levels. Also, the potential risk from LLINs/ITNs using deltamethrin and lamda-cyhalothrin were not assessed because toxicity data was not available. Also, the effect of the insecticide being either coated on polyester or incorporated into polyethylene was not evaluated due to lack of data on differences in diffusion rates for these different types of nets.

In conclusion, if LLINs/ITNs are used for washing/fishing in surface water bodies that are static in nature, have a volume less than or equal to the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** for the LLIN/ITN insecticide(s), and are observed to provide ecological habitat for non-target aquatic species, the results reported here indicate that there is a potential for severe lethality to non-target aquatic species. Further review of the toxicological literature is required to set low and no effect levels, and or a baseline assessment is recommended. The results reported here can be used to qualitatively estimate the potential risk to aquatic species from washing or fishing with LLINs/ITNs in aquatic habitat with the **Minimum Volume of Water Required for Washing/Fishing with LLIN/ITN to Equal LC_{50}** metric.

Risk Characterization – Physical Stressors

The risks of adverse effects from physical stressors such as fishing/washing with LLINs/ITNs represent more of an uncertainty without site data on aquatic habitat. However, fishing/washing with LLINs/ITNs is similar to using a seine net, except perhaps on a smaller scale and with more rudimentary operation/construction techniques.

There are two types of seine nets: 1) purse seines and 2) beach seines. A purse seine encircles a school of fish in mid-water, close to the surface, by a netting wall with small meshes. The beach seine encircles fish schools by a netting wall, made of webbing with meshes small enough that the target species does not get entangled. The seine net is considered to cause less habitat destruction than other types of fishing gear. There is a certain risk of by-mortality with a purse seining method. By-mortality is the mortality of marine organisms caused by injury from the fishing gear during the fishing process. Pelagic fishes are in general sensitive to contact with fishing gears, which leads to loss of scales and results in mortality. There

may be some by-mortality associated with a beach seining method, as well (FAO, 2002). Based on the assumption that LLIN/ITN fishing/ washing is similar to seine netting methods, it is anticipated that LLIN/ITN fishing/washing has the potential to cause by-mortality to aquatic organisms that come in contact with the nets or to aquatic organisms that are damaged by the nets and manage to escape. By-mortality is expected to be caused by the damage from physical contact with the net, but could also be a result of disturbed habitat i.e., increased turbidity or damage to habitat structures necessary for abundant aquatic life. There is also the risk of the removal of fish species, "fishing-out", in aquatic habitats that are unable to replenish the populations of aquatic organisms necessary to support abundant life.

McClanahan et al., 2004 studied population density, species composition and lengths of fish landed by artisanal fisherman using six types of gear including beach seines, which is representative of the type of fishing with LLINs/ITN. This study found that of the six types of gear evaluated, the beach seine caught the smallest fish. Mangi and Roberts, 2006 report that artisanal fishing with beach seines landed significantly ($p<0.001$) higher percentage of juvenile fish (68.4%) compared to other types of gear indicating serious growth overfishing and implicating the beach seine as having the most impact on coral reef biodiversity. BlueVentures (2011) reports that in Madagascar, fisheries legislation prohibits the use of fishing nets below a mesh size of 25mm (Article 10, Decree 5 1922). They report that beach seine net fishing (Tarikaky) often uses large lengths (>500m) of illegal mesh size nets in an effort to capture the small fish that are missed by other larger meshed gill nets and that nets include mosquito nets, which are often in abundance following distribution programs by health agencies and NGO. They also report that the use of such nets has been documented to have serious implications for fisheries sustainability and ecosystem function (Dalzell 1996, McClanahan and Mangi 2004), and at a recent meeting of government officials, marine conservation organizations and community leaders in southwest Madagascar, beach seine net fishing was identified as the top threat to the sustainability of small-scale traditional fisheries in the region. Najmudeen and Sathiadhas, 2008 also report that in open access marine fisheries, the non-targeted catches in the form of juveniles are detrimental, as this reduces future yield and subsequent recruitment to the fishery.

In conclusion, the risk of adverse effects from physical stressors associated with fishing/washing with LLINs/ITN is potentially a risk as is the overfishing of key species in the aquatic ecosystem. The degree of adverse effects will depend on several factors that would need to be evaluated at the site. The factors to consider include: 1) the size of the body of water of concern, 2) the complexity of the aquatic habitat present (e.g., supports invertebrates, small fish, and/or large fish), and frequency of use for fishing/washing. A smaller body of water with aquatic habitat would be expected to suffer more physical stress than a larger body of water because there is less buffer for recovery (i.e., the majority of the area in a small body of water will be affected with each fishing/washing event).

5.3.6. SUMMARY

In summary, of the three specific risk scenarios evaluated in this PEA, the aquatic pathways were found to be at potential risk of adverse effects to non-target aquatic species under the exposure model assumptions and data considered here. Table 5-30 indicates the risk scenarios evaluated here, as well as the findings and recommendations for further action. A recommendation would be to observe the environmental setting and characteristics of human use of larvicides and fishing/washing with LLINs/ITNs in surface water bodies in various representative locations to determine if a chemical and/or physical stress risk is plausible for these scenarios. Because this SLERA is somewhat generic, this recommendation assumes a qualitative assessment will be made in the SEA based on the professional judgment of environmental assessment expert prior to allowing larviciding or fishing/washing with LLINs/ITNs in surface water bodies at a site. There are specific methodologies within EPA to use to determine site-specific ecological risk including an ecological scoping checklist.

A basic ecological habitat-scoping checklist includes evaluating whether the surface water body is in an area that is highly disturbed by human habitation i.e., not suitable for supporting a healthy aquatic ecosystem. Risks of adverse impacts from larviciding and or fishing/washing with LLINs/ITNs are not an issue in disturbed areas. In such areas aquatic fish and invertebrate species will not be observed. If the surface water body is not in an area that is highly disturbed by human habitation i.e., is suitable for supporting a healthy aquatic ecosystem, then risk of adverse impacts from larviciding or LLIN/ITN washing/fishing may be an issue and the nature of the habitat should be observed including data on the species present in the surface water, the volume of surface water, and the flow rate, if not a closed system. A healthy aquatic ecosystem would be a river or pond where plants and wild species are observed. In the case of LLIN/ITN fishing/washing, areas with breeding grounds for aquatic species should be avoided. Some examples of sensitive areas are coral reefs or grassy or sheltered shore areas that support juvenile species.

The DDT domestic livestock (chicken) scenario did not indicate a potential concern for adverse effects, however invertebrate consumption was not evaluated here due to lack of site DDT concentrations in invertebrates.

In general, the exposure and toxicity data used in the three risk models used in this screening assessment can be refined by obtaining site-specific data, particularly the existence of suitable habitat for aquatic species of concern

Table 5-30 Summary of Evaluated Exposure Pathways, by Pesticide and Activity

Activity	Exposure Route	Receptor	alpha-cypermethrin	DDT	deltamethrin	etofenprox	lambda-cyhalothrin	methoprene	permethrin	pyriproxyfen	spinosad	temephos
Post IRS	Ingestion	Chicken		NFA[2]								
Larviciding (spraying)	Whole body	Aquatic Organism						SSA		SSA	SSA	SSA
Washing/ fishing with LLINs/ITNs	Whole body	Aquatic Organism	SSA[1]		NTA[3]	SSA	NTA		SSA	SSA		

[1] SSA = Site –Specific Assessment. A site-specific assessment implies that the ecological habitat needs to be determined. If there is ecological habitat then further assessment of the site is required to characterize the potential risk posed by an activity.

[2] NFA = No Further Action

[3]NTA = No Toxicity Data

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5.4. HUMAN HEALTH AND ENVIRONMENTAL CONSEQUENCES – ENVIRONMENTAL MANAGEMENT

The environmental consequences associated with environmental management are location-specific. As a result, this PEA can only address the potential negative environmental impacts of environmental management interventions in a broad manner.

Because mosquitoes breed in shallow-water habitats, it is not surprising that most environmental management interventions for malaria control are associated with the manipulation of wetland environments. Wetlands can be broadly categorized as freshwater wetlands (which include swamps, flood plains, riverine forest, and swamp forest), mangroves, and coastal wetlands (including lagoons, estuaries, and tidal mudflats) (Shumway, 1999). In some geographical regions, there are also semi-arid grasslands, which maintain areas of temporary flooding. Wetlands provide a wide range of ecological services including soil erosion and flood control, water purification and pollutant and nutrient retention, groundwater discharge and recharge, and provision of habitat and breeding grounds for wildlife. Disturbing wetlands through environmental management may alter the quantity and quality of the services that wetlands provide.

When **wetlands are drained**, their soils lose infiltration capacity. As a result, there is potential for increased surface water runoff and soil erosion. **Clearing of wetland vegetation** can also cause (or exacerbate, if the wetland has been drained) increased surface water runoff and soil erosion. By eliminating the flood storage function of wetlands also increases the risks of flooding. Increased water runoff decreases the amount of water available to groundwater and surface water systems (groundwater constitutes a portion of stream flow, river flow, and sometimes pond depth). This can affect the *availability* of groundwater and surface water for human use throughout the year. It can also reduce the quality of water sources (groundwater and surface water) used for drinking and increase the need for expensive water treatment infrastructure to replace naturally –occurring ecosystems services.

Increased water runoff (or, alternatively, a change in the composition or clearing of wetland vegetation) may also decrease the ability of the wetland to take up and /or transform pollutants and nutrients, potentially diminishing the *quality* of water resources. When excess nutrient enter the stream a as result, they may promote growth and success of mosquito larvae. Increased water runoff may also cause higher peak water flows in streams and rivers during rain events which can eliminate a range of steam habitats. This can dramatically alter the composition of stream macro-invertebrates that support food chains, which in turn may negatively impact populations of economically and nutritionally importance species of fish as well as reduce the abundance and diversity of species that prey on mosquitoes and mosquito larvae (such as amphibians and dragonflies). Increase in water flow may also either increase or decrease the mosquito breeding habitat and may also cause flood damage.

Soil erosion can cause siltation and sedimentation of water bodies, including dams and retention ponds. Soil erosion can reduce the life of dams, and may change the conditions for transport and hydropower production. Soil erosion can also decrease agricultural productivity. Agricultural productivity may also decrease as a result of increased soil acidity following wetland drainage.

Draining wetlands or clearing vegetation may decrease habitat and forage for animal species, and consequently decrease plant and animal biodiversity in the ecosystem, which may decrease the abundance and diversity of flowering species that support pollinators. These pollinators may be important for supporting agricultural crops and natural food chains. Of particular concern may be breeding habitat for migratory birds and animals. In wetlands, vegetation clearing may also decrease spawning ground for aquatic species.

Tree planting may decrease habitat and forage for some animal species (e.g., aquatic species), while increasing it for others (e.g., some bird species). Thus, tree planting changes the ecosystem composition, and may increase or decrease plant and animal biodiversity. This change in ecosystem composition may also decrease the ability of the wetland to take up pollutants, potentially diminishing the quality of water resources. Because *tree planting is used to drain wetlands through transpiration*, groundwater and surface water resources available for human use may decrease.

In a similar manner, the **construction of deep impoundments** may decrease habitat and forage for some species (e.g., terrestrial), while increasing it for others (e.g., aquatic). Impoundments may increase the availability of water resources for upstream communities, but may decrease water availability for downstream communities. Depending on their construction and location, they may increase or decrease infiltration into the groundwater system.

Saltwater flooding may decrease habitat and forage for freshwater aquatic and terrestrial species. It may also decrease the availability of freshwater resources in the target community.

Larvivorous fish are often introduced into commercial fishponds without negative environment impacts. However, the introduction of exotic fish species into the natural environment (e.g., wetlands and marshes) should only be conducted following approval by the USAID Bureau Environmental Officer (BEO). The introduction of exotic (and potentially invasive) fish into a natural environment could disrupt existing predator–prey relationships and alter ecosystem composition.

Lining water sources and canals, in addition to increasing the risk of flooding, my also eliminate habitat for aquatic macro-invertebrates that support natural food chains and decompose organic matter.

Table 5-29 Ranking of Environmental Management Interventions from Low Impact to High Impact

Impact Rank	Environmental Management Interventions	Potential Negative Impacts
Little or No Impact	Deepening/narrowing of existing drains	No significant impacts
Little or No Impact	Synchronized cropping/intermittent irrigation	No significant impacts
Low Impact	Filling breeding sites	Increased or decreased habitat and forage for animal species
Low Impact	Lining water sources and canals	Increased flooding
Medium Impact	Saltwater flooding	Reduction in water availability Decreased habitat for freshwater aquatic and terrestrial species
Medium Impact	Larvivorous fish introduction	Altered ecosystem composition on a small or large scale (invasive species problems) Increase or decrease in biodiversity
High Impact	Impoundment construction	Altered upstream and downstream water availability Increased or decreased habitat and forage for animal species Increase or decrease in plant and animal biodiversity Altered ecosystem composition
High Impact	Biological drainage	Reduction in water availability Reduction or enhancement of water quality Increased or decreased habitat and forage for animal species Increase or decrease in plant and animal biodiversity Altered ecosystem composition

Impact Rank	Environmental Management Interventions	Potential Negative Impacts
High Impact	Vegetation manipulation	Reduction of water availability Reduction in water quality Increased flooding Siltation and sedimentation of water bodies, including dams and retention ponds Change in conditions for transport and hydropower production Decreased agricultural productivity of soil Increased or decreased habitat and forage for animal species Increase or decrease in plant and animal biodiversity Alteration of ecosystem composition
High Impact	Physical drainage	Reduction in water availability Reduction of water quality Increased flooding Siltation and sedimentation of water bodies, including dams and retention ponds Change in conditions for transport and hydropower production Decreased agricultural productivity of soil Increased or decreased habitat and forage for animal species Increase or decrease in plant and animal biodiversity Alteration of ecosystem composition

5.5. CUMULATIVE IMPACTS OF MALARIA VECTOR CONTROL INTERVENTIONS AND AGRICULTURE

Diversion of Malaria Pesticides for Agriculture Uses

A major problem faced by public health programs around the world is the diversion of public health pesticides to the private sector, primarily the agricultural sector but also private pest control enterprises. For multiple reasons, USAID support for malaria vector control using pesticides must ensure that public health pesticides are not diverted from their intended use in malaria vector control. First, public health pesticides may not be registered by the host country for alternative uses, or may be explicitly banned for any use beyond disease vector control (as is usually the case with DDT); thus, the use of the pesticide outside the program may be illegal. Second, individuals using diverted pesticides are probably untrained in appropriate application and unaware of mitigation precautions that should be taken to avoid exposure to the individual and the community. Such use may endanger the health of the individual, the health of others in the community, and the environment. Third, such use may affect the agricultural export market for certain goods (see the description of impacts on agricultural export markets, below). Fourth, the use of diverted pesticides may potentially increase the resistance of pests or disease vectors. Fifth, diversion of pesticides from their intended purpose increases the costs of the malaria vector control program. (2007 PEA)

Impacts on Agricultural Export Markets

Nations, trading groups of countries, and international institutions often define thresholds for pesticide residues present on agricultural commodities beyond which those commodities cannot be sold on the market. These thresholds are called maximum residue limits (MRLs). The MRLs of pesticides in food products intended for human or animal consumption are established and strictly enforced by some countries. The standards vary across countries and according to the type of pesticide, resulting in different requirements for exported agricultural products. The use of public health pesticides in the agricultural sector may increase the risk that agricultural exports exceed importing-country MRLs, thereby reducing economic gains from agricultural exports in the host country. This is of particular concern for DDT, which persists in the environment and accumulates in animal fat. International (CODEX) MRLs are provided in Annex J. The USDA Foreign Agricultural Service (USDA/FAS) hosts an online database containing MRLs for additional countries at

http://www.mrldatabase.com/. European Union MRLs can be found at http://europa.eu.int/comm/food/plant/protection/pesticideshttp://europa.eu.int/comm/food/plant/protection/pesticides.

The impact of public health pesticide use in communities that produce organic agricultural crops is of even greater concern than for those communities producing conventional agricultural crops. For example, in 2008, a consortium of Ugandan farmers that included the Coffee Traders' Federation, the Flower Exporter Association, the Fish Processors and Exporter Association, British America Tobacco Uganda, and the Horticulture Exporters Body, threatened to file a lawsuit against the Ugandan government for allowing the spraying of DDT for the IRS program. They feared that the spraying would contaminate the food and impact organic exports, worth about $500 million annually, if any traces of DDT were found. A blockage of these sales would be a severe flow to the economy.

The potential adverse economic impacts of the diversion of public health pesticides to the private sector must be addressed through monitoring and mitigation activities in the program. This may be achieved

through coordination with the Ministry of Agriculture (MOA), commercial producers, export associations, pesticide manufacturers, and nongovernmental organizations (NGOs).

Agriculture Pesticides use and Resistance Issues

In areas where large quantities of pesticides are used for agricultural crops, especially monocultures such as cotton, rice, and soybeans, resistance of mosquitoes may develop much faster. Resistance testing should be conducted in areas targeted for malaria vector control to help develop strategies tailored to the area. USAID support for malaria vector control should include capacity building for managing resistance and promoting coordination among MOAs, Ministries of Health (MOHs) and the Department of Agriculture to reduce vector or pest resistance prompted by agricultural or public health use of pesticides.

Agriculture Practices and Increase in Malaria

Human activity, including agriculture, has been recognized as one of the reasons for the increased intensity of malaria, because it supports the breeding of mosquitoes that carry the malaria parasite. Agricultural production systems, depending on the type of farming, farming practices, location of farms and farming technologies, could lead to environmental changes that create suitable ecological and climatic conditions for the breeding and survival of the anopheline mosquitoes, which transmit malaria.

Agricultural development has increased the need to water for crop and animal production. Water for agricultural production provides suitable habitat for breeding mosquitoes in and around water related infrastructure including reservoirs, canals, sprinkler systems, boreholes, wells, dugouts and bunds (used as receptacles to collect water during the rainy season) . Malaria transmission is therefore linked to agricultural water resources development. Malaria transmission is also linked to irrigation in rice cultivation. Rice fields are often flooded for long periods and therefore create standing water that allows a considerable multiplication of malaria vectors.

Though areas using irrigation are known to have high densities of mosquitoes, such high densitives may not automatically lead to higher malaria incidence among inhabitants. Agricultural development can result in increased incomes for communities, which would improve access to malaria treatment and use of malaria preventive measures. Other factors that account for low malaria rates in the irrigated communities include effective vector control programs, effective water management, and prevention intervention (IFPRI, 2009).

Agricultural development in Africa has contributed to land use changes that have resulted in the upsurge of malaria transmission in unstable malaria transmission areas. Significant agricultural practices such as urban agriculture, wetland cultivation, clearing of tropical forests and associated deforestation, and agricultural encroachment on highlands have been the primary drivers of malaria transmission in the affected areas. Malaria risks resulting from urban agriculture seems more pronounced in African cities because they have relatively more open space, abandoned lands, and cultivation compared with cities in other regions. Mosquitoes breed in temporary water pools in shallow, standing water in places where wet crops (cabbage, tomatoes and lettuce) are cultivated. Agricultural development is a major contributing factor to deforestation in tropical regions. While deforestation can reduce breeding habitats, changes in environmental and climatic conditions in the deforested region can also promote the survival of some anopheline species. Traditionally, most tropical highlands had little or no malaria. The increasing incidence of malaria in the highlands of Africa, especially in Eastern Africa, to a large extent has been attributed to agricultural practices that have resulted in changes in rainfall patterns, temperature, and vegetation (please see the section on climate change below). The mass movement of farm labor between highlands and malaria lowlands has been blamed for the serious malaria outbreaks in regions where tea and coffee plantations have been established. The reclamation of wetlands for cultivation has led to an increase in temperatures, promoting the breeding and survival of mosquitoes. In addition, because maize

pollen provides nutrition for mosquito larvae, in areas of high maize cultivation, studies have shown malaria to be about 10 times higher than in areas with less maize production.

The impact of malaria on livelihoods and agricultural productivity could be reduced depending on the agricultural and health support systems available to affected households. Given the current public recognition and political will in support of malaria eradication, more investment is needed for malaria research, especially in the linkages between agriculture and malaria. Agriculture is the mainstay of rural livelihoods. Yet there are some agricultural practices, such as irrigation, that inadvertently create the correct environment to support the vectors for the malaria parasite.

5.6. CLIMATE CHANGE

There is a consensus among climatologists that our planet is experiencing a progressive rise in surface temperature due to the increased production of "greenhouse" gasses. The Intergovernmental Panel on Climate Change predicts a rise of 1-3.5°C in global mean surface temperature by 2100. Several studies suggest that climate can affect infectious disease patterns because disease agents and their vectors are sensitive to temperature, moisture and other ambient environmental conditions. The extent of these effects continues to generate intense debate, especially in the projected effect of climate change on the global distribution of malaria, in which different modeling approaches have resulted in widely varying estimates.

Because temperature, precipitation and relative humidity are the main climatic factors that affect malaria transmission, they are the basis for the prediction of the effects of climate change on malaria. These relationships can be best understood in relation to the malaria life cycle. There are maximum, minimum and optimum temperatures (between 18°C - 32°C) for the development and survival of both the malaria parasite and the vector (i.e. the mosquito). The increases in temperature tend to show increases in feeding and egg laying frequency. The amount of precipitation affects the amount of surface water within which the vector can breed. Relative humidity (above 60%) lengthens the life of the mosquito, thereby helping the parasite complete the necessary life cycle so that it can transmit the infection.

Climate variability is widely considered to be a major driver of inter-annual variability of malaria incidence in Africa. The effects of temperature on both the vector and parasite of malaria are easily seen in latitudinal and altitudinal boundaries to malaria transmission. However, these boundaries seem to be changing as many highland areas have experienced malaria epidemics in the past few years. It has been hypothesized that increasing temperatures could partially explain the survival of malaria at higher altitudes. One projected scenario showed a potential increase of 5-7% in altitudinal malaria distribution with little increase in the latitudinal extents of the disease by 2100, although transmission may also decrease in other areas. The effect of the projected climate change indicates that a prolonged transmission season is as important as geographical expansion. At lower altitudes where malaria is already a problem, warmer temperatures will alter the growth cycle of the parasite in the mosquito enabling it to develop faster. This faster development will increase malaria transmission and therefore have implications on the burden of disease. Climate change could increase the epidemic potential of malaria in tropical countries currently susceptible to the disease.

In addition to climate change, there are other factors that may be responsible for changes in malaria incidence distribution that are important to note. These factors may include environmental modification (e.g. deforestation, irrigation, swamp drainage), population growth, limited access to health care, and lack of/or unsuccessful malaria control measures (Patz and Lindsay, 1999).

The findings from climate change studies have important implications for malaria control since both the duration and timing of the malaria transmission season are important to inform efforts in malaria control. Longer seasons allow heightened transmission and high levels of malaria infection in the population.

6. ENVIRONMENTAL MITIGATION AND MONITORING

6.1. MITIGATION AND MONITORING

Human health and environmental mitigation activities are intended to reduce adverse human health and environmental impacts that result from activity interventions. Mitigation measures can be categorized into the following types of actions: avoid impact, minimize or diminish effects, rectify or repair by rehabilitation, reduce or eliminate over time, or provide compensation. Monitoring is conducted to determine when mitigation is necessary and whether or not mitigation is working successfully. During implementation of the intervention, monitoring can identify negative human health or environmental impacts in time for mitigation measures to be adjusted or additional measures put in place. Therefore, monitoring is a necessary complement to the mitigation of negative human health and environmental impacts. Additionally, 22 CFR 216.3(a)(8) says that, "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 the environmental quality, positive or negative, during their implementation."

The following sections contain general recommendations for mitigation and monitoring activities in all operations, in addition to specific recommendations for IRS, LLINs, re-treatment of ITNs, environmental management, larvicidal agents and wall lining interventions. Although these recommendations represent best practices, host-country stakeholders should be involved in reviewing proposed mitigation and monitoring activities to ensure they are technologically appropriate, culturally suitable, and feasible. Mitigation and monitoring activities should then be adapted to the host-country situation without compromising human health and the environment.

6.1.1. MONITORING RECOMMENDATIONS

Several monitoring activities are recommended for the USAID Malaria Vector Control Program: mitigation monitoring, environmental impacts monitoring, entomological monitoring and resistance monitoring, and malaria case monitoring. Based on the results of these monitoring activities, adaptive management of intervention implementation and the overall vector control strategy should be a part of every intervention. Also, organophosphate biomonitoring should be included in every program that is using OPs. These activities are discussed in more detail below. It should be noted, however, that simply monitoring impacts is not sufficient—close communication and coordination between the monitoring staff, malaria control specialists, and decision makers is crucial to enacting mitigation activities successfully and managing the intervention appropriately. To the extent possible, mitigation plans should show causal linkage between the intervention and the negative consequences that may occur during or after implementation.

Mitigation Monitoring. Mitigation monitoring is used to determine if mitigation measures are being implemented and if those measures are effective in preventing or mitigating adverse environmental impacts. During the implementation, independent and implementing partner mitigation monitoring

should be used to assess the effectiveness of mitigation efforts at regular intervals (e.g., at the beginning of the intervention, at 25 percent completion, at 50 percent completion). Mitigation efforts should be adjusted to address any negative impacts on human health or the environment that are observed.

Environmental, Livestock, and Human Health Impacts Monitoring. Environmental impacts monitoring measures ecological change over time as a result of program interventions. This type of monitoring uses key environmental indicators (e.g., vegetation change, water quality, pesticide levels present in the environment, indicator species populations, depending on the intervention or pesticide used) and baseline surveys to determine the impacts of the interventions on target and non-target environmental areas. When pesticides are used, environmental impacts monitoring can also include the monitoring of impacts on domestic livestock. Livestock monitored may include chickens, ducks, geese, bees, fish, goats, cattle, and pigs. Additionally, human health effects from pesticide use can be monitored either indirectly, by using patches on the body to measure exposure, or directly, by sampling breast milk, urine or blood (depending on the pesticide). This type of monitoring could be implemented for both those who apply pesticide and community residents. An environmental monitoring plan for the environment, livestock, or human health should be developed using the following steps:

- Determine the reason for monitoring (e.g., assess the impacts of activity interventions, identify environmental impacts, and monitor mitigation measures)
- Formulate specific questions to be answered by monitoring
- Select indicators
- Determine the monitoring tools required to measure indicators
- Gather and integrate existing data (consider methods of data storage and analysis)
- Identify environmental "hot spots" (location of ecosystems and species at high risk)
- Design a sampling scheme
- Establish baseline conditions
- Establish targets for each indicator
- Validate the relationship between indicators and planned results
- Analyze trends and recommend management actions (e.g., environmental mitigation measures) (USAID, 1996)

Entomological Monitoring (and Resistance Monitoring). The primary function of entomological monitoring associated with vector management is to assure that interventions are effective in controlling the malaria vector. Such monitoring is essential for IRS and larval control and, though not as critical, should also be implemented in areas where LLINs/ITNs (and wall lining) have been deployed. Such monitoring will aid in the identification of resistance issues and the ensuing selection of appropriate pesticides and resistance management methods. The monitoring program must include at least the first three types of tests described below. The fourth category should also be included when possible.

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 IRS, susceptibility studies can be conducted by using the WHO susceptibility test, the WHO cylinder test with pre-impregnated filter papers with diagnostic does, or the CDC bottle assays on adults caught in the wild or adults reared from immature larvae. Although 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. Where possible, both the CDC assays and WHO tests should be done. Larvicides are generally tested for efficacy in small-scale field trials. 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 that code for pesticide resistance in the local vector population. Nevertheless, PCR analysis should not be used as a substitute for "in vivo" resistance analysis.

Verify that the insecticide was applied properly and had an immediate effect. This verification involves routine follow-up observations. For IRS, wall bioassays are used to verify that 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/LLINs, either with the same type of cone used on the wall, or by forming a "basket" with the treated netting. For larviciding, the routine inspection of treated breeding sites will verify that mosquito larvae are no longer present immediately after larvicide treatment and will detect new larvae when they are present.

Determine the geographic and temporal distribution of vector populations. To target areas where vector control for malaria is needed, it is necessary to determine where malaria transmission occurs and the length of the transmission season by establishing when populations of adult vectors are present. This can be done by using a variety of collection techniques, including human landing catches, CDC light traps, cattle-baited hut or net collections, nonbaited hut or net collections, pyrethrum spray catches (PSCs), and window exit traps.

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 are available for human landing catches, CDC light traps, cattle-baited hut or net collections, nonbaited hut or net collections, PSCs, and window exit traps.

Malaria Case Monitoring. Malaria case monitoring is conducted to assess the impacts of malaria control interventions on target human and mosquito populations. The information obtained from this impact monitoring can be used to determine if the interventions are achieving the desired results and to inform changes in the program.

Organophospate Biomonitoring. For most organophosphates, it will be necessary to monitor the level of acetyl cholinesterase in any worker who may have been exposed to contamination. Occupational exposures to OP insecticides are measurable using blood cholinesterases and urinary excretion of chemical biomarkers (please refer to **Annex N**). PMI will evaluate various approaches for monitoring sprayer exposure to Organophosphates (OP), and will develop protocols based on these evaluations. PMI will use these protocols to guide the implementation of the OP monitoring program.

6.1.2. MITIGATION RECOMMENDATIONS

Indoor Residual Spraying Recommendations

In many respects, IRS is operationally homogeneous. Much of the time, the same types of mitigation actions are recommended for IRS regardless of the insecticide used. These general recommendations are

listed in Table 6-1. Descriptions of some of the general recommendations and additional recommendations specific to certain classes of insecticide follow the table.

Table 6-1 IRS Recommendations

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Daily Operations	
Occupational exposure to insecticide from daily indoor residual spraying (IRS) operations	Training of spray operators, team leaders, and supervisors according to best practices, including recognition of insecticide-poisoning symptoms.
	Procurement and proper use of personal protective equipment (PPE) by spray operators, team leaders, and supervisors (cotton overalls, face mask, helmet with visor, hat or neck protection, rubber gloves, gum boots)
	Training of health workers in insecticide-poisoning treatment
	Procurement and distribution of treatment medicines for insecticide exposure
	Daily on-site personal washing (after spraying)
	Reprimand of spray operators who do not follow proper procedure in all aspects of operations (handling, spraying, hygiene, cleanup)
	Training of wash persons (can be spray operators) for proper washing of overalls (PPE).
	Frequent washing of overalls (after spraying)
	Procurement and wearing of PPE by wash person (cotton overalls, chemical apron, rubber boots, rubber gloves, face masks)
	Procurement and distribution of barrels for progressive rinse, and wash-tubs for overall washing and personal hygiene
	Progressive rinse of spray pumps
	Development and implementation of a human health monitoring plan to determine pesticide impacts on spray operators and residents, particularly when using organophosphates.
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Fetal exposure to insecticide from daily IRS operations (female spray operators)	When dichloro-diphenyl-trichloroethance (DDT) is used, institute prohibitions of hiring women of child-bearing age as spray operators.
	Ensure that pregnant or breast-feeding women are not hired as spray operators

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Pregnancy tests prior to every spray campaign
Community and environmental exposure to insecticide from daily IRS operations	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 1 hour after spraying
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
	Prohibition of spraying in protected areas/sensitive ecosystems (e.g., uncultivated wetlands), 100 meters from open bodies of waters, or near beehives.
	Prohibition of spraying in homes where food and utensils have not been removed from the house, and where furniture has not been removed from the house *or* moved to the middle of the room and covered with a tarpaulin by the spray operator
	Information, education, and communication (IEC) campaign, citing importance of removing all food and utensils from house prior to spraying, moving furniture to the center of the room or outside, staying out of the house during and 2 hours after spraying, not allowing children or animals in the house until floor residue is swept and disposed of in a latrine or buried outside, educating about potential impacts of insecticide on domestic animals (e.g., chickens eating insects killed by carbamates)
	Procurement of seat covers or sheets for covering cloth vehicle seats
	Covering of cloth interior seats of program vehicles with seat cover or cloth to prevent seat contamination
	Use of gloves for washing interior and exterior of program vehicle
	Wiping of contaminated bed of truck with damp cloth prior to exterior washing of program vehicles
	End-of-program cleaning/decontamination of interior and exterior of vehicle, according to the United Nations Food and Agriculture Organization's (UNFAO) *Pesticide Storage and Stock Control Manual*
	End-of-campaign washing of seat covers and wiping of seats/bed of program vehicle with damp cloths
	Prior to spraying, covering furniture with tarpaulin that cannot be moved from the house
	Reprimand of spray operators who do not follow proper procedure in all aspects of operations (handling, spraying, hygiene, cleanup)

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Frequent washing of tarpaulin used to cover furniture
	Training of spray operators, washers, storekeepers, drivers, team leaders, and supervisors according to best practices
	Procurement and distribution of barrels for progressive rinse and wash-tubs for overall washing and personal hygiene
	Progressive rinsing of spray pumps and washing of PPE
	Procurement and distribution of materials necessary for collection and decontamination of washtub rinse-water in soak pit
	Daily collection of laundry rinse-water for disposal in soak pit
	Analysis of contaminated rinse-water to determine levels of active ingredient
	Storage and stock management of all insecticides, empty packaging, barrels, and tubs in storage facilities, reducing use of contaminated goods domestically
	Inscription of all program barrels and tubs as District Health Office property, and labeling with host-country-specific poison indicators, to deter sale and domestic use (e.g., storage of food or water for human or animal consumption) in the event of pilferage
	Secure storage of contaminated plastic sachets for recapture by the manufacturer or disposal at an internationally recognized hazardous waste incinerator
	Shredding or puncturing of plastic packaging materials, making them unusable (unless barrels used for progressive rinse)
	Local disposal of noncontaminated cardboard or paper packaging
	Transport of uncontaminated packaging materials to a landfill for disposal, or a power plant or cement kiln for reuse as fuel
	Transport contaminated wastes to approved incinerator for incineration
	Development and implementation of environmental and/or livestock monitoring plan to the extent "feasible" and "relevant"
	Development and implementation of a human health monitoring plan to determine pesticide impacts on spray operators and residents, particularly when using organophosphates
	Development of protocol for decision making when environmental monitoring indicates environmental or agricultural contamination as a result of IRS
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Special Circumstances	

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Pilferage of insecticide, consequential human and environmental exposure	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Double-padlocking and guarding of all storage facilities
	Supervision of spray operators
	Pesticide sachet tracking using stock card records, from distribution to empty sachet (waste management)
	Development and implementation of environmental monitoring plan
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Storehouse fire, inhalation of toxic fumes from insecticide fire	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Procurement and distribution of emergency equipment to insecticide storage facilities
	Training of storekeepers according to FAO guidelines
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Accidents and spillage during transport and storage, leading to human and environmental exposure	Training of drivers for long-distance transport of insecticide and short-distance transport during the campaign period
	Transport of centrally-stored insecticides according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Emergency equipment located in storage facilities
	Storekeeper training for all insecticide storage facilities, both temporary and permanent

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Training of health workers in insecticide-poisoning treatment
	Procurement and distribution of treatment medicines for insecticide exposure
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Flooding of storehouse, leading to environmental contamination	Storage facility sites located on high ground, outside of floodplain
Insecticide Quality and Resistance	
Decreased effectiveness of insecticide, lessening impact on malaria incidence	Selection of insecticide to minimize resistance and maximize residuality on surfaces sprayed
	Laboratory testing of insecticide to ensure quality control
	Entomological monitoring of resistance
	IEC campaign, citing importance of not plastering or painting walls after the home has been sprayed
	Data recording on agricultural insecticides for the purpose of knowing how they may contribute to resistance
	Proper insecticide storage by renovation of storage facilities
	Training of spray operators in proper application for specific wall types (e.g., uniform spray speed, constant and accurate spray distance)
	Procurement and use of sprayers manufactured according to WHO specifications
	Daily sprayer maintenance
	Development and implementation of environmental reporting system for Human Health and Environmental Evaluation Report (see Section 6.2)
Future Activities	
Indirect support of malaria vector control operations that have not undergone environmental review through procurement of sprayers and storage facilities	Importance of an environmental assessment for any pesticides used in IRS will be discussed with MOH and Ministry of Environment staff and online resources for conducting assessments will be provided (http://www.encapafrica.org/)
Adaptive Management (potentially reducing pesticide use for malaria vector control)	Development of a strong malaria surveillance system to target IRS interventions, reducing pesticide use
	Study resting behavior of the target species, so the appropriate surfaces are targeted.
	Pursuit of an integrated strategy involving environmental management and larviciding

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Development of protocol/implementation of measures to mitigate mosquito resistance to insecticides (pesticide rotation or mosaic)
	Submission of Human Health and Environmental Evaluation Report to USAID Contractor, USAID Mission Environmental Officer (MEO), USAID Regional Environmental Officer (REO)

IRS Activities: The following are general mitigation recommendations for IRS activities:

Hygiene Regimen. Scrupulous attention to personal hygiene is an essential component of the safe use of pesticides. For professional spraying staff operating in the tropics, the safety precautions might depend largely on personal hygiene, including washing and changing clothes. A drill for carrying out and supervising personal hygiene, regular washing of protective clothes and cleaning of equipment should be organized along the following lines:

- 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.
- Working clothes must be washed regularly, the frequency depending on the toxicity of the formulation used.
- 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.
- When work involves insecticides of relatively high toxicity (DDT and pirimiphos-methyl), the hours of work must be arranged so that exposure to the material is not excessive; transport should be arranged so that there is not a long delay between the end of the day's operations and return to base for washing.

For some of the older pesticides, washing with soap can increase dermal absorption from contaminated skin. This underlines the importance of avoiding exposure.[8]

Protocol for Pesticide-Poisoning Treatment. The pesticides supported by USAID for IRS have been fully evaluated by the WHO Pesticide Evaluation Scheme (WHOPES) and can safely be used for malaria control in safe and effective quantities by sprayer operators who are adequately protected from the potential toxic effects. To assure minimum risk of pesticide poisoning, any USAID-sponsored IRS program must assure appropriate safety standards for handling, storing, and disposing of pesticides, as described in Table 6-1. Safety supervisors, entomologists, and medical specialists should be aware of the:

[8] WHO Pesticides and their Application for the control of vectors and pests of public health importance. 2006

- The mode of action of the pesticide
- The significance of diagnostic measures
- Recognition of the signs and symptoms of toxic effects; and
- The facilities required for treatment of cases of poisoning (WHO, 2006)

The program must assure that spray operators are trained to identify the signs and symptoms of poisoning and to use emergency first aid techniques, including resuscitation. "All workers should know the hazard of the work they are required to carry out. They should understand the real risks involved and should not be led astray by erroneous preconceptions" (WHO, 2006; 13). Because the treatment for poisoning is specific to each pesticide, country-specific treatment and referral guidelines must be developed based on the specific insecticides being used and the local capacity for poisoning treatment. To assure that appropriate treatment is available in the event of poisoning, the program must assure that country-specific exposure treatment guidelines are developed. Country-specific guidelines should include

- General principles in the management of acute pesticide poisoning
- First-aid procedures and training strategy for spray operators
- Identification of appropriate treatment facilities and assurance that treatment drugs are available (where necessary, the program should provide training to local medical staff to assure that the capability to provide appropriate treatment is established, procure appropriate treatment drugs if not available, and prepare treatment guidelines for the specific country setting and pesticides being used)
- Determination of referral process (transportation of exposure victim, communication with facilities)

In addition, the program should assure financial support for any medical costs incurred in managing or treating the toxic effects of exposure to pesticides used in the program.

The program country-level technical manager will be responsible for an evaluation of the capacity of local facilities to treat poisoning by the pesticides being used, including identification of a referral hospital if treatment for exposure cannot be adequately provided for by local health clinics. The institution implementing the program should assure that appropriate short-term technical assistance is provided by the program to provide necessary training of local medical staff.

Guidelines for treatment of poisoning from IRS insecticide are located in ***Annex I.*** These guidelines are adapted from the U.S. Environmental Protection Agency's (EPA) *Recognition and Management of Pesticide Poisonings* and WHO's report, *Malaria Vector Control: Insecticides for Indoor Residual Spraying*.

Training of Drivers. Prior to long-distance transport of the pesticide from the customs warehouse/central storage facility to the target area, drivers should be informed about general issues surrounding the pesticide and how to handle emergency situations (e.g., road accidents). Training for long-distance transport will include the following information:

- For what use the pesticide is intended
- Toxicity of the pesticide
- Understanding security issues, implications of the pesticide getting into the public
- Handling an accident or emergency (according to the United Nations Food and Agriculture Organization's (UNFAO) *Pesticide Storage and Stock Control Manual*)

- Combustibility and combustion byproducts of pesticide

Drivers hired specifically for the 2-month spray campaign period will receive

- Training provided to spray operators (with the exception of sprayer operation and spray practice)
- Training on handling an accident or emergency (according to UNFAO's *Pesticide Storage and Stock Control Manual*)
- Training on handling vehicle contamination (see below)

If vehicles are expected to be used for purposes other than malaria vector control after 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). Drivers should be responsible for taking care that any cloth vehicle seats are covered to prevent contamination from transportation of spray operators. To prevent pesticide runoff from vehicle washing, drivers should also be responsible for wiping the vehicle bed with a damp cloth prior to washing the exterior of the vehicle. Finally, drivers should be responsible for cleaning and decontaminating the interior of the vehicle and exterior bed at the end of the spray campaign. Drivers should 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.

Packaging Disposal Protocol. Noncontaminated 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 or incinerated at an PMI country program approved incinerator. Table 6-2 provides a list of approved incinerators located in most of the PMI countries.

Table 6-2. Approved Country Incinerators

Country	Incinerator
Angola	RicoLix Facility (in Luanda)
Benin	Hospital incinerator in Atacora-Languieta Hospital
Burkina Faso	Health Center (in Diebougou)
Ethiopia	2 mobile incinerators procured by PMI
Ghana	Incinerator owned by government research institute in Kumasi
Liberia	UN Facility
Madagascar	Private Incinerator registered by the government of Madagascar and owned by a company called Adonis
Mali	1 mobile incinerator procured by PMI

Country	Incinerator
Mozambique	DDT waste shipped to South Africa; Non DDT wastes disposed at a private hazardous waste disposal plant called Enviroserve and operated by South Africans.
Rwanda	Kanombe Military Hospital
Senegal	Regional Hospital incinerator in Dourbel region
Zambia	Repatriation to S. Africa (as DDT use); Non DDT wastes incinerated in government approved incinerators
Tanzania	Privately owned and government certified incinerator in Mwanza: PMI intends to procure an incinerator for Zanzibar
Kenya	Government registered hazardous waste disposal facility and privately owned
Uganda	Nakasongola Military Base
Malawi	St. Gabriel Hospital incinerator

Expired pesticides should be returned to the manufacturer. These wastes can also be shipped to Pretoria to be incinerated at Thermopower Process Technology (PTY) LTD of South Africa. Contaminated wastes can also be disposed of in other incinerators that meet the required specifications.

Progressive Rinse Method. Progressive Rinse is an effective method for rinsing out the spray pumps at the end of each day that minimized the use of water. Seven barrels are placed in a line. The first barrel is empty, the second full of water, the third empty, and so on. Leftover pesticide from the day's operations is dumped in the first barrel, water from the second barrel is used to rinse the sprayer, and then poured into the empty third barrel. Water from the fourth barrel is used for a second rinsing of the sprayer, and is then poured into the empty fifth barrel. This continues until the last rinse water is poured into the last barrel. The contaminated rinse water is then used to fill up the sprayers in the next day's spraying. The water that is not reused in disposed of in a properly constructed soak pit. This method reduces environmental contamination from sprayer rinse-water.

Triple-Rinse Method. Triple rinse is the recommended method for rinsing out empty pesticide containers. A measured amount of water or other specified dilutant is added to the container so that it is one-fifth to one-fourth full. Rinse container thoroughly, pour into a tank, and allow it to drain for 30 seconds. Repeat three times. The water rinsate can be used to mix with or dilute more of the same pesticides or it can be sprayed on a wall. Water that is not reused in disposed of in a properly constructed soak pit.

Double-Padlocking. Storage facilities should have two separate locks on all exterior doors to prevent pilferage or unauthorized entry. The key to one lock is given to the storekeeper and the key to the other lock is given to a second responsible person in a supervisory position.

IRS Pesticides: The following are considerations for the handling of specific IRS pesticides:

Pyrethroids. For lambda-cyhalothrin, hydrolysis can be used to decontaminate containers or packaging material by using a 1:1 mixture (by volume) of:

- either 5 percent sodium hydroxide (caustic soda) solution or saturated (7–10 percent) sodium carbonate (washing soda) solution; and
- a water/oil soluble solvent, such as denatured alcohol, monoethylene glycol, hexylene glycol, or 2-propanol.

Cover the contaminated surface with this hydrolyzing agent and leave it for seven days (in a secure place to avoid pilferage). Before the resulting waste is disposed of, it must be analyzed to ensure that the active ingredient has been degraded to a safe level (IPCS, 1990).

Carbamates. Empty carbamate containers can be neutralized by adding alkaline substances. The following procedure is recommended for 200-liter barrels; use proportionally less material for smaller containers:

1) Add 20 liters of water, 250 milliliters of detergent, and 1 kilogram of flake lye or sodium hydroxide.
2) Close the barrel and rotate to wet all surfaces.
3) Let stand for 15 minutes.
4) Drain completely and rinse twice with water. The rinsate should be drained into a shallow pit in the ground located far away from wells, surface water, or inhabited areas.

Containers cleaned by any of the above methods are still not safe to use for any other purpose. Glass containers should be broken and plastic or metal containers punctured or crushed. Containers can then be buried in an isolated area at least 50 cm below ground surface.

Like the dose of DDT, the dose of propoxur required for use in IRS is 1–2 g/m^2, making packaging of propoxur charges in water-soluble sachets infeasible. As a result, there are several operational implications that should be considered in addition to the mitigation measures listed in Table 6-1. First, propoxur charges need to be emptied into a bucket and stirred to assure that it dissolves into solution before being poured into the spray tank. These buckets and stirrers must be used exclusively for the IRS program and not for any domestic purposes. Second, funnels may be needed to prevent spillage of the propoxur charge when it is being poured into the tank. Third, because propoxur sachets are insoluble, they need to be exported for disposal at an internationally recognized hazardous waste incinerator or returned to the manufacturer.

Organophosphates. When organophosphates are used, cholinesterase activity must be tested prior to the start of spraying and once per week during the spray campaign for all personnel exposed to the insecticide. Spray operators should cease their participation in the spray campaign if their cholinesterase activity decreases to 50 percent or more of their baseline cholinesterase activity (WHO, 2006). **PMI will evaluate various approaches for monitoring sprayer exposure to OPs, and will develop protocols based on these evaluations. PMI will use these protocols to guide the implementation of the OP monitoring program.**

Empty organophosphate containers should be triple-rinsed with water and scrubbed inside thoroughly with a household detergent. "Drums that contained an organophosphate should be given an additional rinse with washing soda at 50 grams per liter (5%) and the solution should be allowed to remain in the container overnight" (WHO, 2006; 15).

The dose of fenitrothion, malathion, or pirimiphos-methyl required for use in IRS is also quite large, making packaging of organophosphate charges in water-soluble sachets infeasible. As a result, there are several operational implications that should be considered in addition to the mitigation measures listed in

Table 6-1. First, the charges need to be emptied into a bucket and stirred to assure that the pesticide dissolves into solution before being poured into the spray tank. These buckets and stirrers must be used exclusively for the IRS program and not for any domestic purposes. Second, funnels may be needed to prevent spillage of the charge when it is being poured into the tank. Third, because the sachets are insoluble, they need to be exported for disposal at an internationally recognized hazardous waste incinerator or returned to the manufacturer.

With regard to storage, EPA recommends that malathion be stored at a temperature of 21°C or lower to prevent degradation of the product to its more toxic product, isomalathion. The need for such storage conditions must be considered when planning an IRS campaign using malathion.

DDT. Environmental monitoring must always be conducted when USAID supports DDT use in IRS operations; this is primarily because it is persistent in the environment, bioaccumulates in animals and humans can cause harm to wildlife, and has serious implications for agricultural trade. Fortunately, the characteristics of DDT that make it environmentally damaging also make it easy to monitor. Additionally, because DDT use is widely banned in the agricultural sector, increases in levels of DDT in the environment can more easily be attributed to its use in IRS (or improper use after any pilferage of DDT intended for IRS).

The dose of DDT required for use in IRS is also quite large, making packaging of DDT charges in water-soluble sachets infeasible. As a result, there are several operational implications that should be considered in addition to the mitigation measures listed in Table 6-1. First, DDT charges need to be emptied into a bucket and stirred to assure that the insecticide dissolves into solution before being poured into the spray tank. These buckets and stirrers must be used exclusively for the IRS program and not for any domestic purposes. Second, funnels may be needed to prevent spillage of the DDT charge when it is being poured into the tank. Third, because DDT sachets are insoluble, they need to be exported for disposal at an internationally recognized hazardous waste incinerator or returned to the manufacturer as per International Treaties for the handling of POPs.

<u>The following are special considerations when using DDT in the IRS program:</u>

WHO has approved twelve insecticides for use in IRS for malaria control. DDT is unique among these insecticides, as it is a persistent organic pollutant (POP); as stated by the Stockholm Convention, POPs such as DDT "possess toxic properties, resist degradation, bioaccumulate and are transported, through air, water, and migratory species, across international boundaries and deposited far from their place of release, where they accumulate in terrestrial and aquatic ecosystems."

The Stockholm Convention places the following **requirements** on Parties to the Convention as stated in Annex B Part II:[9]

1) Notify Stockholm Secretariat and WHO of production and/or use of DDT
2) Restrict production and/or use to disease vector control
3) Produce and/or use DDT in accordance with WHO recommendations and guidelines
4) Use DDT only when locally safe, effective, and affordable alternatives are not available—"Factors to be promoted when considering alternatives or combinations of alternatives shall include the human health risks and environmental implications of such alternatives. Viable alternatives to DDT shall pose less risk to human health and the environment, be suitable

[9] Requirements and recommendations from the Stockholm Convention have been paraphrased for easy reading. Please see the complete text of the Convention at www.pops.int for the precise wording of the text.

for disease control based on conditions in the [countries] in question and be supported with monitoring data."

5) Report on production and/or use of DDT every three years (reporting requirements found at www.pops.int every 3 years. (See Annex K)

In addition, Article 7 of the Stockholm Convention requires that Parties must "develop and endeavor to implement a plan for the implementation of [their] obligations under this Convention." These plans are called national implementation plans (NIPs).

The Stockholm Convention also lays out the following **recommendations**, "with the goal of reducing and ultimately eliminating the use of DDT":

1) Each Party using DDT should develop and implement an action plan as part of its NIP. That action plan should include:

    a. Development of regulatory and other mechanisms to ensure that DDT use is restricted to disease vector control

    b. Implementation of suitable alternative products, methods, and strategies, including resistance management strategies to ensure the continuing effectiveness of these alternatives

    c. Measures to strengthen health care and to reduce the incidence of the disease.

2) All Parties to the Stockholm Convention, within their capabilities, should promote research and development of safe alternative chemical and nonchemical products, methods, and strategies [for vector control].

As a signatory to the Stockholm Convention, the U.S. Government is committed to ensuring that its support of DDT in developing countries is consistent with Stockholm Convention requirements and recommendations, as well as NIPs prepared by the host countries. Thus, USAID will support the following planning, program, and environmental compliance activities where it supports DDT use in disease vector control:

1) *USAID will base its support of insecticides used in disease vector control on a rational selection process* considering the insecticide's effectiveness in reducing or repelling the vector; risk to human health, the environment, and the agricultural and trade sectors; acceptability in the host country; cost; the need for resistance management; and other considerations.

2) *USAID will only provide support of DDT to Parties that have notified the Stockholm Secretariat and the WHO* of their production and/or use of DDT and that restrict DDT use to disease vector control.

3) *All USAID support of DDT use will follow WHO recommendations and guidelines.*

4) *USAID will assist host-country governments in re-examining the need for DDT* based upon the best available information and in identifying the best choice for IRS chemicals, considering safety, effectiveness, and affordability in accordance with Annex B, Part II of the Stockholm Convention. The selection of alternatives or combination of alternatives for malaria control will take into consideration human health risks and environmental implications; viable alternatives to DDT should pose less risk to human health and the environment, be suitable for disease control based on Stockholm Convention Party–specific conditions, and be supported with monitoring data.

5) *USAID will regularly review and revise SEAs pertaining to DDT every year,* to ensure that USAID support remains consistent with stipulations in Annex B, Part II of the Stockholm Convention, the host-country NIP, and Stockholm Convention Party reporting requirements for DDT use.

6) *When local capacity is insufficient, USAID will assist host-country governments in conducting activities to fulfill Stockholm Convention reporting requirements.* To receive USAID support for use of DDT in IRS, the host country must demonstrate concerted effort in developing and following a NIP as well as reporting to the Stockholm Secretariat.

7) *USAID will support the monitoring of DDT in the environments where it is sprayed.* According to CFR 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."

8) *When local capacity is insufficient, USAID will facilitate appropriate disposal of DDT-contaminated waste* resulting from IRS operations in accordance with the Basel Convention and other relevant regional and international treaties.

LLIN Recommendations

Overall, there are few impacts associated with the use of LLINs, though there are more impacts from the misuse of LLINs. **PMI will work with international organizations to develop a strategy/system to manage net waste. In addition, information to net users will address unintended uses of nets and should be tailored to reflect the local environment.** Table 6-3 includes mitigation recommendations for proper use and methods to mitigate misuse.

Table 6-3 LLIN Recommendations

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Efficacy of LLINs	
Environmental and human health Exposure to LLIN pesticide from washing LLIN	Training of residents in correct method for washing mosquito net (as per WHO guidelines)
	Human behavior monitoring and post distribution follow-up campaigns (to determine need for behavior change training)
Misuse of LLINs	
Community and environmental exposure to LLIN pesticides from using nets for other uses than intended	Training of residents on proper use of the mosquito net
	Human behavior monitoring and post distribution follow-up campaigns (to determine need for behavior change training)
	Development and implementation of environmental monitoring plan (to determine pesticide impacts on the environment)
	Development and implementation of a human health monitoring plan (to determine pesticide impacts on residents)
Special Considerations	
LLIN intervention	Training for implementation following "cascade pattern" to address the needs of the different levels of the delivery system.
Storehouse fire, inhalation of toxic fumes from LLIN fire	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Procurement and distribution of emergency equipment to LLIN storage facilities
	Training of storekeepers
	Development and implementation of environmental reporting system
Flooding of storehouse, leading to environmental contamination	Storage facility sites located on high ground, outside of floodplain
Insecticide Quality and Resistance	
Decreased effectiveness of LLIN, lessening impact on malaria incidence	Random Laboratory testing of LLIN to ensure quality control
	Entomological monitoring of resistance
	Data recording on agricultural pesticides for the purpose of knowing how they may contribute to resistance
	Construction or renovation of storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Collection and redistribution of new nets, once nets are no longer viable	Development and implementation of collection and disposal plan during redistribution campaigns
Future Activities	
Indirect support of LLINs that have not undergone WHOPES review	Preparation of PEA Amendment to address new LLINs
Adaptive Management	Development of a strong malaria surveillance system to target interventions, reducing pesticide use
	Pursuit of an integrated malaria vector management strategy
	Development of protocol/implementation of measures to mitigate mosquito resistance pyrethroids
	Submission of Human Health and Environmental Evaluation Report to USAID Contractor, USAID Mission Environmental Officer, USAID Regional Environmental Officer

Re-Treatment of ITNs Recommendations

The impacts for ITN use are the same as for LLINs (please see table 6-3). The re-treatment process has more specific impacts for ITNs. Table 6-4 includes mitigation recommendations for proper re-treatment procedures.

Table 6-4 ITN Re-Treatment Recommendations

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Retreatment of ITNs	
Exposure to insecticide from mixing pesticides and treating nets	Provide training or instruction (verbal, written, and/or pictorial) on the proper procedures
	Wear appropriate gloves, used once and discard; if gloves are to be used again for treating nets, wash before removing
	Mix solution and treat the net according to directions, including proper procedures for hanging the net to dry
	Do not touch face or others while wearing contaminated gloves
	Dispose of left over solution appropriately
	Wash basin with soap and water
	Properly dispose of pesticide containers and used gloves

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Wash hands and contaminated clothing thoroughly once treatment has been completed
	Treat net outside under shade or with open windows
Accidental ingestion	Provide training on proper storage and dangers of pesticide poisoning

Larvicidal Agent Recommendations

Table 6-5 lists recommendations for mitigation for larviciding. It is important to note that larviciding can decrease the need for other pesticide-based interventions, which decreases the potential for harm to human health and the environment from pesticide use. Additionally, "persons applying larvicides are generally much less exposed than staff engaged in indoor house treatment, and exposure is confined mainly to the hands and arms" (WHO, 2006).

Table 6-5 Larviciding Recommendations

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Daily Operations	
Occupational exposure to larvicide from daily operations	Training of spray applicators and supervisors according to best practices.
	Procurement and proper use of personal protective equipment (PPE) by applicators (cotton overalls, face mask, rubber gloves)
	Training of health workers in pesticide-poisoning treatment
	Procurement and distribution of treatment medicines for pesticide exposure
	Reprimand of applicators who do not follow proper procedure in all aspects of operations (handling, application, hygiene, cleanup)
	Procurement and distribution of barrels for progressive rinse and wash-tubs for overall washing and personal hygiene
	Progressive rinse of sprayers and other types of applicators
	Development and implementation of a human health monitoring plan (to determine pesticide impacts on applicators and residents)
Fetal exposure to larvicide from daily operations (female applicators)	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
	Women prohibited from conducting organophosphate (temephos) application while pregnant or breastfeeding
Community and environmental	Care should be taken in deciding when to spray to avoid

Potential Negative Activities/Impacts	Recommended Mitigation Actions
exposure to larvicide from daily operations	larviciding before major storm events
	Care should be taken in deciding where to spray to avoid bodies of water used as drinking water sources for humans or livestock
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
	Reprimand of applicators who do not follow proper procedure in all aspects of operations (handling, application, hygiene, cleanup)
	Training of applicators and supervisors according to best practices
	Procurement and distribution of barrels for progressive rinse and wash-tubs for overall washing and personal hygiene
	Progressive rinsing of sprayers and other types of applicators
	Storage and stock management of all insecticides, empty packaging, barrels, and tubs in storage facilities, reducing use of contaminated goods domestically
	Inscription of ALL program barrels and tubs as District Health Office property, and labeling with poison stickers, to deter sale and domestic use in event of pilferage
	Daily triple-rinsing of contaminated packaging
	Shredding or puncturing of packaging materials, making them unusable (unless barrels used for progressive rinse)
	Transport of uncontaminated rinsed packaging materials to landfill or, if appropriate for incineration, power plant or cement kiln
	Transport of contaminated packaging and other materials to approved incinerator
	Development and implementation of environmental and/or livestock monitoring plan
	Development and implementation of a human health monitoring plan (to determine pesticide impacts on spray operators and residents)
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Special Circumstances	
Pilferage of larvicide, consequential human and environmental exposure	Construction or renovation of central, permanent storage facilities according to the United Nations Food and Agriculture Organization's (UNFAO's) *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Double-padlocking of all storage facilities
	Supervision of applicators
	Development and implementation of environmental monitoring plan
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Storehouse fire, inhalation of toxic fumes from larvicide fire	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Procurement and distribution of emergency equipment to larvicide storage facilities
	Training of storekeepers
	Development and implementation of environmental reporting system
Accidents and spillage during transport and storage, leading to human and environmental exposure	Training of drivers for long-distance transport of larvicide and short-distance transport during the campaign period
	Transport of larvicides according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Procurement and distribution of emergency equipment to larvicide storage facilities
	Storekeeper training
	Training of health workers in pesticide-poisoning treatment
	Procurement and distribution of treatment medicines for pesticide exposure
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Flooding of storehouse, leading to environmental contamination	Storage facility sites located on high ground, outside of floodplain
Insecticide Quality and Resistance	
Decreased effectiveness of larvicide, lessening impact on malaria incidence	Prohibition of applying larvicidal agents where vector larvae are not present
	Whenever possible, use of "source reduction" (emptying, covering, or filling in breeding sites) instead of application of the larvicidal agent

Potential Negative Activities/Impacts	Recommended Mitigation Actions
	Selection of larvicidal agent to minimize vector resistance
	Laboratory testing of larvicidal agent to ensure quality control
	Entomological monitoring of resistance
	Data recording on agricultural pesticides for the purpose of knowing how they may contribute to resistance
	Construction or renovation of storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Procurement and use of sprayers and other applicators according to World Health Organization (WHO) specifications
	Daily sprayer maintenance
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Future Activities	
Indirect support of malaria vector control operations that have not undergone environmental review through procurement of sprayers and storage facilities	Importance of an environmental assessment for any pesticides used in malaria vector control will be discussed with Ministry of Health (MOH) and Ministry of Environment staff and online resources for conducting assessments will be provided (http://www.encapafrica.org/)
Adaptive management (potentially reducing larvicide use for malaria vector control)	Development of a strong malaria surveillance system to target interventions, reducing pesticide use
	Pursuit of an integrated malaria vector control strategy
	Development of protocol/implementation of measures to mitigate mosquito resistance to larvicidal agents through rotation or mosaic
	Submission of Human Health and Environmental Evaluation Report to USAID Contractor, USAID Mission Environmental Officer, USAID Regional Environmental Officer

Environmental Management Recommendations

The site location for an environmental management intervention should be chosen based on larval surveillance—if no vector larvae are present, no intervention should be conducted. When vector larvae are present in an area, the intervention chosen should be based on scientific information about the site, such as soil type and density, slope, species composition, endangered species habitat, and water flow and quality. Additionally, stakeholder and environmental water needs should be assessed and factored into decisions on specific interventions and intervention design.

Adverse environmental and human health impacts in environmental management are heterogeneous, varying according to the intervention chosen. Because the negative environmental impacts of environmental management are location specific, only general impacts and mitigation suggestions are described in this PEA. Table 6-6 breaks down the potential negative impacts by specific environmental management intervention and provides suggestions for mitigation.

It is important to note that the use of environmental management can decrease the need for pesticide-based interventions, which decreases the potential for harm to human health and the environment from pesticide use.

Table 6-6 Environmental Management Recommendations

Environmental Management Interventions	Potential Negative Impacts	Mitigation Measures
Environmental Modification		
Filling of breeding sites	Increased or decreased habitat and forage for animal species	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
Lining of water sources and canals	Increased flooding	Assess the impact of increased water flow on other water resources
Impoundment construction	Altered upstream and downstream water availability	Conduct impoundment planning at the water basin level
	Increased or decreased habitat and forage for animal species	Determine water needs (maximum use level) for stakeholders and the environment; assess impacts on water sources prior to intervention, work with stakeholders for appropriate solutions
	Increased or decreased plant and animal biodiversity	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
	Altered ecosystem composition	Design landscape that resembles the natural ecosystem to help conserve water and soil and provide habitat for wildlife
		Integrate buffer strips into intervention design to decrease adverse effects of water runoff and soil erosion
Biological drainage	Reduced water availability	Use environmental information in activity design
	Reduced or enhanced water quality	Determine water needs (maximum use level) for stakeholders and the environment; assess impacts on water sources prior to intervention, work with stakeholders for appropriate solutions
	Increased or decreased habitat and forage for animal species	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
	Increased or decreased plant and animal biodiversity	Design landscape that resembles the natural ecosystem to help conserve water and soil and provide habitat for wildlife
	Altered ecosystem composition	Use native species when introducing vegetation
Physical drainage	Reduced water availability	Use environmental information in activity design
	Reduced water quality	Determine water needs (maximum use level) for stakeholders and the environment; assess impacts on water

Environmental Management Interventions	Potential Negative Impacts	Mitigation Measures
		sources prior to intervention, work with stakeholders for appropriate solutions
	Increased flooding	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
	Siltation and sedimentation of water bodies, including dams and retention ponds	Design landscape that resembles the natural ecosystem to help conserve water and soil and provide habitat for wildlife
	Change in conditions for transport and hydropower production	Integrate buffer strips into intervention design to decrease adverse effects of water runoff and soil erosion
	Decreased agricultural productivity of soil	Select alternative site
	Increased or decreased habitat and forage for animal species	
	Increased or decreased plant and animal biodiversity	
	Altered ecosystem composition	
Environmental Manipulation		
Deepening/narrowing of existing drains	No significant impacts	Not applicable
Synchronized cropping/intermittent irrigation	No significant impacts	Not applicable
	Reduced water availability	Determine water needs (maximum use level) for stakeholders and the environment; assess impacts on water sources prior to intervention, work with stakeholders for appropriate solutions
Saltwater flooding	Decreased habitat for freshwater aquatic and terrestrial species	Prohibit interventions in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
		Design landscape that resembles the natural ecosystem to help conserve water and soil and provide habitat for wildlife
Introduction of larvivorous fish	Altered ecosystem composition on a small or large scale (invasive species problems)	Use indigenous larvivorous fish whenever possible
	Increased or decreased biodiversity	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
		Establish a license program for the use of larvivorous fish

Environmental Management Interventions	Potential Negative Impacts	Mitigation Measures
Manipulation of vegetation	Reduced water availability	Determine water needs (maximum use level) for stakeholders and the environment; assess impacts on water sources prior to intervention, work with stakeholders for appropriate solutions
	Reduced water quality	Prohibit intervention in sensitive habitats, forest reserves, national parks, wildlife reserves, and endangered species habitats
	Increased flooding	Use native species when introducing vegetation
	Siltation and sedimentation of water bodies, including dams and retention ponds	Design landscape that resembles the natural ecosystem to help conserve water and soil and provide habitat for wildlife
	Change in conditions for transport and hydropower production	Integrate buffer strips into intervention design to decrease adverse effects of water runoff and soil erosion
	Decreased agricultural productivity of soil	Select alternative site
	Increased or decreased habitat and forage for animal species	
	Increased or decreased plant and animal biodiversity	
	Altered ecosystem composition	

Wall Lining Recommendations

Since wall lining is a new intervention that is currently being tested in field trials, the impacts of the activities associated with its installation and use, are not thoroughly understood at this time. It is assumed that the impacts will be similar to the use of LLINs, though resident exposure would be similar to IRS. General impact and mitigation recommendations for wall lining are listed in Table 6-7.

Table 6-7. Wall Lining Recommendations

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Wall lining installation	
Occupation exposure to insecticides in wall lining from installation	Training of wall lining installers and supervisors on best management practices
	Procurement and distribution of personal protective equipment (PPE) – rubber gloves
	Daily personal washing (after installation)
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)

Potential Negative Activities/Impacts	Recommended Mitigation Actions
Efficacy of Wall Lining	
Environmental and human health Exposure to Wall lining pesticide	Training of residents in correct method for washing and caring for wall lining (as per manufacturer's recommendations)
	Development and implementation of environmental monitoring plan (to determine pesticide impacts on the environment)
	Development and implementation of a human health monitoring plan (to determine pesticide impacts on residents)
Special Considerations	
Storehouse fire, inhalation of toxic fumes from wall lining fire	Construction or renovation of central, permanent storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Construction or renovation of temporary storage facilities using main principles of UNFAO's *Pesticide Storage and Stock Control Manual* as a general guideline
	Procurement and distribution of emergency equipment to LLIN storage facilities
	Training of storekeepers
	Development and implementation of environmental reporting system
Flooding of storehouse, leading to environmental contamination	Storage facility sites located on high ground, outside of floodplain
Insecticide Quality and Resistance	
Decreased effectiveness of wall lining, lessening impact on malaria incidence	Laboratory testing of wall lining to ensure quality control
	Entomological monitoring of resistance
	Data recording on agricultural pesticides for the purpose of knowing how they may contribute to resistance
	Construction or renovation of storage facilities according to UNFAO's *Pesticide Storage and Stock Control Manual*
	Development and implementation of environmental reporting system for Environmental Mitigation and Monitoring Plan (see Section 6.2)
Collection and redistribution of new wall lining, once no longer viable	Development and implementation of collection and disposal plan and during redistribution campaigns
Adaptive Management	Development of a strong malaria surveillance system to target interventions, reducing pesticide use
	Pursuit of an integrated malaria vector control strategy
	Development of protocol/implementation of measures to mitigate mosquito resistance pyrethroids
	Submission of Human Health and Environmental Evaluation Report to USAID Contractor, USAID Mission Environmental Officer, USAID Regional Environmental Officer

6.2. ENVIRONMENTAL MITIGATION AND MONITORING PLAN (EMMP)

An Environmental Mitigation and Monitoring Plan (EMMP) presents the best management practices and mitigation measures identified for each malaria control intervention, responsibilities for the implementation of the plan, and monitoring and reporting measures. It is a guiding document that will be provided to management teams and will be used as the tool for ensuring adherence to mitigation and monitoring practices and will assure initial and ongoing compliance with environmental requirement and guidelines. EMMPs are incorporated into work plans and budgets. Project reporting tracks EMMP implementation.

EMMPs consist of a series of components defined by project phase, such as pre, during and post activities. Each component will include the following:

- **Activity**. List all activities that could potentially cause a negative impact to human health or the natural environment.
- **Mitigation Measure(s)**. Describe the mitigation measure(s) that will avoid or reduce the negative impact.
- **Monitoring Indicator(s).** Specify the indicators or criteria that will determine if the mitigation measure is in place (being implemented) and its level of effectiveness (visual observation, tests, institutional reports, etc.).
- **Monitoring and Reporting frequency.** Describe how often the mitigation should be monitored and where the findings should be reported.
- **Parties Responsible.** Describe who is responsible for implementing the mitigation measure, who monitors to verify it is being implemented and who is responsible for reporting on the findings. Responsibilities for implementation of mitigation and monitoring measures should be clearly identified, with the agreement of those identified, and updated regularly (at least annually).

The cost and source of funds for mitigation and monitoring should be included in the initial intervention cost estimates. The mitigation implementation schedule should be seamlessly integrated into the overall malaria disease control activity implementation plan.

The EMMP should provide detailed descriptions of how mitigation measures should be planned for, implemented, monitored, and evaluated, and what action should be taken when mitigation activities are poorly implemented or fail. It should also make evident the links between identified potential human health and environmental impacts and mitigation activities. SEAs should also include the appropriate elements of the EMMP and include the mitigation measures that are relevant to the malaria control intervention(s) that have been selected for that particular country program. It is also important to factor in the reporting and monitoring activities and costs required by the Stockholm Convention if DDT is used in an IRS program. A comprehensive EMMP is included in ***Annex L*** and includes recommended mitigation actions for each malaria control intervention. Additional actions may be warranted (as described in Section 6.1.2) depending on the site-specific situations.

7. REGULATORY, LEGAL, AND INSTITUTIONAL SETTINGS

7.1. THE NATIONAL SETTING

Partnerships are at the heart of PMI's strategy and operational plans. PMI has forged strong partnerships with host country government in all PMI focus countries, and works closely with other agencies and organizations.

The overarching regulatory framework for conducting environmental assessments for USAID funded projects is U.S. Code of Federal Regulations (CFR) 22 CFR 216 (see ***Annex A***); however, host-country environmental policies, laws, and regulations must also be consulted and considered in preparing SEAs and other required approval documents. Support for interventions must abide by host-country environmental regulations, as well as USAID regulations.

Long-term sustainability of any economic or social development project requires that the development interventions be well conceived and that a regulatory framework with enforcement capacity exists.

Public participation in the host country is paramount for successful, sustainable, programs. Host-country government ministries involved in malaria control, pesticide use, or other relevant issues, as well as civil society, should participate in the SEA processes from the onset. Not only do these entities possess the information needed to complete the assessment, but involving them also helps guide the selection of alternative approaches and ensures greater local ownership of the program from the start. Table 7-1 lists the key host-country institutions that should be consulted.

Table 7-1 Host-Country Institutions with Malaria Control Mandates or Related Functions

Institution	Information and Data
Ministry of Health (MOH)	Documents pertaining to malaria control policies, history of control in the country Insecticides registered for use against mosquitoes, pesticide use policies, all donor programs active in the country Maps of vectors and malaria distribution, information about insecticide resistance, pesticide testing procedures, inventories of pesticides and equipment available Organization and malaria control responsibilities in the ministry Measures for treating pesticide poisoning
Ministry of Environment (MOE)	Potential institution for environmental monitoring Documents and maps pertaining to the presence of sensitive habitats, such as world heritage sites, national parks and forests, lists of endangered species and their locations, game parks, bodies of water, and other environmental resources
Ministry of Agriculture (MOA)	Pesticide registration Listing of agricultural development programs currently using pesticides, and information on classes of pesticides used in various agricultural activities and locations, ways to prevent public health pesticides from being used for agriculture Potential agricultural export impacts isolated to use of various pesticides
Ministry of Public Works (MPW)	May be knowledgeable about sanitation laws, regulations, guidelines, and implementation May also work with the MOH in administering routine campaigns to clean up potential malaria mosquito breeding containers or locations
Regional and local governments	Likely to be responsible for implementing some antimalaria campaign activities; information will need to be collected on how and when this is done Measures of program impact
Universities	Potential institutions for environmental monitoring Research studies and data pertaining to malaria control programs, toxicity assays, experimental approaches
Environmental nongovernmental organizations (NGOs)	Potential institutions for environmental monitoring Information and maps pertaining to the presence of sensitive habitats, such as world heritage sites, national parks and forests, lists of endangered species and their locations, game parks, bodies of water, and other environmental resources
Affected citizens	Recommendations and concerns to be taken into account in deciding upon, planning, and implementing an intervention

In order for the product to be used, it must be registered by the country. The registration process will vary by country. WHOPES recommendations will often facilitate the country registration. The WHOPES promotes

and coordinates the testing and evaluation of pesticides for public health. It comprises a four-phase evaluation and testing program, studying the safety, efficacy and operational acceptability of public health pesticides and developing specifications for quality control and international trade. WHOPES collects, consolidates, evaluates and disseminates information on the use of pesticides for public health.

7.2. THE INTERNATIONAL SETTING

7.2.1. INTERNATIONAL TREATIES

International transport and use of pesticides are governed by three major international treaties:

- The **Basel Convention** on the Control of Transboundary Movements of Hazardous Wastes and their Disposal
- The **Rotterdam Convention** on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
- The **Stockholm Convention** on Persistent Organic Pollutants (POPs)

The Basel Convention addresses the transboundary movement, management, and disposal of hazardous wastes, including waste pesticides. Transboundary movements of hazardous waste between Parties can take place only on prior written notification by the exporting state to importing (or transit) states, and the inclusion of movement documents with each shipment. In addition, Parties may not permit hazardous wastes to be exported to or imported from a non-Party except pursuant to an agreement or arrangement that stipulates provisions no less environmentally sound than those provided for by the Basel Convention. Finally, trade in hazardous waste cannot take place under conditions in which such wastes cannot be handled in an environmentally sound manner. Parties are obligated to consider illegal traffic in hazardous wastes as criminal and to notify other Party states upon prohibition of import of hazardous wastes for disposal. Export of waste pesticides may require specific compliance activities by the host-country government.

The Rotterdam Convention addresses the transboundary movement of 22 chemicals, including one chemical used for malaria vector control, dichloro-diphenyl-trichloroethane (DDT). Parties to the Convention must make decisions on each chemical regarding its import, abide by export limitations delineated in the treaty, and notify Parties receiving exported waste according to treaty conditions. Host-country governments are responsible for complying with any import or export treaty conditions applicable to their status as a Party or non-Party. Import or export of the 22 chemicals covered by the Rotterdam Convention, including DDT, may require specific compliance activities by the host-country government.

The Stockholm Convention addresses the production, import, and export of 12 POPs, including DDT. Currently, Parties to the Convention must take measures to eliminate releases of each chemical, with the exception of certain uses listed in the Convention (for example, the exception of DDT use for "disease vector control"). Parties to the Convention must also abide by the Convention's stockpile handling, transport, and disposal requirements intended to eliminate persistent byproducts; thus, management and export of obsolete pesticides may require specific compliance activities by the host-country government. (see discussion on Stockholm DDT requirement in IRS mitigation section).

7.2.2. INTERNATIONAL INSTITUTIONS

Several international and regional organizations fund and implement malaria control initiatives. Coordination and collaboration is essential so as not to duplicate efforts and resources. When writing SEAs, the activities of each of these groups in the country of interest should be researched and catalogued, and recommendations for coordination should be included in the report. Table 7-2 provides

an illustrative list of the organizations and programs that may be funding or implementing malaria control or pesticide management activities in specific countries.

Table 7-2 Illustrative List of Organizations and Programs

Institution	Program
RBM Partnership	The RBM Partnership is the global framework to implement coordinated action against malaria. The RBM Partnership was launched in 1998 by WHO, UNICEF, UNDP and the World Bank, in an effort to provide a coordinated global response to the disease. It mobilizes for action and resources and forges consensus among partners. The Partnership is comprised of more than 500 partners, including malaria endemic countries, their bilateral and multilateral development partners, the private sector, nongovernmental and community-based organizations, foundations, and research and academic institutions. RBM's strength lies in its ability to form effective partnerships both globally and nationally. Partners work together to scale up malaria-control efforts at country level, coordinating their activities to avoid duplication and fragmentation, and to ensure optimal use of resources. RBM's overall strategy aims to reduce malaria morbidity and mortality by reaching universal coverage and strengthening health systems. The Global Malaria Action Plan of malaria control: *(1) scaling-up for impact (SUFI) of preventive and therapeutic interventions*, and *(2) sustaining control over time*.
WHO GMP	WHO Global Malaria Programme (GMP), as part of the World Health Organization, convenes experts to review evidence and set global policies. GMP's policy advice provides the benchmark for national malaria programmes and multilateral funding agencies. GMP's unique position uniting high levels of expertise – and WHO's field presence in all regions and all malaria-endemic countries of the world – ensures harmonized policy advice and the critical technical assistance necessary to effect concrete and sustainable successes at global level. GMP's activities are focused on providing an integrated solution to the various epidemiological and operational challenges. This is done by promoting sound, evidence-based and locally appropriate strategies. The Programme helps countries reach the most vulnerable populations and ensure that needed interventions take into account social, economic and environmental realities.
UNEP GEF projects	The United Nations Environment Program Global Environment Facility (UNEP GEF) helps developing countries fund projects and programs that protect the global environment. The GEF's grants support projects related to biodiversity, climate change, international waters, land degradation, the ozone layer, and persistent organic pollutants (POPs)—a new focal area for GEF, as they are a threat to biodiversity and even have the potential to cause disruption at the ecosystem level.
WHOPES	The WHO Pesticide Evaluation Scheme (WHOPES), set up in 1960, is the only international program that promotes and coordinates the testing and evaluation of new pesticides proposed for public health use. It functions through the participation of representatives of governments, the pesticide industry, WHO Collaborating Centers and university associations, associate laboratories, as well as other WHO Programs, particularly the International Program on Chemical Safety (IPCS). WHOPES facilitates the search for alternative pesticides and application methodologies that are safe and cost-effective and helps develop and promote policies, strategies, and guidelines for the use of pesticides in public health, and ultimately, helps monitor their implementation by the Member States.

Institution	Program
Global Fund for AIDS, Malaria, and Tuberculosis	The Global Fund for AIDS, Malaria and Tuberculosis, created in 2001, funds initiatives to fight AIDS, tuberculosis and malaria. Together, these diseases kill more than 6 million people each year, and the numbers are growing. As a partnership between governments, civil society, the private sector, and affected communities, the Global Fund represents an innovative approach to international health financing. The Global Fund attracts resources ($4.7 billion to date) and manages and disburses those resources to fight AIDS, tuberculosis, and malaria, but does not implement programs directly. As a financing mechanism, the Global Fund works closely with other multilateral and bilateral organizations involved in health and development issues to ensure that newly funded programs are coordinated with existing ones. The Global Fund uses its own grants to catalyze additional investments by donors as well as by recipients themselves. In its first two rounds of grant-making, it has committed US $1.5 billion in funding to support 154 programs in 93 countries worldwide.
The Food and Agriculture Organization of the United Nations (UNFAO)	Pesticide Management is an activity carried out within the overall framework of the Plant Protection Service of UNFAO. It is designed to work together with member countries as a partner to introduce sustainable and environmentally sound agricultural practices that reduce health and environmental risks associated with the use of pesticides. The environmental and health impact of pesticides is being reduced through the implementation of several concrete programs on pesticide management, including residue analysis, product standards setting and methods to analyze them, prevention of accumulation of obsolete stocks of pesticides and means to dispose them, and exchange of information on national actions taken to control pesticides.
Insecticide Resistance Action Committee (IRAC)	IRAC is an inter-company organization that operates as a Specialist Technical Group under the umbrella of CropLife International. IRAC was formed in 1984 to provide a coordinated crop protection industry response to prevent or delay the development of resistance in insect and mite pests. The main aims of IRAC are firstly to facilitate communication and education on insecticide resistance and secondly to promote the development of resistance management strategies in crop protection and vector control so as to maintain efficacy and support sustainable agriculture and improved public health.
CropLife International	"CropLife is the global federation representing the plant science industry. It supports a network of regional and national associations in 91 countries and its membership includes the major R&D companies as well as a large part of the post-patent and generic pesticide industry. The membership's interests cover crop protection, public health, plant biotechnology and seed production. CropLife International promotes the benefit of crop protection, public health and biotechnology products, their importance to sustainable agriculture, food production and public health, and their responsible use through stewardship activities." (Bernhard Johnen)

8. TRAINING AND INSTITUTIONAL CAPACITY BUILDING

8.1. INSTITUTIONAL CAPACITY BUILDING

Regulation 216, Pesticide Procedures §216.3(b) states that "factors to be considered in such an evaluation shall include the provision made for training of users and applicators". UNDP defines capacity building as a long-term continual process of development that involves all stakeholders; including ministries, local authorities, non-governmental organization, professionals, community member, academics and more. The goal of capacity building is to tackle problems related to policy and methods of development, while considering the potential, limits and needs of the people of the country concerned. Capacity building is more than training and includes the following:

- Human resource development, the process of equipping individual with the understanding, skill and access to information, knowledge and training that enables them to perform effectively.
- Organizational development, the elaboration of management structures, processes and procedures, not only within organization but also the management of relationships between the different organization and sectors (public, private and community).
- Institutional and legal framework development, making legal and regulatory changes to enable organizations, institutions and agencies at all levels and in all sectors to enhance their capacities. (Wikipedia)

Training and capacity building are essential components of efforts to assist the host country in developing a sustainable malaria vector control program that ensures the protection of human health and the environment. Different types of training and capacity building are necessary, ranging from in-field training of those who apply pesticides, to local-level management capacity building, to ministry decision making guidance.

8.2. TRAINING OF CONTRACTORS

USAID Mission Environmental Officers (MEOs) and Mission Health Officers (MHOs) should provide training to contractor program managers and other partners involved in USAID-supported malaria vector control interventions. This training should inform program managers of the importance and methods of integrating human health and environmental concerns into malaria vector control. It should also inform program managers of USAID's expectations for implementation of best practices for human health and the environment as detailed in this PEA and the SEA. Finally, the training should express USAID's expectations of what measures are needed to protect human health and the environment be factored into program evaluation. Additional topics for discussion may include

- Factors to consider in intervention selection
- Factors to consider in pesticide selection

- Potential impacts of pesticides
- Best practices and mitigation measures (throughout the life cycle of the intervention or pesticide)
- Adaptive management

8.3. GUIDANCE FOR SENIOR OFFICIALS

Capacity building at an institutional level should involve aiding pre-existing institutions. One of the most fundamental ideas associated with capacity building is the idea of building the capacities of governments in developing countries so they are able to handle the problems associated with environmental, economic and social transformation. Developing a government's capacity, whether at the local, regional or national level, will allow for better governance that can lead to sustainable development and democracy.

The Ministry of Health (MOH), including the National Malaria Control Programme (NMCP), is made up of experts in a variety of fields. It is not always guaranteed that these government staff will have the knowledge and training on all aspects of malaria vector control, or that decision-making on malaria vector control within the MOH takes into account all appropriate facets of the issues.

As a way of supporting sound decision making on malaria vector control across the globe, and as part of country-specific intervention support, USAID should support training for MOH malaria control program managers and other relevant staff to orient them to the elements of well-run integrated vector management (IVM) malaria programs, including environmental mitigation and monitoring. Other factors in the training should include the following:

- Factors to consider in intervention selection
- Factors to consider in pesticide selection
- Potential impacts of pesticides
- Best practices and mitigation measures (throughout the life cycle of the intervention or pesticide)
- Appropriate timing and logistics
- Adaptive management

Additionally, contractor specialists should be paired with counterparts from the MOH malaria control program to provide any on-the-job guidance necessary.

8.4. MID-LEVEL MANAGEMENT

Although health systems in the developing world have decentralized and placed responsibility for malaria program implementation on local and regional managers, the management skills necessary for these local and regional managers to perform effectively have not filtered down from the central ministry. The result is a lack of capacity to manage malaria vector control programs at the local and regional level.

During the period of USAID support, contractor specialists should be paired with local and/or regional counterparts to provide on-the-job guidance, training, and practice. Contractor specialists, as necessary, should train mid-level management in

- Logistics
- Data management

- Best practices and mitigation measures
- Monitoring and evaluation (of all types mentioned in this PEA)
- Surveillance systems
- Adaptive management

Additionally, USAID should facilitate knowledge sharing between ministry staff and local or regional managers. Finally, USAID should promote formal training of mid-level managers as the need for such training arises.

8.5. TRAINING OF IMPLEMENTERS

Every malaria vector control intervention requires staff that implements the interventions in the field: spray operators, larvicide applicators, insecticide-treated net (ITN) distributers, wall lining installers, environmental management or sanitation workers, and intervention supervisors. Each of these implementers should be trained according to the highest standards available based on World Health Organization (WHO) guidelines, PEA guidelines, United Nations Food and Agriculture Organization (UNFAO) guidelines, equipment manufacturer guidelines, pesticide industry guidelines, and ministry guidelines. In situations where the interventions are seasonal, refresher training prior to each intervention may be necessary.

Training of users and applicators

To mitigate adverse impacts from the implementation of the interventions, all individuals who handle pesticides or inadvertently come in contact with pesticides, such as storekeepers, spray operators, washpersons, individuals transporting pesticides, as well as medical practitioners and communities, should be educated on their roles and responsibilities in preventing unwanted exposure to pesticides (or treatment of pesticide exposure, in the case of medical practitioners). Supervisors and team leaders should participate in a "Training of Trainers" (TOT) course. The purpose of "cascade training" is to pass knowledge and skill to colleagues who work at different "levels". In order to teach a trainer how to train well, a "learning by doing" approach is best[10]. The training should be conducted in accordance with standardized training and operations manuals. Essential components of this training are provided in Section 6 of this PEA, Environmental Mitigation and Monitoring.

8.6. CAPACITY BUILDING OUTSIDE THE MALARIA SECTOR

Malaria vector control activities interact with other sectors, most importantly agriculture and environment. To the extent that a host-country institution wants to become involved in environmental monitoring of malaria vector control interventions, promote responsible pesticide use, and prevent pesticide pilferage, etc., USAID-supported interventions should include measures to build the capacity of those institutions and facilitate collaboration between those institutions and the malaria control program.

10 IMPEC Guidelines for Training of Trainers, September 2002

9. PUBLIC CONSULTATION PROCESS

The public consultation process for the PEA was conducted in two phases. The first phase involved a scoping meeting that included relevant stakeholders from organizations, agencies, countries, consultants and companies who have a vested interest in malaria control activities and are affected by the USAID Malaria Vector Control Program. The scope of the USAID Malaria Vector Control Program is quite large, and involves a diverse group of stakeholders, including international organizations (WHOPES), US government agencies (EPA, DOD, CDC, USAID), USAID Missions, pesticide manufacturers (BASF, Vestergaard Frandsen, Clarke, Syngenta, Bestnet, Sumitomo), implementing partners (RTI, Abt and Chemonics), host governments, and public and private institutions. Many of these stakeholders have offices in Washington DC, where the scoping meeting was held. To accommodate other stakeholders located in Africa and other locations that could not travel to the meeting, interested parties were invited to participate via webinar or conference call. The notes from the meeting were then sent to all stakeholders and additional comments and recommendations were requested.

Comments from the scoping process were carefully considered and included in the Draft PEA. The full text of the scoping report can be found in Annex B.

The second public consultation phase involves a 30-day Public Review of the Draft PEA. The Draft PEA was available on the IRG website from August 10th to September 8th, 2011. Notification of its availability was sent to all stakeholders who were involved in the scoping process. Additional stakeholders whom were identified after the scoping process were also contacted. All comments received by midnight on September 8th, 2011 have been carefully considered and included in the development of the Final PEA. All comments received during this period can be found in ***Annex M***.

10. CONCLUSIONS AND RECOMMENDATIONS

The following section summarizes the major conclusions and recommendations of the PEA, presented by theme (vector control, combination of interventions, pesticides, resistance management, and program implementation), and by primary method (IRS, ITN/LLIN, larviciding, environmental management methods and wall lining). These are complemented by supporting conclusions and recommendations that can be found throughout the document. This PEA does not identify the effectiveness of each method in controlling malaria. Rather it reviews the human health and environmental impacts from the methods to determine the potential risks. The PEA is one of several resources available to assist with decision making for the USAID Malaria Vector Control Program. Due to the complicated nature of the malaria control program, no single method or pesticide can be recommended over any others without additional country-specific and site-specific analysis. As such, this PEA should be used as a framing document, and, supplemented by SEAs, executed according to the guidance provided in Annex C.

10.1. THEMATIC CONCLUSIONS

VECTOR CONTROL

Conclusion: *The targeted site-specific control of malaria-infected mosquitoes is an important component of the USAID Malaria Vector Control Program.*

The goal of mosquito control, or malaria vector control, is to prevent the transmission of malaria from infected mosquitos to the human population by a combination of methods, or interventions, such as eliminating mosquito breeding habitat (i.e. environmental management), killing mosquito larvae (i.e. larviciding), protecting humans from mosquito bites (e.g. ITN/LLINs) or killing infected adult mosquitos (e.g. IRS). The implementation of mosquito control includes the targeted, site-specific use of the available methods (such as IRS or ITN/LLINs), predicated on technical and operational feasibility, resources, and infrastructure. Each method should be applied in accordance with an evidence-based decision-making process adapted to local settings, which emphasizes the involvement of communities. The selection of chemical and non-chemical methods should be based on their efficacy, sustainability, and cost effectiveness. Because this PEA does not attempt to determine the cost-effectiveness of all the vector control strategies across the wide range of potential settings, the design of country- and site-specific control methods should take into account the cost benefit aspects for each.

Conclusion: *Each mosquito control method has its advantages and disadvantages.*

Some control methods, such as source reduction to prevent mosquito breeding (e.g. covering or filling breeding sites), may be moderately effective and are highly affordable with the active participation of communities. Other methods, such as IRS, may be effective against malaria. These methods are typically strongly supported by national governments; however, they may carry risks such as resistance development. Obtaining accurate information on the effectiveness of interventions is crucial. Methods such as ITNs and IRS have been well studied and are highly cost-effective in combating malaria. The

effectiveness of other methods in reducing the mosquito population or malaria transmission has received less attention (WHO 2010).

COMBINATION OF INTERVENTIONS

Conclusion: *Mosquito control methods are not mutually exclusive and should be combined whenever possible.*

Mosquito control methods that are combined should be compatible and complementary. For example, when combining IRS and ITNs, the choice of insecticides from different classes (e.g. carbamate for IRS and pyrethroid for ITN) is critical to delay the onset of resistance development. The selection of mosquito control methods requires trade-offs between competing objectives for health, society and the environment (WHO 2010). The Roll Back Malaria (RBM) Vector Control Working Group (VCWG) is currently conducting a comparative assessment on the effectiveness of IRS and LLIN, to determine the appropriate mix of LLIN, IRS and other current and emerging vector control methods including larval source management (LSM) (RBM 2010).

Several studies have examined the effect of combining malaria control methods. In Burkina Faso, a 2010 study reviewed the effects of combining wall lining and ITNs. It concluded that wall lining at low coverage is unlikely to be as effective as ITNs for household protection although wall lining has a potential role for control of malaria at the community level (Chandre, et al 2010). In the Western Kenyan highlands, a 2008 study assessed the contribution of both microbial larvicides and ITNs in reducing malaria incidence. It concluded that mosquito control using microbial larvicides enhanced the effectiveness achieved using ITNs alone (Fillinger et.al 2008). In addition, methods like larvicidng that target other stages and resources, when implemented with IRS or ITNs, could have a synergistic impact on malaria control (Clarke 2008).

PESTICIDES

Conclusion: *Four classes of chemical insecticides – the organochlorines, organophosphates, carbamates, and pyrethroids, are the mainstay of vector control programs.*

The continued use of DDT for disease vector control is conditionally approved under the Stockholm Convention on Persistent Organic Pollutants, in accordance with WHO recommendations and guidelines, when safe, effective, and affordable alternatives are not locally available.

Conclusion: *The pesticide formulation can markedly affect the result obtained in practical use.*

Safety, efficacy, residual life, costs, availability, and ease of use must all be considered in selecting a pesticide formulation. When absorbent surfaces such as mud are sprayed, suspensions of pesticides often have a longer residual effect than emulsions or solutions of pesticides, which tend to be absorbed below the surface. Though more effective, suspensions may leave an unpleasant deposit on treated surfaces.

Recommendation: *In selecting a pesticide and the appropriate formulation, consideration should be given to its biological effectiveness against the pest concerned, the susceptibility of the target organisms to the pesticide, the methods of application, its safety to humans, its toxicity to non-target organisms, the registration status of the pesticide for the required use, and its costs.*

In choosing a pesticide, consideration should also be given to ease of handling and application, the availability of application equipment as well as transport requirements. The dose of active ingredient per unit area and the concentration of the active ingredient in the formulation must be known for

determining the quantities of pesticide formulation required. Due regard should also be given to the impact of the compounds on the environment, including fish, birds, and beneficial invertebrates.

RESISTANCE MANAGEMENT

Conclusion: *The widespread development of mosquito resistance to pesticides has resulted from their use on a vast and increasing scale..*

Recommendation: *Monitoring mosquito resistance to pesticides should be an integral component of the planning and development of malaria and mosquito control programs.*

Reported resistance of a particular mosquito species in a particular area does not in itself justify an immediate change in policy for control programs in that area. If current measures are inadequate to control malaria to the required level, the strategy or pesticide should immediately be adjusted. Nevertheless, even in the presence of resistance, the use of the pesticide might be sufficient to suppress transmission, either because the level of resistance of the mosquito species is not sufficiently high or because the pesticide has some effect. This complexity underlines the need to document resistance and its impact on the efficacy of control methods carefully before adopting corrective measures.

Conclusion: *Resistance management consists of preventing, or delaying as long as possible, the development of resistance to a pesticide while at the same time maintaining an effective level of malaria control.*

***Recommendations*:** The following are suggested approaches for managing resistance:

- Use of non-chemical control methods, either alone or as a supplementary measure, in the seasons or areas in which they are applicable and cost-effective.
- Limitation of pesticide use to areas with high levels of disease transmission.
- Use of adulticides rather than larvicides resulting in approximately half the selection pressure for resistance.
- Rotation among unrelated insecticides according to a pre-arranged plan based on knowledge of the likelihood of resistance developing to each compound.
- Choice of a compound that has been found by experience to select for a narrow spectrum of resistance rather than a broad one.
- Use of mixtures or mosaic treatment with unrelated compounds.

MOSQUITO CONTROL PROGRAM IMPLEMENTATION

Conclusion: *All pesticides are toxic to humans to some degree; therefore the key to safe use is to minimize the possibilities of unsafe exposure during pesticide handling.*

Recommendation: *Identify and implement best management practices to minimize or avoid negative human and environmental health risks.*

Care in handling pesticides, particularly by IRS staff and persons living in sprayed houses, should be a routine practice and form an integral part of any program involving the application of pesticides.

Conclusion: *Public health pesticides have the potential to be diverted to agricultural applications and private pest control enterprises.*

Public health pesticides should not be diverted from their intended use because:

1. It may be illegal. Public health pesticides may not be registered by the host country for alternative uses, or may be explicitly banned for any use beyond disease vector control (as is usually the case with DDT);
2. It may endanger the health of the individual, the health of others in the community, and the environment. Individuals using diverted pesticides are probably untrained in appropriate application and unaware of mitigation precautions that should be taken to avoid exposure to the individual and the community;
3. The use of diverted pesticides in the agricultural sector may increase the risk that agricultural exports exceed importing-country maximum residue limits (MRLs); thereby reducing economic gains from agricultural exports in the host country;
4. The use of diverted pesticides may potentially increase the resistance of pests or disease vectors. In areas where large quantities of pesticides are used for agricultural crops, especially monocultures such as cotton, rice, and soybeans, resistance of mosquitoes may develop much faster than in areas that do not use large quantities of agricultural pesticides; and,
5. The diversion of pesticides from their intended purpose increases the costs of the malaria vector control program.

Recommendation: *Identify and implement best management practices to avoid public health pesticides being used for agriculture purposes.*

The potential adverse economic impacts of the diversion of public health pesticides to the private sector must be addressed through monitoring and mitigation activities in the program. This may be achieved through coordination with the Ministry of Agriculture (MOA), commercial producers, export associations, pesticide manufacturers, and nongovernmental organizations (NGOs).

Recommendations: *Resistance monitoring should be conducted in areas where large quantities of pesticides are used for agricultural crops and are targeted for malaria vector control to help develop strategies tailored to the area.*

USAID support for mosquito control should include capacity building for managing resistance and promoting coordination among MOAs, Ministries of Health (MOHs) and the Department of Agriculture to reduce vector or pest resistance prompted by agricultural or public health use of pesticides.

Conclusion: *Agricultural development in Africa has contributed to land use changes and has resulted in the upsurge of malaria transmission in unstable malaria transmission areas.*

Agricultural production systems, depending on the type, practices, location and technologies, could lead to environmental changes that create suitable ecological and climatic conditions for the breeding and survival of the mosquitoes which transmit malaria.

Recommendation: *Consider larval source management (LSM) methods like environmental management to minimize larvae habitat. Also monitor the incidence of malaria and adjust the interventions to account for increases in malaria cases.*

The impact of malaria on livelihoods and agricultural productivity could be reduced depending on the agricultural and health support systems available to affected households. Given the current public recognition and political will in support of malaria eradication, more investment is needed for malaria research, especially in the linkages between agriculture and malaria.

Conclusion: *Inter-annual variability of malaria incidence and altitudinal malaria distribution may be influenced by climate change.*

The effects of temperature on both mosquitoes and the malaria parasite are easily seen in latitudinal and altitudinal boundaries to malaria transmission. However, these boundaries seem to be changing as many highland areas have experienced malaria epidemics in the past few years. It has been hypothesized that increasing temperatures could partially explain the survival of malaria at higher altitudes.

Recommendation: *Monitor the incidence of malaria and adjust the boundaries and control methods accordingly to account for changes in malaria cases due to climate change.*

Conclusion: *Human health and environmental mitigation activities can reduce adverse human health and environmental impacts that result from mosquito control methods. Monitoring is conducted to determine when mitigation is necessary and whether or not mitigation is working successfully.*

Recommendation: *Mitigation and monitoring activities should be adapted for each country-specific program and included in the SEA* (refer to **Annex C** for guidelines).

Conclusion: *Partnerships with host country government and other agencies and organizations are an integral part of PMI's strategy and operational plans.*

Recommendation: *Host-country environmental policies, laws, and regulations must also be consulted and considered; key host-country institutions should be consulted; and all relevant international treaties pertaining to the transport and use of pesticides should be considered; coordination and collaboration must be emphasized during implementation of malaria control initiatives with other international and regional malaria programs.*

Conclusions: *Training and capacity building are essential components in the effort to assist the host country in developing a sustainable malaria vector control program that ensures the protection of human health and the environment.*

Recommendations: *Include different types of training and capacity building for the various levels needed, including program managers and other partners involved in USAID-supported malaria vector control interventions; local, regional or national level government staff; local and/or regional counterparts; and local implementing staff such as sprayer, driver, store managers, etc.*

10.2. SPECIFIC CONCLUSIONS BY INTERVENTION

The 2012-updated PEA utilizes the results from the 2002 and 2007 PEAs. The 2012 PEA identified pesticides with high risks that required further assessment. As such, many of the low risk pesticides (addressed in the 2002 and 2007 PEAs) did not require further assessment in this PEA.

INDOOR RESIDUAL SPRAYING (IRS)

Conclusion: Indoor residual spraying remains a valid intervention for malaria vector control.

Over the past 60 years, IRS has saved millions of lives around the world. WHO reaffirmed the importance of IRS as one of the primary intervention for reducing or interrupting malaria transmission (WHO 2006). Due to the observed impact of IRS in PMI focus countries, its use in Africa has grown substantially. During 2010, the PMI-supported IRS programs protected more than 27 million people from malaria (PMI 2010).

Conclusion: Wearing facemasks, gloves, and overalls when handling IRS pesticides reduces worker exposure.

The PEA risk assessment showed that wearing a facemask, gloves, and overalls (i.e. personal protection equipment or PPE), effectively reduced worker exposure risks during the mixing and spraying of most of

the IRS pesticides. Wearing such PPE reduced the risks associated with handling chlorfenapyr, propoxur, and fenitrothion to acceptable levels. Wearing PPE also reduced the risks associated with mixing DDT and pirimiphos-methyl to low levels, though the calculated hazard values were slightly above the threshold. Recent studies in Uganda have not shown detrimental effects to workers spraying DDT, even though the PEA calculated risks substantially above acceptable levels for workers wearing PPE. For sensitive workers (e.g. pregnant or nursing mothers) spraying DDT, wearing PPE such as respirators, protective overalls, and gloves may be inadequate to reduce risks.

Recommendation: Workers should wear PPE when handling pesticides, especially DDT and pirimiphos-methyl.

The PEA assessed using facemasks for inhalation protection, and gloves and overalls for dermal protection. Additional PPE, including boots, helmets with visors, neck protection and chemically impermeable overalls, may be required to protect workers who are more sensitive to exposure levels.

Recommendation: PMI should evaluate various approaches to monitoring sprayer exposure to organophosphate (OP) pesticides and should develop protocols, based on these evaluations, for a monitoring program. PMI will use the protocols developed to inform the implementation of PMI program monitoring for organophosphate pesticides.

Conclusion: Workers may be exposed from spills occurring during pesticide preparation. If spills in the vicinity of homes being sprayed for IRS are not properly cleaned up, subsequent resident exposures may also be of concern***.***

Recommendation: Worker should implement BMPs to minimize worker and resident exposures to pesticides from spills. Preparation of pesticides in a location outside of the homes being sprayed, and proper maintenance of tanks, lines, and nozzles to minimize dripping during application, are appropriate precautions for reducing exposures due to leaks and spills.

Conclusion: Soak pits for pesticide disposal must be installed at appropriate locations to avoid potential ground water contamination. DDT, etofenprox, fenitrothion, pirimiphos-methyl, and propoxur are mobile in soil and are likely to contaminate groundwater if disposed of inappropriately.

Recommendation: Soak pits should not be located in sandy soils or directly upgradient of water sources. All pesticides should be diluted before disposal in soak pits. (According to best management practices, DDT residual should only be disposed of in designated evaporation tanks.)

Conclusion: The pesticides listed in Table 10.1 are appropriate for use in the IRS program. DDT and pirimiphos-methyl have been determined to be high risk. Etofenprox, fenitrothion, chlorfenapyr, and propoxur have been determined to be moderate risk.

Recommendation: DDT, etofenprox, fenitrothion, pirimiphos-methyl, propoxur and chlorfenapyr have a higher risk for human and environmental impacts than others and should be used with caution in accordance with strict best management practices.

Note: There was a concern about the results of the Human Health Risk Assessment for fenitrothion, malathion and pirimiphos-methyl, therefore approaches for biomonitoring organophosphates were reviewed (please see Annex N). ***PMI will evaluate various approaches for monitoring sprayer exposure to OPs, and will develop protocols based on these evaluations. PMI will use these protocols to guide the implementation of the OP monitoring program.***

Conclusion: The risks to residents exposed to IRS residual on wall surfaces from pirimiphos-methyl were calculated at low levels, though the calculated hazard values were slightly above the threshold. Because there is considerable uncertainty in the analysis, it is not clear that the risks fall within acceptable ranges.

Recommendations: The collection of samples of surface material from sprayed walls at intervals following IRS is recommended to refine the results the post-IRS resident exposure risk assessment. Specifically, collection of samples of wall scrapings are recommended to establish the time course of exposure concentrations for the synthetic pyrethroids, organophosphates, and carbamates. Sampling of floor sweepings to determine whether incidental ingestion and/or dermal absorption of IRS pesticides from residual pesticide on floors may be a significant contributor to overall post-IRS resident exposure should also be considered.

Conclusion: *Risks to households eating home-raised chicken may be significant after IRS with DDT.*

Recommendation: *Monitor free-range chicken meat for DDT during next round of IRS. Where chickens range in and around sprayed homes, sampling of DDT in chicken meat and eggs should be considered to determine the possible relevance of this pathway for the malaria vector control program.*

Conclusion: *Risks to nursing infants from households after IRS with DDT may be significant.*

Recommendation: *Monitoring nursing infants should be considered to determine the possible relevance of this pathway for the malaria vector control program.*

Conclusion: *Resistance to DDT and pyrethroids, as well as resistance to carbamates, has been found in parts of Africa.* The operational implications of insecticide resistance are not yet fully understood (WHO 2006).

Recommendation: *Monitor resistance and the potential impact of IRS efficacy.* The development of resistance to insecticides is a major threat for the chemical control of malaria control vectors and special considerations should be made to include resistance management.

Conclusion: Based on the ecotoxicological risk assessment, domestic chickens are not at risk from DDT exposure from eating soil or crops*. Because data was not available, exposure from eating worms and other invertebrates, which has been found to increase in wild birds, could not be calculated.*

Recommendation: None

Table 10-1 IRS Pesticide Review

Pesticide	Properties	Toxicology	PEA findings
Alpha-cypermethrin	Pyrethroid	Low risk to humans, skin and eyes irritant; can bioaccumulate in aquatic organisms; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Low risk*
Bendiocarb	Carbamate	Some risk to humans; reversible cholinesterase inhibition; moderately toxic in mammals; exposure to treated surfaces there were risks of concern for children and adults; degrades rapidly in water and has low persistence in soil; moderately toxic to birds and fish, and	*Low risk*

Pesticide	Properties	Toxicology	PEA findings
		toxic to bees.	
Bifenthrin	Pyrethroid	Used in agriculture: skin and eye irritation; biodegrades readily; moderately toxic to birds; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Low risk*
Cyfluthrin	Pyrethroid	No long term problems to humans, skin and eye irritation; no evidence of carcinogenic potential of cyfluthrin has been reported in animals; can bioaccumulate in aquatic organisms; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Low risk* Found in breast milk
DDT	Organo-chlorine	Past use in agriculture; high persistence; concern for prenatal exposure; persistent in soil, shorter life in warm, wet tropics; bioaccumulates in marine life; synergisms between DDT and OP may produce greater toxicity to the nervous system; nontoxic to birds, but impacts reproduction; highly toxic to aquatic species; non-toxic to bees.	*High Risk* In humans, oral exposure is thought to be most significant; concern with DDT in breast milk; high risk of cancer during preparation and spraying for high end exposure estimate (with 2 year exposure); may need extra PPE protection; high noncancer risks during preparation and spraying due to dermal exposure, recommend use of PPE (may need extra PPE protection); low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground water; unacceptable acute exposures from food sprayed during IRS; minimum cancer risk from ingestion of chickens exposed to DDT; studies have found that DDT is migrating into the environment from sprayed homes – *note: recommend appropriate packaging (leak proof) and BMP handling of all*

Pesticide	Properties	Toxicology	PEA findings
			DDT, only for indoor use (not eaves / outside of homes)
Deltamethrin	Powerful broad-spectrum pyrethroid	Low risk to humans; skin and eye irritation; moderate toxicity to mammals; degrades in soil and plants; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Low risk* Found in breast milk
Etofenprox	Pyrethroid	Low risk for acute toxicity in humans; not a cholinesterase inhibitor; degrades in sunlight; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Moderate Risk* Low cancer risk during preparation and spraying; low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground water.
Fenitrothion	Organo-phosphate	Overstimulation of the nervous system due to cholinesterase inhibition; evidence of noncarcinogenicity for humans; broad-spectrum insecticide uses have been cancelled in the United States, it is now only registered for use in ant and roach baits with child-resistant packaging; breaks down in soils; somewhat toxic to birds and fish, highly toxic to aquatic invertebrates; highly toxic to bees.	*Moderate Risk* High noncancer risk during preparation and spraying; wearing PPE reduces risk to reasonable level; low quantities can contaminate groundwater; avoid disposal on land with sandy soil and shallow ground water; unacceptable acute exposures from food sprayed during IRS.
Lambda-cyhalothrin	Pyrethroid	Used for agriculture and animal health; degrades rapidly by sunlight, and is slightly persistent; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	*Low risk*
Malathion	Broad-spectrum organo-phosphate	Used for agriculture and animal health; causes neurological effects by inhibiting cholinesterase in the blood and brain; no longer permitted in the United States for any indoor uses; degrades rapidly; moderately toxic to birds; wide range of toxicity to fish; highly toxic to bees.	*Low Risk* Unacceptable acute exposures from food sprayed during IRS
Pirimiphos-methyl	Fast-acting, broad-spectrum, non-	Acts by inhibiting cholinesterase activity; low mammalian toxicity; moderately toxic to freshwater fish and invertebrates; highly toxic to estuarine	*High Risk* High noncancer risk during preparation and spraying from dermal exposure,

Pesticide	Properties	Toxicology	PEA findings
	cumulative organo-phosphate	invertebrates.	recommend use of PPE (observable adverse effects); may need extra PPE protection; risk of dermal exposure from residue on walls; unacceptable acute exposures from food sprayed during IRS; avoid disposal on land with sandy soil and shallow ground water.
Propoxur	Broad-spectrum carbamate	Reversible cholinesterase inhibition; moderate toxicity in mammals; mobile in the soil; potential to leach into groundwater; degrades rapidly in water; highly toxic to birds, moderately toxic to fish, highly toxic to bees.	*Moderate Risk* Low cancer risk during preparation and spraying; low quantities can contaminate groundwater, avoid disposal on land with sandy soil and shallow ground water.
Chlorfenapyr (new)	Pyrroles class	Good for resistance to OPs, carbamates and pyrethroids; degrades slowly in soil, sediment and water; toxic to birds, fish and highly toxic to bees.	*Moderate Risk* High noncancer risk during preparation and spraying, wearing PPE reduces risk to reasonable level.

ITNS AND LLINS

Conclusion: ITNs and LLINS remain a valid intervention for malaria vector control.

The United Nations goal for ITNs (and LLINs), as set by the Secretary General in 2008, aims to protect all people living in malaria-endemic areas by providing one ITN (LLIN) per two persons at risk (PMI 2011). The PMI program is one of the many partners who are working to help meet this goal.

Conclusion: *ITNs/LLINs show a low risk for negatively impacting human and environmental health.*

As shown in Table 10-2, only pyrethroid insecticides are approved for use on ITNs/LLINs due to their safety for humans and repellency, high knock down effect, and efficacy at low dosages. These insecticides have been shown to pose very low health risks to humans and other mammals. The results from the risk assessment for the distribution and use of ITNs/LLINs assessed dermal exposure during the use of the nets and determined that there is a low risk for contamination.

Table 10-2 LLIN/ITN Pesticide Review

Pesticide	Properties	Toxicology	PEA findings
Deltamethrin	Powerful broad-spectrum pyrethroid	Low risk to humans; skin and eye irritation; moderate toxicity to mammals; degrades in soil and plants; fish are not harmed in field conditions; toxic to bees.	Low risk Found in breast milk

Alpha-cypermethrin	Pyrethroid	Low risk to humans, skin and eye irritant; can bioaccumulate in aquatic organisms; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	Low risk
Permethrin	Pyrethroid	Low risk to humans; EPA likely to be carcinogenic to humans by the oral route; skin and eyes irritant; binds with soil so does not leach into groundwater; degrades rapidly in sunlight; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations; extremely toxic to bees.	Low risk Found in breast milk; higher chemical hazard than deltamethrin.
Lambda-cyhalothrin	Pyrethroid	Used for agriculture and animal health; degrades rapidly in sunlight; slightly persistent; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations.	Low risk
Piperonyl butoxide (new)	Synergist	Degrades somewhat rapidly in the environment	Low risk

Conclusion: *The amount of pesticide released during net washing could not be determined during this assessment.*

Recommendation: *Use appropriate best management practices to avoid potential human or environmental contamination during net washing*. Risks are from either dermal exposure from washing the nets, or ground water contamination from disposal of the wash water.

Conclusion: *The qualitative assessment of risks from washing or fishing with ITNs/LLINs shows that for certain pesticides, the potential for lethality to aquatic organisms is high.*

If nets treated with PBO are washed in a volume of water less than 300 liters, potential lethal effects are expected. Conversely, if nets treated with PBO are washed in a volume greater than 300 liters, effects are not expected to be lethal. Based on the qualitative evaluation, the low or zero level of lethality could not be determined. Similarly, washing nets treated with alpha-cypermethrin in a volume of water less than 950,000 liters is potentially lethal to aquatic organisms.

Recommendation: Perform ecological habitat review to determine if the water body is suitable habitat for susceptible aquatic species. If the habitat is highly disturbed and does not support suitable habitat, then the concerns for lethality do not exist. If, however, the ecosystem is healthy, then the risk of adverse impacts from LLIN/ITN washing/fishing may be an issue and the nature of the habitat should be observed including data on the species present in the surface water, the volume of surface water, and

the flow rate, if not a closed system. Washing or fishing with LLINs/ITNs in areas with breeding grounds for aquatic species should be avoided. Some examples of sensitive areas are coral reefs or grassy or sheltered shore areas that support juvenile species.

Alternative recommendation: *Observe the environmental setting and characteristics of human use of fishing/washing with LLINs/ITNs in surface water bodies in various representative locations to determine if a chemical and/or physical stress risk is plausible for these scenarios.* Because this PEA is somewhat generic, this recommendation assumes a qualitative assessment will be made in the SEA based on the professional judgment of environmental assessment expert prior to allowing fishing/washing with LLINs/ITNs in surface water bodies at a site.

Conclusion: *The potential misuse of the nets, especially for fishing could release pesticide into aquatic ecosystems and also impact biodiversity by removing important juvenile fish and other aquatic species.*

Recommendation: *Monitor how the nets are being used and include an educational program on appropriate use during distribution campaigns. Nets should also be appropriately labeled to include use and care instructions.* PMI should develop IEC/BCC materials that discourage washing or fishing with LLINs/ITNs in sensitive ecosystems, and should distribute such materials to communities in close proximity to such water bodies.

Conclusion: *The human health and environmental consequences assessment determined, that, to avoid acute toxicity to sensitive aquatic species from fishing with the nets, the volume of water must be greater than 100,000 L.*

Conclusion: *Pyrethroid resistance already exists in some major malaria vectors, especially Africa.* The operational impact of resistance on the efficacy and effectiveness of LLIN interventions is not yet fully understood (WHO 2007).

Recommendation: *Monitor resistance and the potential impact to net efficacy.*

Conclusion: *The quantity of nets distributed is carefully monitored, though currently there is no information on the quantity of net material that will eventually need to be collected and disposed of in an appropriate manner once the nets are no longer viable.* WHO is currently conducting a study to identify the proportion of overall plastic waste that will occur after the nets lose their efficacy.

Recommendation: *Monitor the amount of waste accumulating three years after net distribution campaigns.*

PMI will work with international organizations to develop a strategy/system to manage net waste. In addition, information to net users will address unintended uses of nets and should be tailored to reflect the local environment.

LARVICIDING

Conclusion*: Larviciding can be a useful method for malaria control, particularly in areas where breeding sites are accessible and relatively limited in number and size.* Larviciding has the potential to have a synergistic impact on malaria control when implemented with other interventions, such as adult targeting programs of IRS and LLIN. It is also an appropriate intervention to include with environmental management methods in situations where habitat elimination is not possible and instead chemical insecticides can be applied directly to the larval habitats. The use of bacterial insecticides (Bti and Bs) has increased in response to the demand for safe, pest-specific compounds. Insect growth regulators have also become more widely used in recent years.

Conclusion*: Wearing facemasks, gloves, and overalls, have been found to reduce the exposure when handling larvicide agents.* The PEA risk assessment showed that wearing a facemask, gloves, and overalls (i.e. personal protection equipment or PPE), effectively reduced worker exposure risks during the mixing and spraying of larvacides. The hazards of spraying temephos were reduced from slightly above the acceptable

threshold when workers were not wearing PPE to well below the acceptable threshold when they were wearing PPE.

Recommendation*: Workers should wear PPE when handling larvacides.*

Conclusion*: There are negligible risks for human health when potable water is treated with larvicides.* In general, larvicides have low persistence and bioaccumulation, though they are toxic to aquatic species, the low application rate and high biodegradability reduce the probability of a toxic exposure. The results of the semi-quantitative PEA risk analysis support these general statements as very little dilution is required to reduce the applied larvicide concentration to concentrations in the water to levels below the acceptable risk threshold.

Conclusion*: The qualitataive assessment of risks shows that there is potential for adverse effects to sensitive non-target aquatic species to water bodies treated with larvicides.* In order for a larvicide not to be acutely toxic to the most sensitive freshwater aquatic species, the minimum volume of water to which it may be applied is larvicide specific. Methoprene is the least potent larvacide with a minimum volume of water required for applying larvicide of 64 L. Temephos (emulsifiable concentrate) is the most potent with a minimum volume of water required for application of 4875 L.

If methoprene is applied to water bodies with a volume of water of less than 64 liters, potential lethal effects are expected. Conversely, if the volume of water treated with methoprene is greater than 64 liters, effects are not expected to be lethal. Based on the qualitative evaluation, the low or zero level of lethality could not be determined. Similarly, the application of temephos to a water body with a volume of less than 4875 liters is potentially lethal to aquatic organisms.

Recommendation: Perform ecological habitat review to determine if the water body is suitable habitat for susceptible aquatic species. If the habitat is highly disturbed and does not support suitable habitat, then the concerns for lethality do not exist. If, however, the ecosystem is healthy, then the risk of adverse impacts from larvaciding may be an issue and the nature of the habitat should be observed including data on the species present in the surface water, the volume of surface water, and the flow rate, if not a closed system.

Alternative recommendation: *Observe the environmental setting and characteristics of human use of larvicides in surface water bodies in various representative locations to determine if a chemical and/or physical stress risk is plausible for these scenarios.* Because this PEA is somewhat generic, this recommendation assumes a qualitative assessment will be made in the SEA based on the professional judgment of environmental assessment expert prior to allowing larviciding in surface water bodies at a site.

Conclusion*: Larvicide agents identified for the PMI program have been determined to be a low risk for negatively impacting human and environmental health.* (Table 10.3)

Table 10-3 Larvicide Agents Review

Pesticide	Properties	Toxicology	PEA findings
Methoprene		Slightly to nontoxic; only hazardous to target species; not a skin or eye irritant; low persistence in soil, degrades in sunlight, degrades rapidly in water; slightly toxic to birds and fish.	Low risk
Microbial		Pose no danger to humans, non-	Low risk

larvicides		targeted animal species, or the environment.	
Temephos	Organophosphate	Not for use in potable water; compared with other organophosphates, temephos is of low-to-moderate toxicity; causes its effect by inhibiting cholinesterase; low toxicity in humans; short persistence in water; highly to moderately toxic to birds; EC and WP formulations are highly toxic to aquatic organisms, potential to accumulate; highly toxic to bees.	Low risk
Monomolecular oils and films		Minimal detrimental effects on non-target organisms; an "oil slick" can be viewed on the water surface; both the odor and appearance may be objectionable.	Low risk
Spinosad (new)	actinomycete soil bacterium	Very low acute mammalian toxicity; degrades in soil and sunlight; highly selective to insects only.	Low risk
Pyriproxyfen (new)	juvenile hormone mimic	Acute toxicity in mammals is relatively low; brief and minor irritation to skin; low risk for groundwater contamination; toxic to aquatic organisms.	Low risk

ENVIRONMENTAL MANAGEMENT METHODS

Conclusion: *Environmental management is a particularly effective approach where mosquito-breeding habitats are located in relatively small-scale and readily identifiable areas.* It is well suited to areas that have a high human population density (e.g., urban settings). Environmental management is not intended to replace other control strategies. Rather it aims to provide a foundation for an integrated approach and reduce human and environmental exposure to insecticides (Lindsay, Summary Report). Environmental management, in comparison to insecticides, is more effective in the long term than in the short term.

Conclusion: *Environmental management methods range in their impact on the environment; the applicability of each method depends on careful analysis of the specific site (*please refer to Table 10.4*).* The following is a review of the environmental management methods that are considered for use in the PMI program:

Table 10-4 Environmental Management Methods Review

Method	Potential impacts	PEA findings
Deepening/narrowing of existing	No significant impacts	*Little impact*

drains		
Synchronized cropping/intermittent irrigation	No significant impacts	*Little impact*
Filling breeding sites	Decreased habitat and forage for animal species	*Low impact*
Lining water sources and canals	Increased flooding	*Low impact*
Saltwater flooding	Reduced in water availability Decreased habitat for freshwater aquatic species	*Medium impact*
Larvivorous fish	Invasive species Decrease in biodiversity	*Medium impact*
Impoundment construction	Altered water availability Decreased habitat Decreased biodiversity	*High impact*
Biological drainage	Reduced water availability Impact water quality Decreased habitat Altered ecosystem	*High impact*
Vegetation manipulation	Reduced water availability Impact water quality Increased flooding Siltation/sediment Decrease agriculture productivity Decreased habitat Decreased biodiversity	*High impact*
Physical drainage	Reduced water availability Impact water quality Increased flooding Siltation/sediment Decrease agriculture productivity Decreased habitat Decreased biodiversity	*High impact*

Wall Lining

Conclusion: *Wall lining has the potential to be a low risk intervention for the PMI program.* Wall lining is a new product that is currently being tested for efficacy and practicality. It has potential as a long-lasting insecticide against indoor resting mosquitoes when used to line the interior walls and ceilings of homes. Wall lining will have similar human health and environmental impacts to an LLIN/ITN as both are treated with similar insecticides. Wall lining may have a less exposure risk to humans than an LLIN/ITN as the lining is attached to the wall where there is less a chance for dermal contact. Like an LLIN/ITN,

the wall lining is treated only with pyrethroids because they have been shown to pose very low health risks to humans and other mammals.

***Conclusion**: Wearing gloves are expected to reduce the exposure when handling the wall lining.* The PEA risk assessment did not directly assess the risks of the installation of wall lining; however, it is expected that, like the handling of LLIN/ITN pesticides, wearing gloves (i.e. PPE) will reduce exposure.

***Recommendation:** Appropriate PPE should be worn when installing the wall lining.* Workers should wear gloves during installation to minimize dermal exposure to the new material that will have the highest concentration of pesticide. In particular, workers installing the lining in numerous homes should wear PPE.

***Conclusion:** As with LLINs, pyrethroid resistance could be a future issue for the efficacy and effectiveness of this intervention.*

***Recommendation:** Monitor resistance and the potential impact to wall lining efficacy.*

***Conclusion:** No information is available on the quantity of material that will eventually be collected and disposed of in an appropriate manner once the lining is no longer viable because wall lining is a new technique.*

***Recommendation:** Monitor the amount of waste accumulating three years after wall lining distribution campaigns.*

Conclusion*: The pesticides used for wall lining have been determined a low risk for negatively impacting human and environmental health.* (see table 10.5)

Table 10.5 Wall lining Pesticide Review

Pesticide	Properties	Toxicology	PEA findings
Deltamethrin	Powerful broad-spectrum Pyrethroid	low risk to humans; skin and eye irritation; moderate toxicity to mammals; Degrades in soil and plants; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations	*Low risk* Found in breast milk
Permethrin	Pyrethroid	low risk to humans; EPA likely to be carcinogenic to humans by the oral route; skin and eyes irritant; binds with soil so doesn't leach into groundwater; degrades in sunlight; highly toxic to bees and fish although these organisms will not be harmed when product is applied according to label recommendations	*Low risk* Found in breast milk; has a higher chemical hazard than deltamethrin.

11. NEXT STEPS – APPLYING THE PEA

11.1. PLANNING

Knowing where the most malaria cases occur and where environmental conditions promote increased vector prevalence provides guidance in choosing locations where the intervention will have the most impact. Targeting areas for intervention, rather than implementing a broad-spectrum approach, will simultaneously protect more people from malaria and promote judicious use of insecticides, larvicides, and nonchemical interventions. Targeting the right areas requires sustained surveillance.

Sustained surveillance in turn requires substantial technical support and capacity building, and involves the following aspects:

- Gathering historical malaria and environmental data
- Developing computerized databases
- Analyzing historical malaria and environmental data
- Developing protocols and providing training for malaria sentinel sites
- Analyzing seasonal patterns of malaria transmission (where applicable)
- Creating tools for forecasting and detecting malaria epidemics (where applicable)

Location-Specific Appropriateness

The different interventions proposed in this PEA are more or less appropriate depending on the intervention location chosen. Entomological monitoring should be conducted to determine the geographic and temporal distribution of vector populations. Different interventions may be better suited to the endemic or epidemic nature of the disease in a particular location. Additionally, environmental factors can be a determinant for selecting (or emphasizing) a particular intervention. In a semi-arid or arid environment, breeding sites are typically found in small, well-defined areas. In such conditions, year-round environmental management and larviciding may provide more benefits at a lower cost than in tropical areas. Also, more specific environmental factors need to be taken into account, such as proximity to sensitive areas and critical habitats, which may require an intervention that has been determined to be a low risk to the environment. Population density can indicate which intervention is more suitable; environmental management and indoor residual spraying (IRS) generally have greater impact and cost less per person in urban than in rural areas. Finally, the type of housing structure in the location can dictate the appropriateness of an intervention.

Choosing or emphasizing an intervention that is location-appropriate will ensure that pesticides are used judiciously. Yet even after selecting a location-appropriate intervention, it may have to be implemented at an appropriate time to maximize impact. This is particularly important in IRS, where spraying should be conducted as close as possible to the start of a rainy season. Larviciding must also be timed in a manner that increases its impact on the vector population. Once a location, one or more location-specific interventions, and the timing of these interventions have been determined, further operational planning and implementation can commence. To ensure that decisions about future interventions make the most impact with the least

harm to humans and the environment, surveillance should be conducted to determine the extent to which each intervention contributes to malaria reduction. Conclusions derived can then be used to adjust which interventions are chosen or emphasized in the future.

Considering Sustainability

To ensure that a USAID-supported intervention will be sustainable, USAID should support interventions in host countries where the following conditions prevail:

- Political commitment to the intervention at all levels of government
- Stakeholder commitment to the intervention
- Commitment to addressing human health and environmental concerns of the intervention at all levels of government
- Stakeholder commitment to addressing human health and environmental concerns of the intervention
- Financial sustainability of the intervention in-country
- Future availability of human and institutional resources for implementation, monitoring, and evaluation of the intervention

Planning for the Intervention

Pesticide Selection

The chemicals used in IRS, LLINs, Wall Lining and Larviciding all have different properties and are more or less appropriate in different circumstances. The following considerations must be met in making decisions on pesticides used in malaria vector control:

- Pesticide registration in the host country
- Acceptability of the pesticide to the national malaria control program
- Risk to human health
    - Pesticides must be approved by the WHO and should be preferred based on their safety as described in Section 5.
- Risk to environment, livestock, and/or agricultural trade

With particular regard to dichloro-diphenyl-trichloroethane (DDT), "viable alternatives to DDT should pose less risk to human health and the environment, be suitable for disease control based on [country]-specific conditions, and be supported with monitoring data (UNEP, 2001)."

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

- Vector resistance.

Secondary factors include:

- Appropriateness of surface for spraying
- Duration of effectiveness (and implications for cost)

- Cost of pesticide.

Tertiary factors include:

- The need for a pesticide of a different class to prevent resistance
- Major classes of pesticide used in other vector control interventions that could promote resistance
- Major classes of pesticide used in the agricultural sector that could promote resistance
- Host-country capacity to prevent pilferage for each country program.

Supplemental Environmental Assessments (SEAs) must describe how these factors have been addressed in the pesticide selection process.

Planning for Health and Safety

The planning process for integrated vector management (IVM) malaria interventions should integrate human health and environmental considerations from the start. When intervention needs are initially assessed and budgets developed, mitigation and monitoring components and costs identified in an SEA should be included.

11.2. SEA GUIDELINES

This PEA provides a broad view of the human health and environmental impacts that could result from implementation of malaria vector control interventions. However, the PEA cannot account for inter-country and interregional variation regarding issues such as the capacity to manage pesticides used for vector control and the environment likely to be impacted. For this reason, SEAs must be developed to describe in-country impacts of interventions and describe country-specific activities to minimize those impacts. This process of using the PEA as the basis on which the country-specific SEA is developed is called "tiering." Tiering off from the PEA saves substantial time and money by not having to repeat environmental review that applies generically to all activities within a program. Tiering also ensures basic consistency and quality across all of the program's activities, no matter where they are undertaken.

Whenever an in-country malaria vector control activity involves "assistance for the procurement or use, or both, of pesticides," SEAs supplementing the PEA must address the pesticide procedures found in 22 CFR 216.3(b).

In sum, the SEA should be looked upon as the overall picture within the country. The SEA should address the human health and environmental impacts that may occur as a result of USAID support of malaria vector control activities. See ***Annex C*** for guidelines for preparing SEAs.

SEAs are required before any country program can commence and are valid for five years, whereupon an updated SEA must be prepared. Annual SEA's are required for all programs that are using DDT. SEA Amendments are required if there are any changes to the program that were not addressed in previous SEAs. Letter Reports must be submitted annually and consist of a summary of the SEA components, with detailed discussions on any programmatic changes, including discussions on the results of all monitoring efforts.

11.3. ENVIRONMENTAL EVALUATIONS

To assist USAID implementing partners in achieving compliance with Regulation 216, USAID procured a contract to provide technical assistance, training and compliance oversight where needed for the PMI program. The Environmental Monitoring and Capacity Building (EMCAB) for the Vector Control

Interventions project has been implemented as a support project for the Global Health (GH) Bureau and participating USAID Missions as well as relevant partner country agencies and USAID PMI implementing contractors. One of EMCAB's principle tasks is to provide independent environmental evaluations of the IRS activities at a country level upon BEO and Mission request.

The primary objective of the EMCAB evaluation visits are to assist the Missions to ensure that the IRS activities and other malaria control interventions that are being implemented under PMI are being carried out in accordance to environmental best management practices and compliance with Regulation 216. The visits also allow EMCAB to provide problem solving support (as required) to the USAID Missions, their PMI Implementing Partners, and host country counterpart ministries.

Environmental evaluation activities should include the following:

- Review the goals and objectives of the evaluation, and discuss the specific issues and concerns of the Mission and Implementing partner.
- Review all up-to-date Environmental Compliance Documents (IEE, SEA, Amendments, Environmental Reports, etc.) from the USAID Mission and PMI Team in question to develop an up-to-date understanding of the program, its achievements and challenges, from the environmental perspective.
- Meet with host country government agencies and partners to review the goals and objectives of the evaluation, and discuss the specific issues and concerns.
- Visit Malaria control activities in the field with the implementing partner, PMI advisor and MEO.
- Provide a debriefing of general findings and recommendations to the Mission and implementing partner.
- Prepare a field report that will highlight the issues and opportunities noted during the field inspection visit, and draw conclusions and recommendations for the country program

Field evaluations should be conducted annually for each host country PMI program. The subsequent field report should be submitted to the BEO, the country Mission PMI Advisor and the Implementing Partner.

A comprehensive environmental evaluation for USAID Malaria Control Intervention should include the following, where applicable:

- Post-spray Campaign Survey, assessing Knowledge, Attitude, and Practices (KAP) of community regarding IRS responsibilities
- Post-training evaluation of spray operators or applicators, supervisors, storekeepers and medical practitioners when applicable
- Post-training evaluation of instructors
- Stock management records
- Mitigation monitoring reports
- Environmental impact monitoring reports
- Entomological monitoring reports

- Malaria case monitoring reports
- Mitigation Checklists

During its 2010-2011 fiscal year, EMCAB has also conducted workshops on how to conduct environmental evaluations for IRS programs. These training courses were designed to prepare host country professionals working with the PMI program in sub-Saharan Africa to use a uniform environmental approach for IRS activities that will ensure compliance with USAID and host country environmental regulations. The expected outcome of the workshop was to create a cadre of technical experts from sub-Saharan Africa who would then be able to evaluate and provide guidance on how to effectively implement environmental compliance for IRS programs. The participants included private consultants and government employees, who are now capable of conducting independent environmental evaluations of the IRS activities. Additional training would help build the sustainability of the USAID Malaria Control program.

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