



INDOOR RESIDUAL SPRAYING
FOR MALARIA CONTROL

Supplemental Environmental Assessment:

Indoor Residual Spraying (IRS) For Malaria Vector Control in Zimbabwe, 2012-2016 Indefinite Quantity Contract (IQC) TO4

April 2012

Prepared for: Zimbabwe Mission
United States Agency for International Development

Prepared by:

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Table of Contents



INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL

.....	1
LIST OF FIGURES.....	4
LIST OF TABLES.....	5
ACRONYMS.....	6
SUMMARY OF FINDINGS.....	8
I. <i>Malaria Burden in Zimbabwe.....</i>	8
II. <i>PMI Support in Africa and in Zimbabwe.....</i>	8
III. <i>Adverse Health and Environmental Impacts from IRS and Mitigation Measures.....</i>	9
IV. <i>Safer Use Action Plan.....</i>	10
1.0 BACKGROUND.....	15
1.1 <i>Background to the Proposed Action.....</i>	15
1.2 <i>Project Objectives.....</i>	15
1.3 <i>Malaria Burden in Zimbabwe.....</i>	16
1.4 <i>Institutional Framework for Malaria Control in Zimbabwe.....</i>	18
1.5 <i>IRS Activities in Zimbabwe.....</i>	21
2.0 DESCRIPTION OF ALTERNATIVES, INCLUDING THE PROPOSED ACTION.....	33
2.1 <i>Proposed Action.....</i>	33
2.2 <i>The Insecticide Selection Process.....</i>	34
2.3 <i>Preferred Insecticide Classes.....</i>	36
2.4 <i>Rejected Insecticide Classes.....</i>	36
2.5 <i>Quantification of Pesticide Requirements.....</i>	36
2.6 <i>Alternative IRS Geographical Sites Considered.....</i>	50
2.7 <i>No Action Alternative.....</i>	50
2.8 <i>Environmental Management Alternative.....</i>	51
2.9 <i>Larviciding.....</i>	51
3.0 AFFECTED ENVIRONMENT- ZIMBABWE.....	52
3.1 <i>Geography and Administrative Subdivisions.....</i>	52
3.2 <i>Climate.....</i>	53
3.3 <i>Topography.....</i>	54
3.4 <i>Hydrology.....</i>	54
3.5 <i>Vegetation.....</i>	55
3.6 <i>Agro-Ecological Zones.....</i>	57
3.7 <i>Agriculture.....</i>	58
3.8 <i>National Parks and Wildlife.....</i>	59
4.0 PESTICIDE PROCEDURES.....	62
a. <i>The United States Environmental Protection Agency’s Registration Status of the Requested Pesticide.....</i>	62
b. <i>The Basis for Selection of the Requested Pesticides.....</i>	62
c. <i>The Extent to Which the Proposed Pesticide Use Is Part of an Integrated Pest Management (IPM) Program.....</i>	65

<i>d. The Proposed Method or Methods of Application, Including Availability of Appropriate Application and Safety Equipment.....</i>	<i>66</i>
<i>e. Any Acute and Long-Term Toxicological Hazards, either Human or Environmental, Associated with the Proposed Use and Measures Available to Minimize Such Hazards.....</i>	<i>67</i>
<i>f. The Effectiveness of the Requested Pesticide for the Proposed Use</i>	<i>69</i>
<i>g. Compatibility of the Proposed Pesticide with Target and Non-Target Ecosystems.....</i>	<i>70</i>
<i>h. The Conditions under Which the Pesticide Is To Be Used, Including Climate, Flora, Fauna, Geography, Hydrology, and Soils.....</i>	<i>71</i>
<i>i. The Availability and Effectiveness of Other Pesticides or Non-Chemical Control Methods</i>	<i>71</i>
<i>j. The Requesting Country's Ability to Regulate or Control the Distribution, Storage, Use, and Disposal of the Requested Pesticide.....</i>	<i>72</i>
<i>k. The Provisions Made for Training of Users and Applicators</i>	<i>73</i>
<i>l. The Provisions Made for Monitoring the Use and Effectiveness of the Pesticide.....</i>	<i>74</i>
5.0 PUBLIC CONSULTATIONS.....	75
5.1 Ward Level	75
5.2 Provincial Level	75
5.3 National level.....	76
6.0 ENVIRONMENTAL IMPACTS AND THE MITIGATION AND MONITORING PLAN	77
6.1 Potential Positive Effects of the IRS Program	77
6.2 Potential Adverse Impacts.....	77
6.3 Human Exposure Risks/Impacts.....	80
6.4 Cumulative Impact	82
6.5 Mitigation Measures	82
6.6 Pesticide Quality Assurance.....	90
6.7 Conclusion	90
7.0 EMMP IMPLEMENTATION.....	92
ANNEX 1: ENVIRONMENTAL MITIGATION AND MONITORING PLAN (EMMP).....	93
ANNEX 2: GENERAL PRINCIPLES IN THE MANAGEMENT OF ACUTE PESTICIDE POISONINGS	101
ANNEX 3: USA REGULATION 22CFR 216.3.(B)	104
ANNEX 4: PESTICIDES PROFILES	107
ANNEX 5: BIBLIOGRAPHIC REFERENCES	143

List of Figures

FIGURE 1: 2010 MALARIA INCIDENCE RATES BY DISTRICT	17
FIGURE 2: LAMBDA-CYHALOTHRIN 2011-2012	28
FIGURE 3: MALARIA DISTRIBUTION REGIONS.....	29
FIGURE 4 : ZIMBABWE AGRO-ECOLOGICAL.....	30
FIGURE 5: PROVINCIAL MALARIA INCIDENCE BY YEAR 2005 TO 2010	31
FIGURE 6: MALARIA CASES AND NATIONAL TOTAL MONTHLY RAINFALL IN ZIMBABWE 2010	31
FIGURE 7: ZIMBABWE ALTITUDE ZONES	32
FIGURE 8: MAP SHOWING THE ALL THE PROVINCES OF ZIMBABWE	37
FIGURE 9: CHINHOYI PROVINCIAL WAREHOUSE (MASH WEST) FIGURE 10 : MUTOKO DISTRICT WAREHOUSE (MASH EAST)	38
FIGURE 11: PESTICIDE CHAIN OF CUSTODY AND MANAGEMENT	39
FIGURE 12: OPERATORS DRESSED IN PPE.....	41
FIGURE 13: SPRAY PUMPS USED IN IRS OPERATIONS	43
FIGURE 14: PROGRESSIVE RINSING (BMP MANUAL).....	46
FIGURE 15: OUTLINE OF SOAK PITS DESIGN (BMP MANUAL)	47
FIGURE 16: TYPE OF SOAK PITS AND WASHING AREAS	48
FIGURE 17: MUTARE PROVINCIAL HOSPITAL INCINERATOR (MANICALAND PROVINCE)	50
FIGURE 18: ZIMBABWE ADMINISTRATIVE MAP	52
FIGURE 19 : ANNUAL RAINFALL IN ZIMBABWE	53
FIGURE 20: ZIMBABWE SATELLITE MAP.....	54
FIGURE 21: MAN-MADE WATER BODY IN MASH EAST	55
FIGURE 22: ZIMBABWE VEGETATION MAP	56
FIGURE 23: ZIMBABWE NATIONAL PARKS MAP.....	59
FIGURE 24: TYPE OF RURAL MUD HABITATS IN MASH WEST AND MASH EAST OF ZIMBABWE	63
FIGURE 25: SPRAY PUMPS USED IN IRS OPERATIONS	67
FIGURE 26: COMMUNITY HEALTH WORKERS OF NYAGUNDI FIGURE 27: KADOMA IRS CONFERENCE	75
FIGURE 28: DEBRIEFING MEETING IN NMCP/MOHCW	76
FIGURE 29 : EMERGENCY RESPONSE TO INSECTICIDE SPILLS.....	85

List of tables

TABLE 1: MALARIA-SPECIFIC FUNDING 2007-2011	19
TABLE 2: ROOMS SPRAYED AND POPULATION COVERED 2001- 2010	21
TABLE 3 : LEVEL 3 SPRAY OPERATOR TRAINING	22
TABLE 4: BIOASSAYS CONDUCTED ON SPRAYED SURFACES (2007 TO 2011).....	23
TABLE 5: STUDY AREA FOR SUSCEPTIBILITY TESTS.....	23
TABLE 6: SUSCEPTIBILITY TESTING, FOUR CLASSES OF PESTICIDE.....	25
TABLE 7: WHO RECOMMENDED PESTICIDES	36
TABLE 8 : DRUGS RECOMMENDED FOR TREATMENT OF PYRETHROID EXPOSURE	44
TABLE 9 : NUMBER OF CAMPS BY PROVINCE AND DISTRICT.....	48
TABLE 10 : ZIMBABWE ECOREGIONS (VINCENT AND THOMAS, 1960).....	57
TABLE 11: PESTICIDE TOXICITY	64
TABLE 12: INSECTICIDE, COMBUSTION BYPRODUCT, AND EXTINGUISHING INSTRUCTIONS	86
TABLE 13 : ANTIDOTES FOR PESTICIDE CLASSES.....	89
TABLE 14: DECISION CRITERIA MATRIX.....	91

ACRONYMS

ACT	artemisinin-based combination therapy
ADS	Automated Directives System
AIDS	Acquired Immune Deficiency Syndrome
AEZ	Agro-Ecological Zones
AL	artemether/lumefantrine combination therapy
BCC	Behavior change communication
BMP	(USAID's IRS) Best Management Practices Manual
BEOs	(USAID) Bureau of Environment Officers
CBD	Convention on Biological Diversity
CCC	Convention on Climate Change
CITES	Convention on Trade of Endangered Species
DARS	Department of Agricultural Regulatory Services
DFID	Department for International Development
DEHO	District Environment Health Officer
DHS	Demographic Health Survey
DDT	Dichloro Diphenyl Trichloroethane
EIA	Environmental Impact Assessment
EMA	Environment Management Agency
EMMP	Environmental Monitoring and Mitigation Plan
EU	European Union
FAO	Food and Agriculture Organization
GFTAM	Global Fund to Fight AIDS, Tuberculosis, and Malaria
GHI	Global Health Initiative
GoZ	Government of Zimbabwe
HIV	Human Immuno Deficiency Virus
IEC	Information, education and communication
IQC	Indefinite Quantity Contract
IPTp	Intermittent preventive treatment in pregnancy
IRS	Indoor Residual Spraying
IVM	Integrated Vector Management
ITN	Insecticide Treated Net
LADD	Life Time Average Daily Dose
LLIN	Long-lasting insecticidal net
M&E	Monitoring and Evaluation
MENR	Ministry of Environment and Natural Resources
MIMS	Multiple Indicator Monitoring Survey
MOHCW	Ministry of Health and Child Welfare
MOP	Malaria Operational Plan
NGO	Non-Governmental Organization
NHS	National Health Strategy
NIHR	National Institute of Health Research
NIMR	National Institute for Medical Research
NMCP	National Malaria Control Program
NR	Natural Region

MSDS	Material Safety Data Sheets
OC	Organochlorine
ODP	Out Patient Department
OP	Organophosphate
PEA	Programmatic Environmental Assessment
PERSUAP	Pesticide Evaluation and Safer Use Action Plan
PEHO	Provincial Environmental Health Officer
PSI	Population Services International
PMI	President's Malaria Initiative
PPE	Personal Protective Equipment
POP	Product Organic Persistent
REA	Regional Environment Advisor
RDT	Rapid Diagnostic Test
RBM	Roll Back Malaria
SADC	Southern Africa Development Committee
SEA	Supplemental Environmental Assessment
SOW	Scope of Work
UNICEF	United Nations Children's Funds
UNEP	United Nations Environment Program
UNFAO	United Nations Food and Agriculture Organization
USAID	United States Agency for International Development
USG	United States Government
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme
WG	Wetable Granules
WHT	Ward Health Team
WP	Wetable Powder
ZACPPLAN	Zimbabwe Action Plan for Environment Management
GAL	Government Analyst Laboratory

SUMMARY OF FINDINGS

I. Malaria Burden in Zimbabwe

Malaria remains the second cause of morbidity and mortality after HIV and AIDS related illnesses in the country. Malaria accounts for 30% of all out patient attendances, and 12% of hospital admissions. The groups most vulnerable to this preventable disease are children below the age of 5 years, pregnant women, the elderly, and people living with HIV and/or AIDS. Ninety-eight per cent (98%) of all cases of malaria are caused by the parasite *P. falciparum*, carried primarily by the vector *An.arabiensis*.

Malaria is mainly seasonal in Zimbabwe with potential for epidemics during the rainy season. Malaria transmission varies across the country, with high to moderate transmission in northern and eastern provinces bordering Zambia and Mozambique, and low transmission in southern provinces bordering South Africa and Botswana. An estimated 50% of the populations in Zimbabwe reside in malaria endemic areas.

The NMCP has a malaria control policy and strategic plan aligned with the overall National Health Strategy 2009-2013. Technical guidelines and training manuals are available to support priority interventions. The Government of Zimbabwe considers malaria as a key target disease, as reflected in the old National Health Strategy (NHS) 1997-2007 as well as in the current NHS 2009-2013.

All WHOPEs approved insecticides are registered in Zimbabwe. Currently the class of insecticides most frequently used is pyrethroids. However, due to vector resistance that may develop over time, the program could shift to carbamate and/or organophosphate classes in future campaigns.

II. PMI Support in Africa and in Zimbabwe

The President's Malaria Initiative (PMI) is a core component of the Global Health Initiative (GHI), along with HIV/AIDS, and tuberculosis. Programming of PMI activities follow the core principles of GHI: encouraging country ownership and investing in country-led plans and health systems; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; implementing a woman- and girl-centered approach; improving monitoring and evaluation; and promoting research and innovation.

Zimbabwe was selected as a PMI country in FY 2011, but USAID has previously provided limited malaria support, including funding and technical assistance to conduct emergency IRS in 2009, and an emergency procurement of ACTs in 2011. Historically, Zimbabwe has had a solid IRS program date backing to late, but the use of ITNs is relatively new to the country. For 2012, PMI will support NMCP in implementation of IRS in 17 Districts in 3 provinces of Manicaland, Mash East and Mash West.

In 2004, a Positive Threshold determination was made in regard to the USAID PMI IRS program under the pesticide procedures set forth in §216.3(b) of the 22 CFR 216. That determination triggered the need for a Programmatic Environmental Assessment (PEA), which was written in

2004 and revised in 2005 and 2006. A further revision was drafted to the PEA in 2011, and is under review as of the writing of this document.

The PEA is a comprehensive analysis of Integrated Vector Management from an environmental, health and safety perspective. What the PEA does not do is account for country-specific factors, such as government organization and capabilities, logistics, water resources, important biodiversity resources, and sensitive areas such as apiculture and aquaculture, and cultural diversity.

These factors must be analyzed in a country-specific Supplemental Environmental Assessment (SEA), which supplements the PEA. The SEA takes into account those country- and site-specific conditions which must be considered before embarking on malaria vector control programs in a particular country.

This Supplemental Environmental Assessment (SEA) considers and proposes the use of three classes of WHO-approved pesticides (pyrethroids, carbamates, and organophosphates) for IRS activities in all of Zimbabwe for a period of five years (2012-2016), with the exception of areas within 30 m of water bodies, wetlands, beekeeping areas, national forests and parks. The use of organochlorines such as DDT is not proposed or approved under this SEA.

This assessment draws on the Programmatic Environmental Assessment (PEA) for Integrated Vector Management, approved in March 2006. (http://www.ehproject.org/PDF/ehkm/ivm-env_assessment.pdf).

III. Adverse Health and Environmental Impacts from IRS and Mitigation Measures

Based on USAID's experience with implementation of IRS in 17 other sub-Saharan African countries under the President's Malaria Initiative (PMI), the most likely potential adverse health impact of the IRS intervention is unintentional pesticide exposure, leading to acute but mostly transitory health impacts on beneficiaries and spray operators. However, the health effects from toxic exposure to organophosphates may not be transitory, and so should be guarded against with greater vigilance. If the use of organophosphates is planned, additional efforts must be made to train and sensitize all IRS personnel to the risks involved, the symptoms of organophosphate toxicity, and the medical treatment protocol. It may also be necessary to develop a cholinesterase monitoring program for operators and others in potential close contact with these pesticides.

To mitigate risks of exposure, all individuals involved in the implementation of spraying – from spray operators to washpersons to storekeepers – will be provided with appropriate and adequate personal protective equipment (PPE), and will be trained in the best management practices contained in the President's Malaria Initiative IRS Best Management Practices Manual. Community members will be informed on how to minimize direct and indirect exposure to insecticides (e.g., removing furniture and food from houses prior to spraying, keeping animals away, staying out of houses sprayed for two hours, sweeping dead bugs and properly disposing of them, etc.).

The highest risk to the environment is likely contamination to water resources, with subsequent die-off of fish and other aquatic life, since all the IRS insecticides are hazardous for aquatic life,

with the exception of malathion, and risk to bees, which are extremely sensitive to all WHO-recommended pesticides for malaria control. In Zimbabwe, the ecosystems considered as sensitive to IRS implementation are National Parks, rivers, water bodies, fish farms, bee-keeping areas and protected forests.

No households were found in the critical ecosystems during the field visits for SEA preparation, although observations were limited to a very small sample size. If houses are found within 30 meters of sensitive areas, they should be noted by mobilizers, marked (physically, as well as by the use of GPS if available), and not sprayed.

The PMI IRS Best Practices Manual specifies that all washing areas and soak pits must be constructed according to specific guidance in order to protect human and animal health as well as prevent environmental damage. Additional mitigation measures include utilization of PPE, best practices in pesticide storage and management, re-use/disposal of contaminated water from operations, and strong supervision and oversight at all levels.

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

IV. Safer Use Action Plan

During implementation, USAID/PMI/Zimbabwe and its implementing partners will adhere to the conditions detailed in this SEA, which are summarized below, and in more detail in the Environmental Monitoring and Mitigation Plan (EMMP) Annex 1 of this report.

General implementation conditions: Project-level implementation procedures

The following project-level implementation procedures are recommended as a general condition for approval of this SEA. Contingent upon such approval, their implementation will therefore be mandatory. They are intended to assure that the SEA findings and conditions are implemented in project work plans, monitoring and reporting requirements:

USAID/Zimbabwe IRS team shall undertake the following for implementation of IRS in Zimbabwe:

1. The prime contractor for the project ("the contractor") or his designee will develop this SEA that specifies the conditions under which IRS may be implemented.
2. The contractor or implementing partner(s) will follow the prescriptions of the EMMP contained herein, including monitoring to assure appropriate implementation and the sufficiency of environmental compliance measures.
3. The contractor or implementing partner(s) shall integrate these environmental compliance measures into the project work plan and report on them in the normal basis of project reporting. The PMI/IRS team shall assure that this integration occurs.
4. The contractor will ensure that training is provided to all IRS staff and workers as prescribed by the EMMP and Automated Directives System (ADS) 204.5.4 manual.

5. The contractor or implementing partner will notify PMI/IRS of any work plan activities outside the scope of the SEA, and the PMI unit will independently audit the work plan against the requirements of the SEA.
6. Any activities not addressed within the SEA must be addressed with an SEA amendment that must be approved by the GH and AFR BEO before the activities in question can go forward.
7. The PMI/IRS team shall ensure that the contractor's or implementing partner's responsibilities will be incorporated into contracts, grants or any other sub-agreement and SOWs.
8. For projects currently in implementation, USAID/Zimbabwe-PMI unit, with the assistance of the Mission Environmental Officer and/or the Regional Environmental Advisor as necessary, will discuss SEA conditions with the contractor; and where necessary, come to appropriate agreement regarding the process for implementing these conditions as a mid-project adjustment.
9. As devising and implementing environmental compliance approaches should be an integral part of work plan development, these procedures place this responsibility principally on prime contractors. PMI/IRS Team's primary role is thus to review and monitor, as with the execution of any other part of the work plan. Where such review and monitoring indicates unforeseen environmental impacts or that mitigation and control measures are insufficient, the PMI/IRS unit will consult promptly with the Regional Environmental Advisor (REA) at USAID/ South Africa in Pretoria to revise and adapt the environmental mitigation measures as necessary.

Policy, Planning and Institutional Requirements

- Prohibit the use of IRS insecticides in sensitive ecosystems (i.e. 30 meters from flood zones, wetlands, National Parks, biodiversity preserves, rivers, dams, lakes, fish farms, beekeeping areas, etc.). In line with the established best practices for IRS, and relevant national and USAID policies, the implementing partner will establish and implement mitigation measures to assure adequate protection of these sensitive ecosystems.
- Develop and implement vector resistance management. Appropriate measures will be undertaken to prevent/manage resistance and to ensure the continued effectiveness of insecticides used for IRS.
- Promote inter-sectoral collaboration frameworks and institutional arrangements to facilitate a comprehensive approach to vector control and associated pesticides management. Coordination between the malaria control program and major stakeholders will be strengthened. This will include collaboration with:
 - Ministry of Agriculture – Department of Agricultural Registration Services for appropriate integration of vector and pest management activities aimed at enhancing judicious use of insecticides, especially within the rural farmer community settings.
 - Ministry of Environment and Natural Resources (MENR) which has overall responsibility for environmental management and protection.
 - Environment Management Agency which is responsible for enforcement of all environmental laws, guidelines, policies, standards and regulations in Zimbabwe, as well as enforcing compliance with provisions of international

agreements, protocols, conventions and treaties on the environment to which Zimbabwe is a signatory.

Operational Requirements

The IRS implementing contractor will work closely with NMCP to access relevant country level authorization and support needed for successful IRS implementation:

- Quality assurance for commodity procurement and IRS operations, to minimize risks to human health and the environment. This will include ensuring legitimate procurement sources, verifiable chain of custody of commodities, and representative sampling and analysis of pesticide, as well as effective quality compliance inspections of IRS activities in the field.
- Ensure compliance with national regulations on pesticides and USAID Best Management Practices for registering, importing, transporting, labeling, handling, use, storage, and disposal of pesticides.
- Train relevant categories of workers involved in IRS operations (e.g. district program managers/coordinators, spray operators, storekeepers, pesticide transporters, and supervisors) on best practices in accordance with national pesticides regulations and recommendations/guidelines of WHO and this SEA. Criteria for reprimanding non-observance of best practices by these workers will be established.
- Ensure use of appropriate personal protective equipment and best practices, including effective field supervision of spray operations, for adequate protection of spray operators and other handlers of pesticides.
- Train health workers in the management of insecticide poisoning. This will include program-specific guidelines on poison treatment; designation of district hospitals within the target areas for appropriate treatment of insecticide poisoning; training of IRS workers to recognize early danger signs of poisoning and taking appropriate action.
- Enforce protection of fetus and suckling-children against exposure in spray operations. Exclude pregnant women and breast-feeding mothers from direct handling of pesticides (e.g. spray operations, washers). Before each spray season, and every thirty days thereafter during operations, pregnancy testing will be established for potential female handlers of pesticides.
- Carry out IEC activities for targeted communities and households to reduce exposure. Provide information on the removal of food, cooking and water utensils, covering of unmovable furniture with impermeable plastic prior to spraying; exclusion of spraying rooms used by pregnant women or sick individuals who are unable to leave their homes; preventing the reentry of sprayed rooms for at least two hours after spraying; sweeping of floor residues before reentry of children or animals and disposal cleaning wastes including dead insects in pit latrines.
- Establish strict practices to reduce environmental contamination. This will include comprehensive auditing of pesticide stocks and usage, as well as enforcing best practices related to the handling, washing and disposal of containers; progressive use of waste/wash water and ablution blocks.
- Establish best practice for the transport of spray operators. This includes providing trucks with benches for transport of spray operators, and ensuring that spray operators are not

transported with insecticides. Contract specific insurance for covering spray operators during spray operation. Strengthen training of drivers to limit risk of accident.

- Provide training support, as necessary, to strengthen the supervisory capacity of Environment Management Agency at National, Provincial and District level for day-to-day monitoring of environment compliance of IRS activities.

In coordination with Abt Associates, NMCP, Environmental Health Department, NIHR and EMA will carry out routine compliance inspections of all IRS districts, including unannounced spot inspections, to verify compliance with all relevant national regulations. PMI and EMA will independently conduct inspections of IRS activities and facilities in the IRS districts.

PMI contractor (Abt Associates) will work with the NMCP to ensure that IRS Training of Trainers (IRS level 1 training), IRS provincial training (IRS level 2 training) and Training of Spray Operators (IRS level 3 training) includes use of local language on minimizing environmental contamination of IRS by: a) ensuring appropriate language in community mobilization efforts about sweeping houses and burying materials in latrines or dug holes, b) reminding spray operators to be cautious when spraying eaves to avoid environmental contamination, and c) training of spray operators, team leaders, and supervisors on proper maintenance of spray pumps to prevent spray pump leakages.

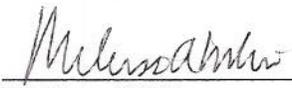
APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:

The United States Agency for International Development's Global Health Bureau has determined that the proposed indoor residual spraying effort, as described in the Supplemental Environmental Assessment: Indoor Residual Spraying for malaria control in Zimbabwe April 2012, responds to the needs of the community and country as it relates to managing malaria in Zimbabwe as well as conforms to the requirements established in 22 CFR 216.

This document does not mandate the execution of the proposed IRS, rather, documents the environmental planning and impact analysis executed by the IRS team in preparation for the proposed action. The design and standards of operation of the IRS program are established to avoid and reduce any potential impact. USAID has concluded that the proposed action, when executed as described in the Supplemental Environmental Assessment and the Programmatic Environmental Assessment, is consistent with USAID's goal of reducing malaria incidence in Zimbabwe while minimizing negative impact to environmental and human health.

CLEARANCE:

Mission Director, USAID/ Zimbabwe

 Date: 6/28/2012
Melissa Williams

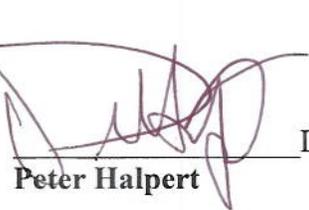
CONCURRENCE:

Bureau Environmental Officer, Global Health:

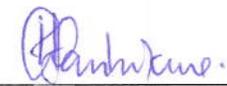
Teresa Bernhard

ADDITIONAL CLEARANCES:

Health, Population and Nutrition
USAID/ Zimbabwe:

 Date: 6/28/2012
Peter Halpert

Mission Environmental Officer
USAID/ Zimbabwe:

 Date: 6/28/2012
Hamfrey Sanhokwe

Regional Environmental
Advisor, USAID/Southern Africa:

Date: _____

Environmental Officer
Africa Bureau:

Brian Hirsch

Belemvire, Allison (GH/HIDN/ID)

From: Bernhard, Teresa (E3/AA)
Sent: Friday, July 13, 2012 11:18 AM
To: Belemvire, Allison (GH/HIDN/ID); Hirsch, Brian(AFR/SD)
Subject: RE: Approvals document - Zimbabwe SEA for signature

Brian is out until Monday and I am out until the 26th. Pending Brian's agreement I clear on the document. Please use this email as concurrence when Brian has signed. Also, please send a hard copy to Brian to sign on Monday.

Teresa Bernhard
Economic Growth, Education and Environment (E3) Bureau Environmental Officer
202-712-4313
(m) 443-744-2200
tbernhard@usaid.gov
tbernar@verizon.net

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Friday, July 13, 2012 9:26 AM
To: Bernhard, Teresa (E3/AA); Hirsch, Brian(AFR/SD)
Subject: RE: Approvals document - Zimbabwe SEA for signature

Hi Teresa,

I wanted to follow up with you; the Zim SEA is still missing your & Brian's signatures; do you know when we can expect them? Abt is tendering for a pooled procurement but hasn't purchased or shipped anything for Zim yet. Please let me know, as spraying starts in Sept.

Thanks,
Allison

-----Original Message-----

From: Bernhard, Teresa (E3/AA)
Sent: Tuesday, July 03, 2012 12:20 PM
To: Belemvire, Allison (GH/HIDN/ID)
Subject: RE: Approvals document - Zimbabwe SEA for signature

I think Brian is out for the week. I will get with him as soon as he gets back.

Teresa Bernhard
Economic Growth, Education and Environment (E3) Bureau Environmental Officer
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(m) 443-744-2200
tbernhard@usaid.gov
tbernar@verizon.net

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Tuesday, July 03, 2012 11:04 AM
To: Bernhard, Teresa (E3/AA)
Subject: RE: Approvals document - Zimbabwe SEA for signature

Hi Teresa,

I know you've got a lot on your plate, but do you know where we are with the SEA? I haven't heard anything from Brian, and it seems that Walter is in DC now?

Thanks,
Allison

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Thursday, June 28, 2012 3:07 PM
To: Knausenberger, Walter (AFR/SD); Bernhard, Teresa (E3/AA); Hirsch, Brian (AFR/SD)
Subject: FW: Approvals document - Zimbabwe SEA for signature

Hi all,

The mission has signed the Zim SEA, please let me know if you have any questions, I look forward to receiving your signatures as well.

Best regards,
Allison

-----Original Message-----

From: Billingsley, Christie [mailto:cbillingsley@usaid.gov]
Sent: Thursday, June 28, 2012 10:34 AM
To: Knausenberger, Walter (AFR/SD)
Cc: Sanhokwe, Hamfrey (HARARE/PHN); Halpert, Peter (HARARE/PHN); Pacific, Erik (PRETORIA/PPD); Geiser, Roy (PRETORIA/PPD); Belemvire, Allison (GH/HIDN/ID); Josh Rosenfeld; Peter Chandonait
Subject: Fwd: Approvals document - Zimbabwe SEA for signature

Dear Walter,

We have collected all the signatures from USAID/Zimbabwe for the SEA.
Would you kindly add yours here and return to all those copied? Many thanks.

Cheers
Christie

Christie Billingsley, MA, MPH
PMI Malaria Resident Advisor
USAID/Zimbabwe
1 Pascoe Ave, Belgravia
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cbillingsley@usaid.gov

----- Forwarded message -----

From: Sanhokwe, Hamfrey <hsanhokwe@usaid.gov>
Date: Thu, Jun 28, 2012 at 4:21 PM
Subject: Approvals document
To: Christie Billingsley <cbillingsley@usaid.gov>, Kwame Asamoah <kasamoah@usaid.gov>, "Halpert, Peter (HARARE/PHN)" <phalpert@usaid.gov>

Here you go, the Mission level approvals are all done.

Regards

--

Hamfrey Sanhokwe
Strategic Information Specialist/Mission Environmental Officer US-AID Zimbabwe
Email: hsanhokwe@usaid.gov
Cell - 0773 048 598
Land - 252 401 Ext 273
It's not the strongest species which survive, but those that adapt to change!

----- Forwarded message -----

From: Knausenberger, Walter (AFR/SD) <wknausenberger@usaid.gov>
Date: Mon, Jun 18, 2012 at 10:03 AM
Subject: RE: 2nd draft Zimbabwe IRS SEA
To: "Sanhokwe, Hamfrey (HARARE/PHN)" <hsanhokwe@usaid.gov>, "Billingsley, Christie" <cbillingsley@usaid.gov>
Cc: Peter Chandonait <Peter_Chandonait@abtassoc.com>, Josh Rosenfeld <Josh_Rosenfeld@abtassoc.com>, Dereje Dengela <Dereje_Dengela@abtassoc.com>, Bradford Lucas <Bradford_Lucas@abtassoc.com>, "Bernhard, Teresa (EGAT/ESP)" <tbernhard@usaid.gov>, "Hirsch, Brian (AFR/SD)" <BHirsch@usaid.gov>, "Pacific, Erik (PRETORIA/PPD)" <epacific@usaid.gov>, "Geiser, Roy (PRETORIA/PPD)" <rgeiser@usaid.gov>

Hi, Hamfrey:

Just to let you know that i have given my clearance to the 2nd edition of the Zim IRS SEA, though normally I would want to have Mission input first. I noticed that the loops have been separate, with Abt and Mission staff and BEOs.

I have largely deferred to Teresa, BGH BEO (now Acting) and E3 BEO.

Walter @ South Sudan TDY

From: Sanhokwe, Hamfrey [hsanhokwe@usaid.gov]
Sent: Monday, June 18, 2012 9:42 AM

To: Knausenberger, Walter (AFR/SD)

Cc: Peter Chandonait; Josh Rosenfeld; Dereje Dengela; Bradford Lucas; Bernhard, Teresa (EGAT/ESP); Hirsch, Brian (AFR/SD)

Subject: Re: 2nd draft Zimbabwe IRS SEA

Hello,

Was away for the last 2 weeks, only seeing the documents today, will go through it and provide feedback in due course - when are the comments due?

On Wed, Jun 6, 2012 at 7:36 PM, Knausenberger, Walter (AFR/SD)

<wknausenberger@usaid.gov<mailto:wknausenberger@usaid.gov>> wrote:

Peter:

I do appreciate the challenges in developing this sort of document and program in Zimbabwe, in particular. Good to hear that Abt has hired a dedicated Environmental Compliance Officer in Zim, someone who knows well the relevant GoZ staff. I understand there originally was resistance among NMCP staff regarding the SEA and its purpose. And clearly, as the ultimately responsible implementers, the GoZ staff will need to "own" the IRS process. I would hope that the SEA will be viewed as a quality assurance support tool, not just a regulatory document.

In fact, I submit that the SEA does not need to be "approved," apart from the recommended pesticides and related practices, for it to be applicable to capacity building and holding a safer use dialogue, and starting training related to delivery of sound IRS programs.

Walter I.

Allison Belemvire <abelemvire@usaid.gov>

RE: Approvals document - Zimbabwe SEA for signature

Hirsch, Brian(AFR/SD) <BHirsch@usaid.gov>

Tue, Jul 17, 2012 at 4:32 PM

To: "Belemvire, Allison (GH/HIDN/ID)" <abelemvire@usaid.gov>Cc: "Bernhard, Teresa (E3/AA)" <tbernhard@usaid.gov>

Hi Allison -- I am happy to approve, except the one thing I keep getting hung up on is whether the comments Teresa submitted were incorporated in a revision of the SEA. Do you happen to know? Teresa initially only sent them to me, but I think she later sent them to the mission. In short, the comments Teresa made seemed to highlight important issues that should be addressed. With the understanding that the mission would make an attempt to address those, I am happy to clear. Actually, so much time has passed on this one, and the identified issues were not so significant, I'll be happy to clear regardless. Do you have the final document? I'm sure it's in my email somewhere if you don't.

Brian

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)

Sent: Tuesday, July 17, 2012 11:25 AM

To: Hirsch, Brian(AFR/SD)

Cc: Bernhard, Teresa (E3/AA)

Subject: RE: Approvals document - Zimbabwe SEA for signature

Hi Brian,

I wanted to follow up and see if you clear the Zimbabwe SEA, which was re-submitted on 6/6/12. The Mission Director approved it while you must've been out, and Teresa has sent pending approval, waiting for your ok. Please let me know if you have any questions.

Best regards,

Allison

Allison Belemvire, MPH | Malaria Technical Advisor | President's Malaria Initiative USAID | Bureau for Global Health | Office of Health, Infectious Disease & Nutrition

1201 Pennsylvania Avenue NW, Suite 200 | Washington DC 20004

Phone: 202-684-9954

abelemvire@usaid.gov

-----Original Message-----

From: Bernhard, Teresa (E3/AA)

Sent: Friday, July 13, 2012 11:18 AM

To: Belemvire, Allison (GH/HIDN/ID); Hirsch, Brian(AFR/SD)

Subject: RE: Approvals document - Zimbabwe SEA for signature

Brian is out until Monday and I am out until the 26th. Pending Brian's agreement I clear on the document. Please use this email as concurrence when Brian has signed. Also, please send a hard copy to Brian to sign on Monday.

Teresa Bernhard
Economic Growth, Education and Environment (E3) Bureau Environmental
Officer
[202-712-4313](tel:202-712-4313)
(m) [443-744-2200](tel:443-744-2200)
tbernhard@usaid.gov
tbernar@verizon.net

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Friday, July 13, 2012 9:26 AM
To: Bernhard, Teresa (E3/AA); Hirsch, Brian (AFR/SD)
Subject: RE: Approvals document - Zimbabwe SEA for signature

Hi Teresa,

I wanted to follow up with you; the Zim SEA is still missing your & Brian's signatures; do you know when we can expect them? Abt is tendering for a pooled procurement but hasn't purchased or shipped anything for Zim yet. Please let me know, as spraying starts in Sept.

Thanks,
Allison

-----Original Message-----

From: Bernhard, Teresa (E3/AA)
Sent: Tuesday, July 03, 2012 12:20 PM
To: Belemvire, Allison (GH/HIDN/ID)
Subject: RE: Approvals document - Zimbabwe SEA for signature

I think Brian is out for the week. I will get with him as soon as he gets back.

Teresa Bernhard
Economic Growth, Education and Environment (E3) Bureau Environmental
Officer
[202-712-4313](tel:202-712-4313)
(m) [443-744-2200](tel:443-744-2200)
tbernhard@usaid.gov
tbernar@verizon.net

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Tuesday, July 03, 2012 11:04 AM
To: Bernhard, Teresa (E3/AA)
Subject: RE: Approvals document - Zimbabwe SEA for signature

Hi Teresa,

I know you've got a lot on your plate, but do you know where we are with the SEA? I haven't heard anything from Brian, and it seems that Walter is in DC now?

Thanks,
Allison

-----Original Message-----

From: Belemvire, Allison (GH/HIDN/ID)
Sent: Thursday, June 28, 2012 3:07 PM
To: Knausenberger, Walter (AFR/SD); Bernhard, Teresa (E3/AA); Hirsch, Brian (AFR/SD)
Subject: FW: Approvals document - Zimbabwe SEA for signature

Hi all,

The mission has signed the Zim SEA, please let me know if you have any questions, I look forward to receiving your signatures as well.

Best regards,
Allison

-----Original Message-----

From: Billingsley, Christie [mailto:cbillingsley@usaid.gov]
Sent: Thursday, June 28, 2012 10:34 AM
To: Knausenberger, Walter (AFR/SD)
Cc: Sanhokwe, Hamfrey (HARARE/PHN); Halpert, Peter (HARARE/PHN); Pacific, Erik (PRETORIA/PPD); Geiser, Roy (PRETORIA/PPD); Belemvire, Allison (GH/HIDN/ID); Josh Rosenfeld; Peter Chandonait
Subject: Fwd: Approvals document - Zimbabwe SEA for signature

Dear Walter,

We have collected all the signatures from USAID/Zimbabwe for the SEA. Would you kindly add yours here and return to all those copied? Many thanks.

Cheers
Christie

Christie Billingsley, MA, MPH
PMI Malaria Resident Advisor
USAID/Zimbabwe
1 Pascoe Ave, Belgravia
Harare
Tel: 263 4 252401, ext. 285
Cell: 0772149042
cbillingsley@usaid.gov

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Subject: Approvals document
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Hamfrey Sanhokwe
Strategic Information Specialist/Mission Environmental Officer
US-AID Zimbabwe
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Land - 252 401 Ext 273
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Walter I.

1.0 BACKGROUND

1.1 Background to the Proposed Action

In July 2005, the U.S. Government announced a 5-year, \$1.2 billion malaria initiative to rapidly scale up malaria prevention and treatment interventions in 15 high-burden countries in sub-Saharan Africa. The U.S. President's Malaria Initiative (PMI) began with \$30 million in bilateral funding in fiscal year (FY) 2006 that was increased to \$135 million in FY 2007 and \$300 million in FYs 2008 and 2009. The 2008 Lantos/Hyde Act provided for the continuation of support to the 15 PMI focus countries and an expansion to other endemic countries in Africa. In FY 2011, Zimbabwe joined the PMI group of countries. The goal of the expanded PMI is to halve the burden of malaria (morbidity and mortality) in 70% of the at-risk populations.

The objective of this initiative is to assist African countries, in collaboration with other partners, to rapidly scale-up coverage of vulnerable groups with four highly effective interventions: artemisinin-based combination therapy (ACT), intermittent preventive treatment for malaria in pregnancy (IPTp), insecticide-treated mosquito nets (ITNs), and indoor residual spraying (IRS) with residual insecticides.

Programming of PMI activities follows the core principles of GHI: encouraging country ownership and investing in country-led plans and health systems; increasing impact and efficiency through strategic coordination and programmatic integration; strengthening and leveraging key partnerships, multilateral organizations, and private contributions; implementing a woman- and girl-centered approach; improving monitoring and evaluation; and promoting research and innovation.

The Government of Zimbabwe considers malaria as a key target disease as reflected in the old National Health Strategy (NHS) 1997-2007 as well as in the current NHS 2009-2013. The NMCP has a malaria control policy and strategic plan aligned with the overall National Health Strategy 2009-2013.

The FY2012 Malaria Operational Plan presents a detailed implementation plan for Zimbabwe, based on the PMI Multi-Year Strategy and Plan, and the National Malaria Control Program's (NMCP's) five year National Malaria Control Strategy. It was developed in consultation with Zimbabwe's NMCP, with participation of national and international partners involved with malaria prevention and control in the country. The activities PMI is proposing to support align with the 2008-2013 National Malaria Control Strategy, and build upon investments made by other partners to improve and expand malaria-related services.

1.2 Project Objectives

By the end of 2014, PMI will assist Zimbabwe to achieve the following targets in populations at risk for malaria:

- >90% of households with a pregnant woman and/or children under five will own at least one ITN;
- 85% of children under five will have slept under an ITN the previous night;

- 85% of pregnant women will have slept under an ITN the previous night;
- 85% of houses in geographic areas targeted for IRS will have been sprayed;
- 85% of pregnant women and children under five will have slept under an ITN the previous night or in a house that has been sprayed with IRS in the last 6 months;
- 85% of women who have completed a pregnancy in the last two years will have received two or more doses of IPTp during that pregnancy;
- 85% of government health facilities have ACTs available for treatment of uncomplicated malaria; and
- 85% of children under five with suspected malaria will have received treatment with ACTs within 24 hours of onset of their symptoms.

With FY2012 funding, PMI will support IRS operations for approximately 1 million structures in 17 districts in the three provinces of Manicaland, Mash East and Mash West. Funding will cover the procurement of insecticides and equipment for spray operations, along with training, implementation, and environmental compliance for IRS implementation.

PMI will also procure approximately 1 million ACT treatments for distribution to primary health facilities throughout the country and will procure approximately 1.3 million RDTs for distribution to primary health facilities.

1.3 Malaria Burden in Zimbabwe

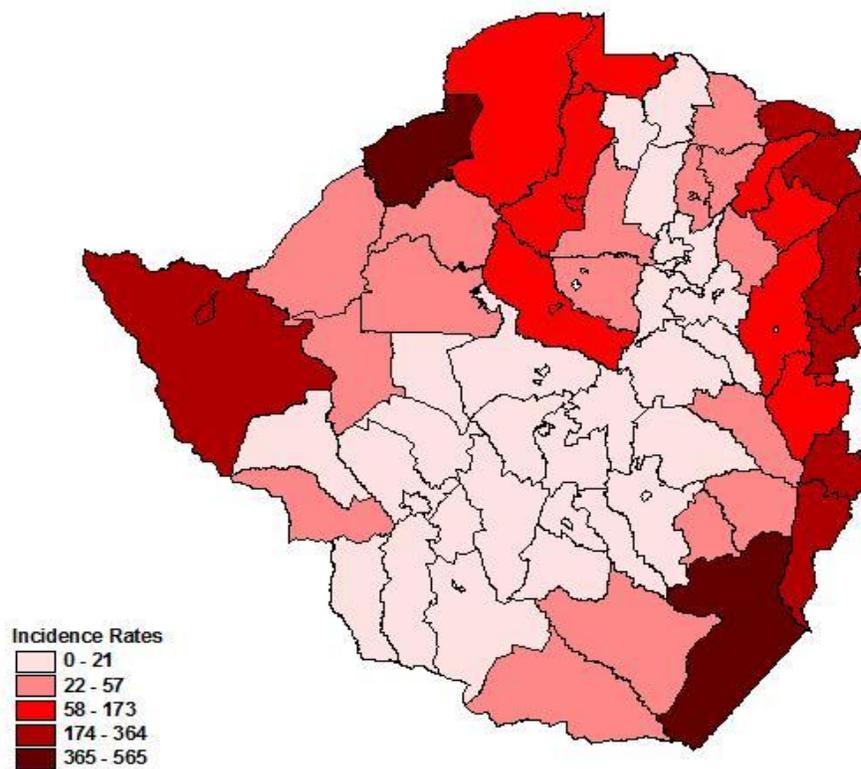
Malaria remains the second cause of morbidity and mortality after HIV and AIDS related illnesses in the country. Malaria accounts for 30% of all out patient attendances, and 12% of hospital admissions. Ninety-eight per cent (98%) of all cases of malaria are caused by *P. falciparum*. The primary vector is *An. arabiensis*. The groups most vulnerable to this preventable disease are children below the age of 5 years, pregnant women, the elderly, and people living with HIV and/or AIDS.

Zimbabwe is divided into ten provinces (8 rural and two urban provinces: the urban provinces are the two cities Harare and Bulawo), 62 rural districts and 1,200 wards. 45 districts are considered malaria endemic, ranging from moderate to high malaria transmission zones, with 3 categorized as high burden districts. The total population estimates vary according to source, and are complicated by the large recent population movement. The current estimate is approximately 12.5 million persons, extrapolated from the 2002 census. The 2002 malaria stratification estimated that about 50% the population was living in areas of malaria risk.

Malaria transmission varies across Zimbabwe, with high to moderate transmission in northern and eastern provinces bordering Zambia and Mozambique, and low transmission in southern provinces bordering South Africa and Botswana. The map below shows the 2010 malaria incidence rates by district (Figure 1).

Figure 1: 2010 Malaria Incidence Rates by District

2010 Malaria Incidence Rates By District



Malaria is mainly seasonal in Zimbabwe with potential for epidemics during the rainy season. Malaria transmission varies across Zimbabwe, with high to moderate transmission in northern and eastern provinces bordering Zambia and Mozambique, and low transmission in southern provinces bordering South Africa and Botswana. An estimated 50% of the population of Zimbabwe resides in malaria endemic areas.

1.3.1 Socio-economic impact

Malaria is ranked second among the causes of Out Patient Department (OPD) attendance contributing 20-30% of out-patients, and 12% of in-patients, and is the second highest cause of death for in-patients per annum. The malaria incidence rate in the twenty most affected districts ranged between 158-700 cases per 1000 per annum in 1999. In year 2000, 15% of outpatient attendance and approximately 20% of inpatient admission to public health facilities were due to malaria. The socio-economic impacts are large, both in terms of health care costs, and the suffering, mortality, lost productivity and disruption that occurs.

1.4 Institutional Framework for Malaria Control in Zimbabwe

Zimbabwe has a long history of implementing IRS, dating back to 1949. Malaria prevention and control activities in the country have evolved from comprising a thinly staffed central office at the former Blair Research Institute now called the National Institute of Health Research (NIHR) in 2000 to 2001, to a fully-fledged unit by the end of 2010. Between 2000 and 2001 malaria activities were mainly focused on Vector Control especially Indoor Residual Household Spraying (IRS). During 2001 support from the RBM partnership resulted in the development of the RBM Strategic Plan 2001-7 which led to the creation of additional posts for malaria control activities. The RBM Strategic Plan saw the scope of malaria control interventions being widened to include the use of insecticidal nets, Intermittent Preventive Therapy in pregnancy and other approaches. It also recommended the creation of a fully-fledged Malaria Unit, and activities were decentralized to provinces and districts. Additional resources were availed to 10 Front Runner districts in the country to scale up malaria control interventions in these high burdened districts.

1.4.1 Competent Authorities for IRS

The Ministry of Health and Child Welfare of Zimbabwe has a Department of Environment Health represented at the provincial and district levels. At the province and district levels, IRS is coordinated by the provincial and district environment health officers respectively. They are trained as IRS trainers and they have responsibility of training spray operators before IRS operations start. In Zimbabwe, the Ministry of Environment and Natural Resources is not fully involved in IRS. The Environment Management Agency (EMA) is the environment management authority and is represented at national, provincial and district levels. It is a young institution, as it only started activities in 2008 and it needs to be strengthened to participate in environment monitoring for IRS.

1.4.2 Major partners

NMCP's main partners to implement the malaria control program are Plan International, which is involved mainly in vector control, and PSI, which is involved in LLIN distribution, community mobilization and behavior change communication. These partners have worked with NMCP for more than a decade. Earlier on they had separate funding sources and of late they have been sub-sub recipients of Global Funding. The partners have been meeting on an *ad-hoc* basis with NMCP overseeing their programming.

The Government and partners fund the malaria program. The budgeting from the Government of Zimbabwe is done on an annual basis but for most partners budgeting is done according to specific agreements and the budget cycle of the partner. The National Malaria Control Program has been receiving the biggest budget allocation from the health budget compared to the other programs within MOHCW over the past six years.

Table 1: Malaria-specific funding 2007-2011

Partners	2007	2008	2009	2010	2011
GOZ*	\$600,000	\$850,000	\$1,400,000	\$1,200,000	\$1,000,000
Global Fund	6,800,000	2,100,000	11,320,000	24,500,000	2,600,000
WHO	-	-	1,200,000	-	-
UNICEF	150,000	320,000	450,000	25,000	-
USAID	-	-	200,000	-	1,000,000
DFID	-	-	300,000	-	-
Private Sector	60,000	47,250	60,000	20,000	12,500
Total	\$7,610,000	\$3,317,250	\$14,930,000	\$25,745,000	\$4,612,500

In addition, several NGOs, both local and international, have supported malaria control activities through their own funding (sometimes provided in kind) and as sub-recipients for specific **SDAs** under the various GF grants. The European Union (EU) too supported major malaria activities for the years 2007 to 2010. An amount of US\$3.5million was given through Plan International (PI) for support to 6 project districts. Through this fund PI was able to procure and distribute 60,000 ITNs, and support trainings, IRS and procurement of medicines.

1.4.3 Private sector partnerships

Zimbabwe has had a history of partnership with the private sector for vector control. Large plantations, agricultural operations and mining companies often implemented their own stand-alone IRS activities in liaison with MoHCW in general, NMCP in particular. These private entities procured their own insecticides (following the NMCP recommended insecticide class), then equipped and trained their own spray operators under MoHCW supervision, in order to protect their workers from contracting malaria.

With Zimbabwe's recent economic and political instability, many agricultural proprietors and large farm owners have left the country and the land they used to occupy has been divided up. Unfortunately this means that in many cases private entities cannot be relied upon to carry out IRS and other vector control activities as they had in the past. Although PMI will not be specifically targeting the gaps in private sector entities, in FY2012 PMI will support the NMCP's IRS program and LLIN distributions in high-burden malaria transmission areas.

1.4.4 Environmental legislation

Zimbabwe environmental legislation is quite comprehensive. Acts relating to the environment are enforced by a number of different ministries. There are almost twenty acts and twice as many statutory instruments for the environment. They include the Natural Resources Act, Environmental Management Act, Forest Act, Parks and Wildlife Act, Trapping and Animals Control Act, Hazardous Substances and Articles Act, Atmospheric Pollution Prevention Act, Noxious Weeds Act, Plant, Pests and Diseases Act, Mines and Minerals Act, Water Act,

Regional Town and Country Planning Act, Rural District Councils Act, Communal Land Act, and Communal Forest Product Act.¹

One of the most important pieces of legislation is the Natural Resources Act, which aims to control the use of resources. However, it cannot be applied in the communal areas, about half of the total land area of Zimbabwe, since it is enforced by way of legal title to land.

Generally, the enforcement of some of these acts is difficult due to the provision of exemptions, which allow companies to pollute. In some cases, the various pieces of legislation are conflicting, which leads to further problems of implementation. Furthermore, poor management and under-funding has severely weakened the effectiveness of the government to ensure compliance.

1.4.5 International Conventions and Regulations

Zimbabwe is presently a party to the following treaties and conventions:

- Convention Concerning The Protection of The World Cultural and Natural Heritage
- Preferential Trade Area Treaty (PTA)
- Lome Convention
- World Heritage Convention
- International Conventions on International Trade in Endangered Species (CITES)
- Agreement on the Action Plan for the Environmentally sound Management of the Zambezi River System (ZACPPLAN)
- Climate Change (CCCC),
- Convention on Biodiversity (CDB)
- Protection of Ozone Layer
- Transboundary movement of hazardous waste (Basel Convention)
- Stockholm convention on Persistent Organic Pollutants (POP)

1.4.6 Pesticide Regulation and Control

Zimbabwe has regulations for the control and distribution of pesticides. The Ministry of Agriculture of Zimbabwe, Department of Agriculture Regulatory services (DARS) is solely responsible for the registration, control and management of pesticides in the country. Under the Environment Management Act, and statutory instrument 12 of 2007, Environment Management (Hazardous substances, pesticides and other toxic substances) Regulation, 2007 and Statutory Instrument 10 of 2007; Environment Management (hazardous wastes management) Regulation, 2007, there are detailed guidelines and frameworks governing the procurement, packaging and storage, as well as transport and disposal of pesticides.

1.4.7 Waste Disposal Regulations, Policies, and Practices in Zimbabwe

Waste management in general and medical waste in particular has emerged as one of the greatest challenges facing local authorities throughout Zimbabwe. The volume of waste being generated continues to increase at a faster rate than the ability of authorities to improve the financial and

¹ African Development Bank African Development Fund Country Environmental Profile Zimbabwe Environment and Social Policy Working Paper Series Working Paper No. 2

technical resources needed to parallel this growth. Waste management services have increasingly become inadequate, as evidenced by the rise in illegal dumping and proliferation of the now seemingly permanent piles of rubbish in some commercial, industrial, and residential areas of urban settings.

Although a legislative framework for managing waste is in place in the country, concern is raised about the non-enforcement of the legislation. In terms of specific laws bearing on the management of waste in the country, there are inter alia: the Environmental Management Act (CAP 20:27), the Urban Council Act (CAP 29:15), and the Public Health Act (CAP 15:09). In addition, a number of policies have been drafted to improve the management of waste in the country, including the Environmental Impact Assessment Policy (1994), the draft Waste Management Strategy (2006), and the National Environmental Policy (2003).

As a matter of practice, there is no national policy or legislation on medical wastes. Essentially, individual hospitals develop their own system of disposal. In essence, biological waste and infectious waste are packed in plastic bags and incinerated. Some provincial hospitals have high temperature incinerators that reach a maximum of 1200 degrees Celsius.

1.5 IRS Activities in Zimbabwe

Currently, the NMCP IRS strategy targets 45 districts distributed in all rural provinces. There is not yet an articulated strategy on the combination or balance of IRS and LLINs. There continues to be more confidence in the traditional IRS than in LLINs. The Zimbabwe Global Fund Round 10 quotes; “The MIS in 2008 provided information on the status of malaria control in Zimbabwe. One of the most telling statistics show that while knowledge of the causes of malaria is high (89%), only 4.5% of pregnant women and 9.2% of children under 5 slept under an ITN the previous night despite net ownership of approximately 34%.” Thus, for the time-being, IRS will remain the mainstay of the vector control program.

The program began spraying with BHC (an organochlorine related to DDT but no longer in use) then switched to the longer-acting DDT, which was used until 1991, when it was replaced with pyrethroids. However, after the switch to the shorter-acting pyrethroids there was a marked increase in reported cases, prompting the reintroduction of DDT in 2004. The program continues with a mix of DDT and pyrethroids, where DDT is used only in tobacco growing areas that use pyrethroids for agricultural purposes to avoid risk of resistance.

Due to financial constraints, the total number of rooms sprayed and population protected from 2001-2007 were below the targets as shown in the table below. From 2008 to 2010, resources from the Global Fund, the European Commission, DfID and USAID improved and IRS coverage expanded (Table 2).

Table 2: Rooms sprayed and population covered 2001- 2010

Season	Target Rooms	Rooms sprayed	% Coverage	Target Pop	Pop protected	% Pop. Protected
2001	1,191,950	762,848	64	1,602,334	1,229,798	33
2002	2,235,151	680,577	30	4,732,872	1,022,603	44
2003	2,235,151	284,128	28	4,732,872	435,748	20
2004	2,175,026	1,350,403	62	3,373,034	2,031,509	60

Season	Target Rooms	Rooms sprayed	% Coverage	Target Pop	Pop protected	% Pop. Protected
2005	1,839,727	1,271,474	69	1,875,472	1,608,848	86
2006	1,764,368	1,212,572	69	2,920,561	1,659,393	57
2007	1,413,074	588,994	42	2,436,172	742,289	30
2008	1,111,663	958,045	85	1,630,915	1,242,346	80
2009	1,992,181	1,638,303	86	3,096,049	2,575,116	86
2010	2,255,318	2,023,159	90	3,478,413	3,090,289	89

1.5.1 Training

IRS training has been divided into three levels: Level I training for provincial managers; Level II training for IRS district managers; and Level III training for spray operators. The Zimbabwe NMCP uses training materials developed within the program itself, WHO training materials, and training materials developed by the major insecticide manufacturers and vendors who sometimes provide technical assistance.

Table 3 : Level 3 Spray Operator Training

Year	2001	2002	2003	2004	2005	2006	2007	2008	2009	2010
Target	1,120	1,120	1,120	1,120	1,120	1,120	1,120	1,120	1,120	1,120
Trained	829	1,019	538	482	381	918	*	918	1,030	1,154
Percent trained	74	91	48	43	34	82	*	82	92	103

In addition to hands on spraying implementation, training also includes materials on malaria epidemiology and entomology. Health and safety issues are also included in the IRS training, including the provision and use of personal protective equipment (PPE) and safe handling of pesticides. The training for district and provincial managers includes mosquito rearing, bioassays and larviciding.

1.5.2 Entomological Monitoring

Entomological monitoring in Zimbabwe has traditionally been a core part of the program. Conducted by several partners, technical support and coordination is provided by the National Institute of Health Research (NIHR). A total of sixteen entomological monitoring sites in different parts of the country were established with Global Fund support.

Wall bioassays

There was extensive information available on wall bioassays of sprayed surfaces, using locally collected *An. Arabiensis*. The mean mortality % in table 4 below implies that the insecticides used were effective and properly applied by the spray operators (Table 4).

Table 4: Bioassays conducted on sprayed surfaces (2007 to 2011)

Year	Insecticide	District	Months post spray	Range (%)	Mean mortality (%)
2011	DDT	GokweSouth	4	77-100	92
2010	Deltamethrin 5WP	Kwekwe	1	80-100	90
			2	80-100	94
2009	Deltamethrin 5WP	Beit Bridge	1	78-100	93
			2	100	100
			3	83-100	95
			4	88-100	97
			5	80-100	93
			6	84-100	97.7
2008	Lambda-cyhalothrin 10WP	GokweNorth	3	61.5-100	68.9
2007	Lambda-cyhalothrin CS	GokweSouth	2	51-80	74.5
			3	11.1-100	61.4

Note: The 2007-08 bioassay results appear to indicate a short on-the-wall effectiveness lifetime for Lambda-cyhalothrin, even though the most recent susceptibility data shows an excellent response and mortality rate (see below). This should be considered carefully, and more recent data obtained, to determine if this is an ongoing problem, and if the effectiveness can last through the peak transmission cycle for Zimbabwe.

Insecticide susceptibility status

In addition to the above bioassay data, the National Institute for Health and Research conducted insecticides susceptibility testing from 19 March - 05 April 2012 in 16 vector surveillance sites (From NIHR report April 2012 report). Insecticide susceptibility status is one of the requirements in any malaria control program because it guides insecticide choice for the next Indoor Residual Spraying (IRS) cycle.

Zimbabwe's 16 vector surveillance sites, 2 in each province, represent low to high malaria transmission profiles. Insecticide susceptibility tests were conducted over 11 days using the standard World Health Organization tube test that involved exposing field collected *Anopheles gambiae sensu lato* mosquitoes for 1 hour to insecticide treated papers and reading mortality after 24 hours.

Table 5: Study area for susceptibility tests

Province	District	Site
Mashonaland Central	Rushinga	Mazowe River bridge Rural Health Centre
	Centenary	Muzarabani Rural Health Centre
Manicaland	Mutasa	Zindi Rural Health Centre
Masvingo	Chiredzi	Chilonga Rural Health Centre

Matabeleland South	Beit Bridge	Makakabule Rural Health Centre
Matabeleland North	Lupane	Jotsholo Rural Health Centre
	Binga	Manjolo Rural Health Centre
Midlands	Gokwe south	Kamhororo Rural Health Centre
Mashonaland East	Mudzi	Kotwa Rural Health Centre
	Uzumba Maramba Pfungwe	Maramba Rural Health Centre
Mashonaland West	Hurungwe	Kasimure Rural Health Centre
	Sanyati	Chakari Rural Health Centre

One hundred percent mortality rate of mosquitoes exposed to 4% DDT, 0.1% bendiocarb, 0.05% lambda-cyhalothrin and 5% malathion was recorded in 10/12 (67%) sites visited except for Chakari and Kotwa which scored 98% for 0.1% bendiocarb and 0.05% lambda-cyhalothrin (Table 6). All mosquitoes were susceptible to all the insecticide groups tested. Susceptibility tests could not be done in 4/12 (33%) sentinel sites due to an inadequate number of mosquitoes.

Table 6: Susceptibility testing, four classes of pesticide

Province	District	Site	Insecticide	Knock down	Kd ₅₀	Kd ₉₀	24hr mortality
Mashonaland Central	Rushinga	Mazowe River bridge	4% DDT	80/80 (100%)	20.1	38.0	80/80 (100%)
			0.1% bendiocarb	80/80 (100%)	13.5	24.7	80/80 (100%)
			0.05% lambda-cyhalothrin	80/80 (100%)	14.4	30.5	80/80 (100%)
			5% malathion	80/80 (100%)	16.3	23.8	80/80 (100%)
	Centenary	Muzarabani RHC	4% DDT	40/40 (100%)	20.1	39.6	40/40 (100%)
			0.1% bendiocarb	40/40 (100%)	20.7	37.2	40/40 (100%)
			0.05% lambda-cyhalothrin	40/40 (100%)	18.9	34.7	40/40 (100%)
			5% malathion	40/40 (100%)	19.0	41.0	40/40 (100%)
Manicaland	Mutasa	Zindi RHC	0.05% lambda-cyhalothrin	20/20 (100%)	19.5	30.8	20/20 (100%)
Masvingo	Chiredzi	Chilonga RHC	4% DDT	40/40 (100%)	22.0	40.2	40/40 (100%)
			0.1% bendiocarb	40/40 (100%)	11.5	20.4	40/40 (100%)
			0.05% lambda-cyhalothrin	40/40 (100%)	12.1	18.9	40/40 (100%)
			5% malathion	40/40 (100%)	31.4	48.0	40/40 (100%)
Matabeleland South	Beit Bridge	Makakabule RHC	4% DDT	40/40 (100%)	19.7	38.7	40/40 (100%)
			0.1% bendiocarb	40/40 (100%)	9.6	16.8	40/40 (100%)

Province	District	Site	Insecticide	Knock down	Kd ₅₀	Kd ₉₀	24hr mortality
			0.05% lambda-cyhalothrin	40/40 (100%)	11.0	21.0	40/40 (100%)
			5% malathion	20/20 (100%)	21.4	35.9	20/20 (100%)
Matabeleland North	Lupane	Jotsholo	4% DDT	19/20 (95%)	25.9	47.2	20/20 (100%)
			0.1% bendiocarb	20/20 (100%)	13.2	26.6	20/20 (100%)
			0.05% lambda-cyhalothrin	20/20 (100%)	10.6	26.3	20/20 (100%)
			5% malathion	20/20 (100%)	14.7	42.6	20/20 (100%)
	Binga	Manjolo	4% DDT	20/20 (100%)	36.6	79.8	20/20 (100%)
			0.1% bendiocarb	20/20 (100%)	21.0	36.6	20/20 (100%)
			0.05% lambda-cyhalothrin	20/20 (100%)	22.8	34.0	20/20 (100%)
			5% malathion	20/20 (100%)	28.7	39.0	20/20 (100%)
Midlands	Gokwe south	Kamhororo	4% DDT	80/80 (100%)	24.0	43.6	80/80 (100%)
			0.1% bendiocarb	80/80 (100%)	13.4	27.4	80/80 (100%)
			0.05% lambda-cyhalothrin	80/80 (100%)	11.3	21.0	80/80 (100%)
			5% malathion	80/80 (100%)	17.8	36.3	80/80 (100%)
Mashonaland East	Mudzi	Kotwa	4% DDT	80/80 (100%)	22.8	39.8	80/80 (100%)
			0.1% bendiocarb	80/80 (100%)	22.5	35.1	80/80 (97.5%)

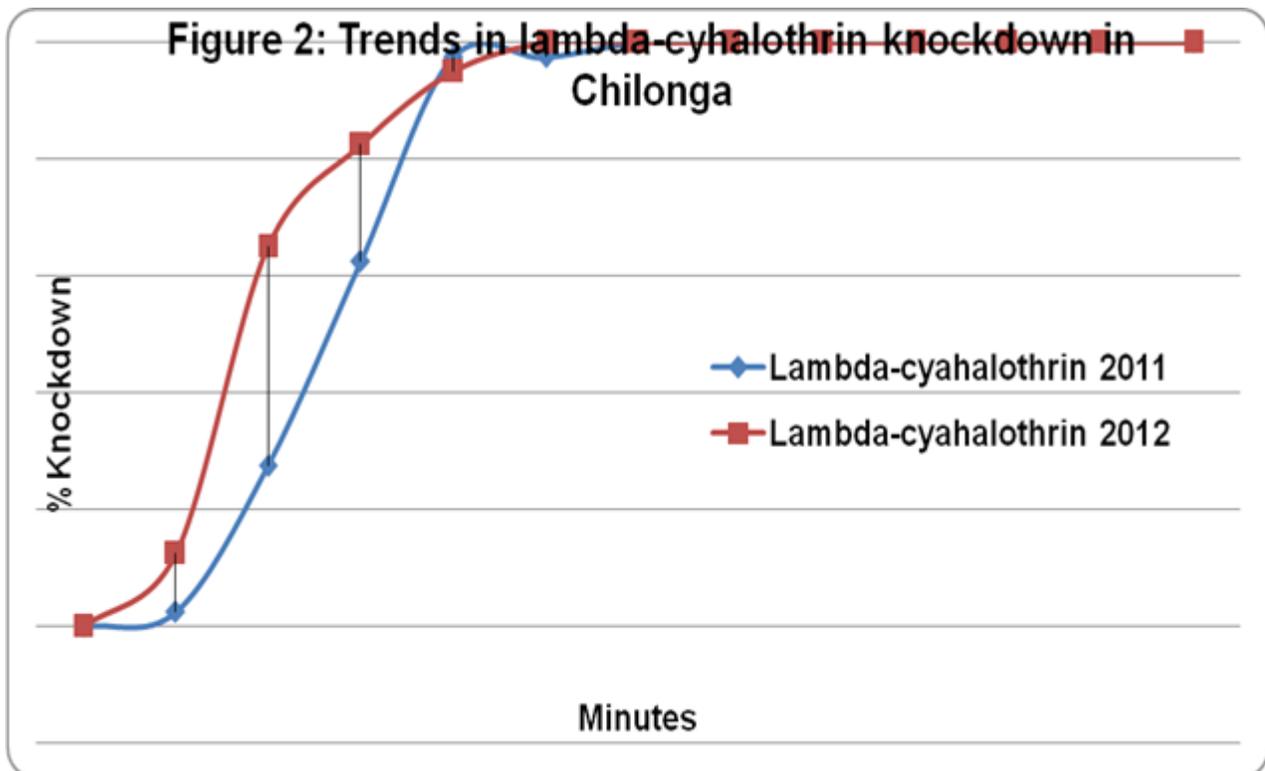
Province	District	Site	Insecticide	Knock down	Kd ₅₀	Kd ₉₀	24hr mortality
			0.05% lambda-cyhalothrin	80/80 (100%)	17.2	29.9	78/80 (97.5%)
			5% malathion	80/80 (100%)	30.0	46.8	80/80 (100%)
	UMP	Maramba RHC	4% DDT	40/40 (100%)	21.0	37.7	40/40 (100%)
			0.1% bendiocarb	20/20 (100%)	20.2	45.4	20/20 (100%)
			0.05% lambda-cyhalothrin	40/40 (100%)	19.0	31.0	40/40 (100%)
			5% malathion	20/20 (100%)	22.6	40.0	20/20 (100%)
	Mashonaland West	Hurungwe	Kasimure	4% DDT	20/20 (100%)	27.6	44.0
0.1% bendiocarb				20/20 (100%)	21.7	33.4	20/20 (100%)
0.05% lambda-cyhalothrin				20/20 (100%)	18.5	29.0	20/20 (100%)
Sanyati		Chakari	4% DDT	40/40 (100%)	24.6	39.5	40/40 (100%)
			0.1% bendiocarb	60/60 (100%)	22.6	39.0	59/60 (98%)
			0.05% lambda-cyhalothrin	40/40 (100%)	24.3	40.6	39/40 (97.5%)
			5% malathion	40/40 (100%)	24.4	32.3	40/40 (100%)

Knockdown

The Kd_{50} (minutes required to knock down 50% of the mosquitoes) and Kd_{90} (minutes required to knock down 90% of the mosquitoes) rates varied in all the sites visited. A comparison of results on susceptibility tests conducted in the year 2011 and 2012 on mosquitoes collected from Chilonga and Kamhororo did not show any significant difference.

Trends in lambda-cyhalothrin knockdown from 2011 and 2012 data are shown in Figure 4. The knockdown rates were not significantly different for the 2 years ($p=0.72$).

Figure 2: Lambda-cyhalothrin 2011-2012



1.5.3 Current Studies of Malaria in Zimbabwe

The most recent Demographic Health Survey (DHS) was carried out from September 2010 to March 2011. The United Nations Children's Fund (UNICEF) conducted a Multiple Indicator Monitoring Survey (MIMS) from August to October 2009. UNICEF is planning to implement the next MIMS in either 2013 or 2014 to measure progress towards Millennium Developmental Goals. Zimbabwe has achieved steady gains in many key malaria indicators, but efforts to scale up interventions must continue for Zimbabwe to achieve the Roll Back Malaria (RBM), PMI and national targets.

1.5.4 Geophysical Aspects

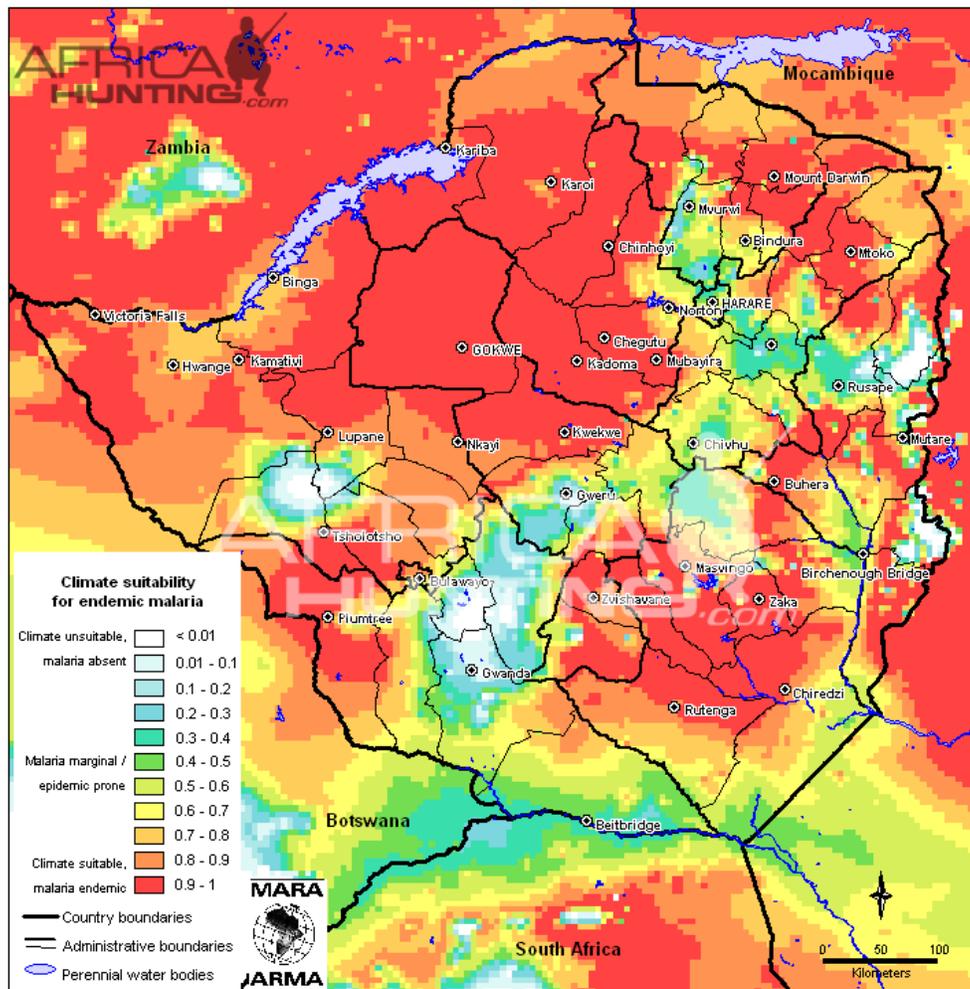
There is direct correlation between ecosystem characteristics and seasonality and incidence of malaria transmission. Provinces with high rainfall have a very high incidence of malaria

In Zimbabwe there are five natural agro-ecological regions:

- Region I: characterized by high level of rainfall (> 1000 mm) and occupied 2% of the territory (Manicaland Province)
- Region II: Annual rainfall is between 750-1000 mm and cover 15% of Zimbabwe territory (Mash Central and Mash East Provinces)
- Region III: Annual rainfall ranges 650-800 mm and covers 19% of the territory (Mash West and Mat North provinces)
- Region IV: Rainfall ranges between 450-650 mm and cover 38% and experiences seasonal periods of drought (Mash south province)
- Region V: Rainfall is very low, less than 450 mm and the region is devoted to extensive livestock and game reserves (Mat south province)

Figure 3: Malaria Distribution regions

Zimbabwe: Distribution of Endemic Malaria



This map is a product of the MARA/ARMA collaboration (<http://www.mara.org.za>). July 2002, Medical Research Council, PO Box 70380, Overport, 4067, Durban, South Africa
 CORE FUNDERS of MARA/ARMA: International Development Research Centre, Canada (IDRC); The Wellcome Trust UK; South African Medical Research Council (MRC);
 Swiss Tropical Institute, Multilateral Initiative on Malaria (MIM) / Special Programme for Research & Training in Tropical Diseases (TDR), Roll Back Malaria (RBM).
 Malaria distribution model: Craig, M.H. et al. 1999. Parasitology Today 15: 105-111.
 Topographical data: African Data Sampler, WRI, http://www.igc.org/wri/sdis/maps/ads/ads_idx.htm

Figure 4 : Zimbabwe agro-ecological

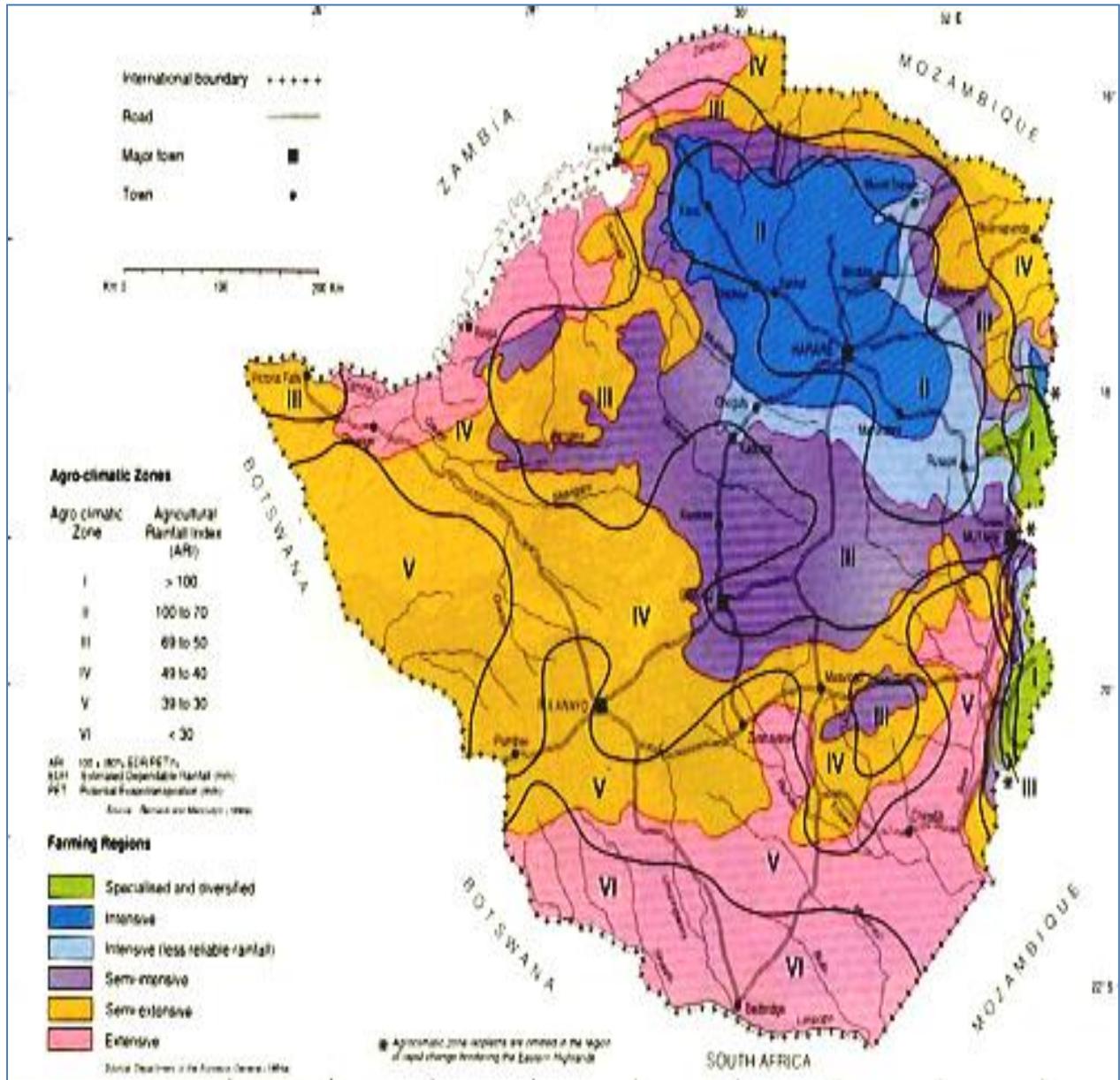
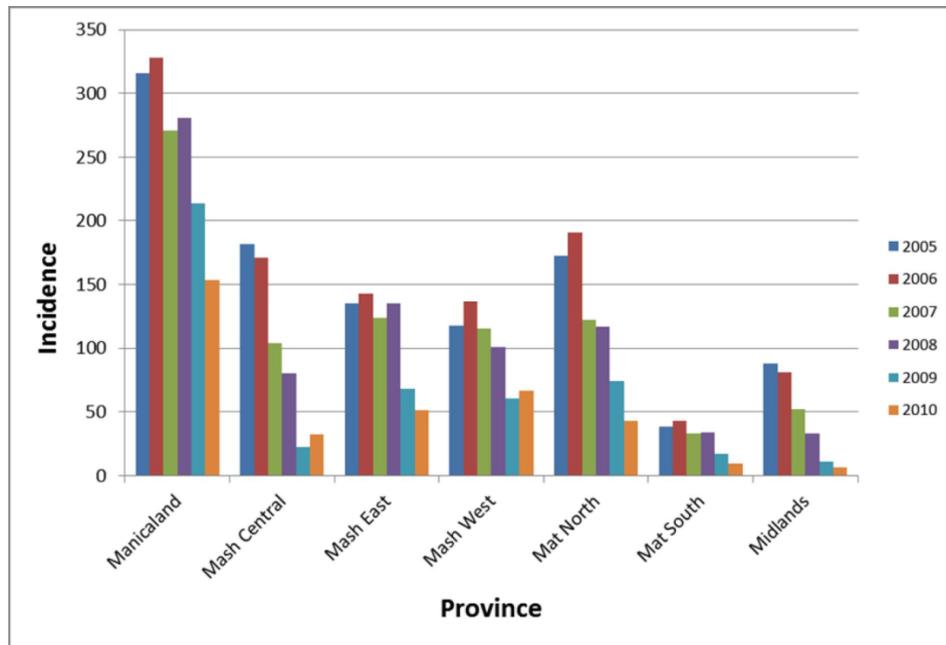
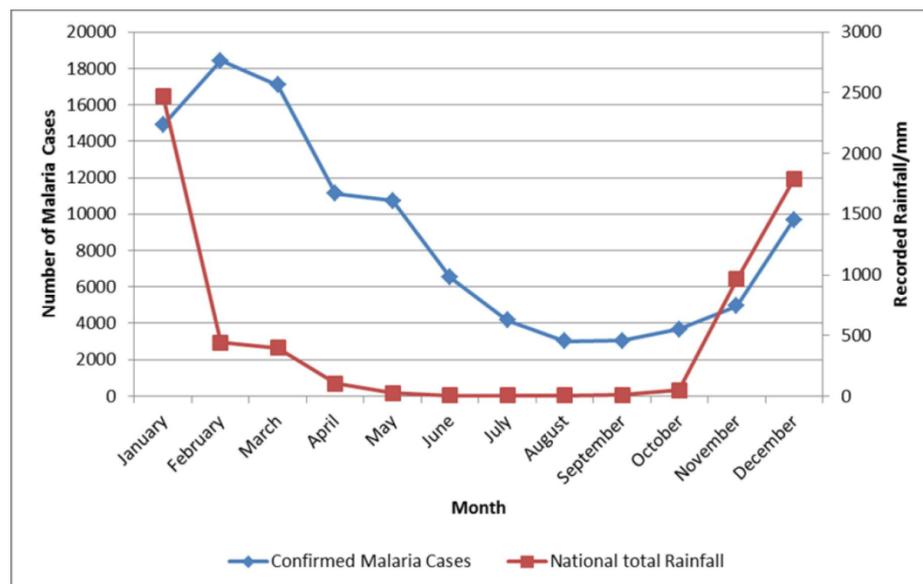


Figure 5: Provincial malaria incidence by year 2005 to 2010



Temperature and rainfall influence the lifecycles of both *P.falciparum* and *A.arabiensis*. Zimbabwe is warm and wet from November to April, cold and dry from May to August, and hot and dry from September to October. Most of the malaria transmission occurs during the warm and wet season with peak from February to April. Cold months in June and July limit malaria transmission even in endemic malaria areas. Although temperatures from September to October are suitable for malaria transmission, dry conditions limit mosquito breeding.

Figure 6: Malaria cases and national total monthly rainfall in Zimbabwe 2010



Elevation Effects

Zimbabwe is divided by a central watershed lying 1200 meters above seas level and flanked north and south by low lying areas. In 1986 the country was divided into three epidemiological malaria areas. The three epidemiological zones in terms of malaria transmission were: (1) areas where malaria was considered to be perennial - below 900 meters elevation to the north and below 600 meters in the southern parts, (2) areas where malaria was considered as seasonal - between 900 -1200 meters north and 600-900 south, and, (3) areas above 1200 meters north and 900 meters south where malaria transmission does not normally occur. Traditionally all higher areas have been described as unstable and lower areas as stable in terms of malaria transmission. (Fig 6)

Figure 7: Zimbabwe Altitude zones



2.0 DESCRIPTION OF ALTERNATIVES, INCLUDING THE PROPOSED ACTION

This section describes the alternatives that were considered in the preparation of the report including those that were accepted or rejected. The section begins with the preferred proposed intervention, and the key components of this option, before discussing other alternative interventions that were considered alongside the IRS intervention. Alternative spray sites and alternative insecticide classes are also discussed in this section.

2.1 Proposed Action

The proposed action is for PMI to work with the NMCP in support of IRS operations and management to:

1. Strengthen the Zimbabwean national IRS strategy,
2. Plan for a demonstration of a high quality spray operation through training and educational opportunities,
3. Use state-of-the-art IRS Best Management Practices to provide impetus for strengthening and adapting the national strategy so that high quality spraying can be adopted in all provinces and districts.

In year 2012 of this preferred, proposed action, PMI will:

- *Support spray operations:* PMI proposes to support implementation of IRS in 17 high malaria-burden districts in three provinces (Manicaland, Mash West and Mash East), covering a population of approximately 1.5 million using a pyrethroid insecticide. The IRS support would include procurement of insecticide, as well as other IRS equipment such as PPE, camping equipment, spray pumps, spare parts, and other necessary equipment for provincial-level pump repair workshops. The remaining funds would support spray operations in the 17 districts, including contract-labor (i.e., non-government employees) spray operators, camp guards and community mobilizers. The funds will complement GoZ contributions to IRS, including non-contract labor government staff.
- *Entomological Surveillance and Monitoring:* Zimbabwe plans to have sixteen entomological monitoring sites throughout the country, with the National Institute of Health Research (NIHR) serving as a reference laboratory for molecular identification and determination of insecticide resistance mechanisms. Sixteen sites is above the standard in most PMI-supported programs and so a subset of these, approximately four in the three PMI – focus provinces will be the initial focus of PMI support. In addition, PMI will provide insecticide resistance monitoring equipment and training support to the central NIHR laboratory. One critical task was a comprehensive update of insecticide susceptibility status in Zimbabwe, which was just completed in April 2012, and shows a high level of vector susceptibility to all four pesticide classes.
- *IEC/BCC:* Zimbabwe’s 2008-2013 National Malaria Communication Strategy document utilizes advocacy, social mobilization and behavior change communication (BCC) for malaria prevention and control through traditional and religious community leaders and community volunteers organized into ward health teams (WHT). While WHT cover several

health issues, community malaria committees focus on interpersonal communication of malaria messaging in 6 malaria Districts, and NMCP intends to extend community malaria committees to all 45 Districts. The NMCP uses WHTs and community malaria committees to promote IRS campaigns and raise awareness about LLIN distribution and use. In FY 2012, PMI will work with the NMCP and partners to strengthen IEC/BCC approaches for malaria prevention and treatment. PMI will be a major contributor to IEC/BCC activities supporting universal LLIN coverage and IRS, and will also collaborate in activities to improve malaria treatment-seeking and prevention behaviors.

- *Monitoring and evaluation (M&E):* The NMCP, with the support of Global Fund and other partners, has developed a National Malaria M&E Strategy and Plan. This plan covers 2008-2013, and describes by program area the type of data needed, the indicators, data collection and flow, analysis, reporting, feedback and stakeholders' responsibilities. With FY 2012 funding, PMI will strengthen M&E nationally by supporting training from the provincial level down to the primary health facility level. Training will be co-funded with Global Fund, and will include malaria stratification, improved reporting quality, epidemic surveillance and epidemic detection/ response. PMI will also support the end use verification tool to periodically assess the availability of malaria commodities in health facilities.
- Technical assistance to implement PMI IRS activities: One USAID technical assistance visit to support overall IRS operations, including enhanced insecticide resistance monitoring.
- USAID/PMI will conduct an independent environmental audit and evaluation each year of the program, to ensure that the terms of the Environmental Mitigation and Monitoring Plan are adhered to, and that they are achieving their desired outcomes.

2.2 The Insecticide Selection Process

The pesticide regulating body in Zimbabwe is the Registration Service of the Department of Plant Protection of the Ministry of Agriculture. For insecticides to be used in public health, the National Institute for Health Research (NIHR) proposes to the ministry the type of insecticides to be registered after tests of efficiency in the natural setting. All WHOPES-approved pesticides are registered and available for use in Zimbabwe.

Insecticide selection for any PMI supported program is also subject to international procurement requirements of the US Federal laws. Requisitions for public health insecticides used in IRS must be initiated at class level, rather than for a particular insecticide (active ingredient, or AI). The selection of insecticide class for use in IRS is based on a number of considerations.

2.2.1 Primary Selection Criteria

- Must be WHOPES approved,
- Must be registered for IRS use in the country,
- Should have a residual efficacy pertinent to transmission pattern,
- Should be suited to the main type of wall surface,
- Local vectors must show high susceptibility,
- Must be able to manage and minimize environmental impacts.

Should the economic and resistance criteria between formulations be similar (that is to say similar cost and similar vector susceptibility), then toxicity of formulations should be considered when making procurement decisions.

2.2.2 Secondary Selection Criteria:

Once the local selection committee, including NMCP, endorses a pesticide selection, then the criteria is expanded to include international procurement language in which the criteria is clearly stipulated, and then tendered out in accordance with international open competitive procurement rules. For pyrethroids, there is possibility of local procurement because there are insecticide supplier companies in Zimbabwe. Once there are responses to the call for bids, the resulting proposals are subjected to secondary criteria including:

- Appropriate packaging for safety and standard delivery tools
- Unit cost of insecticide.
- Timely delivery of the insecticide to the preferred point of delivery.
- Local representation of supplier in host country
- Technical assistance with training and troubleshooting by supplier

Once a winning bid is selected, it is then submitted to PMI for approval and the local selection committee (including the NMCP), is informed of the now-named insecticide that has been selected and the reasons for its selection for the current IRS round. Once PMI/USAID grants its approval, then procurement of the insecticide starts.

2.2.3 Alternatives Considered and Insecticide Classes Selected

For IRS to be implemented, a pesticide approved by World Health Organization Pesticide Evaluation Scheme (WHOPES) must be selected for use. The PMI program does not allow for procurement of pesticides that are not approved for IRS by WHO and the host government.

WHOPES is the institution that analyzes and recommends the pesticides that should be used in IRS based on their residual effectiveness, toxicity to human health and the environment.

To date WHOPES has so far approved the use of pesticides within the following four classes: pyrethroids, carbamates, organochlorines and organophosphates. Table 8 below highlights the recommended insecticides for IRS in vector control. The proposed action includes the use of carbamates, pyrethroid and organophosphate formulations. Organochlorines, a class that includes DDT (dichlorodiphenyl- trichloroethane) are not proposed for use in any of the PMI provinces.

Table 7: WHO Recommended Pesticides

<i>Insecticide compounds and formulations(1)</i>	<i>Classgroup (2)</i>	<i>Dosage (ga.i./m²)</i>	<i>Mode of action</i>	<i>Duration of effective action (months)</i>
<i>DDTWP</i>	OC	1-2	contact	>6
<i>MalathionWP</i>	OP	2	contact	2-3
<i>FenitrothionWP</i>	OP	2	contact&airborne	3-6
<i>Pirimiphos-methylWP&EC</i>	OP	1-2	contact&airborne	2-3
<i>BendiocarbWP</i>	C	0.1-0.4	contact&airborne	2-6
<i>PropoxurWP</i>	C	1-2	contact&airborne	3-6
<i>Alpha-cypermethrin WP&SCP</i>	PY	0.02-0.03	contact	4-6
<i>BifenthrinWP</i>	PY	0.025-0.05	contact	3-6
<i>CyfluthrinWP</i>	PY	0.02-0.05	contact	3-6
<i>DeltamethrinWP,WG</i>	PY	0.02-0.025	contact	3-6
<i>EtofenproxWP</i>	PY	0.1-0.3	contact	3-6
<i>Lambda-cyhalothrinWP,CS</i>	PY	0.02-0.03	contact	3-6

(1)CS:capsulesuspension;EC=emulsifiableconcentrate;SC=suspensionconce
ntrate;WG=waterdispersiblegranule; WP=wetttablepowder.

(2)OC=Organochlorines;OP=Organophosphates;C=Carbamates;PY=Pyrethroids.

2.3 Preferred Insecticide Classes

Since 2004, pyrethroids have been the preferred insecticide of choice in Zimbabwe, following the decision by GOZ to stop using DDT in some districts and continue to use DDT in Districts where tobacco is grown to avoid risk of resistance because tobacco farms also use pyrethroids. In the three PMI supported provinces, no DDT will be used and NMCP preference is for insecticides of pyrethroid class (Lambda-Cyhalothrin and Deltamethrin). Lambda-Cyhalothrin is preferred by the NMCP based on past success and continued efficacy, and by beneficiaries because also it kills cockroaches and other household pests. However, carbamates and organophosphates are proposed here for future use throughout Zimbabwe in order to manage vector resistance on an ongoing basis.

2.4 Rejected Insecticide Classes

Organochlorines, including DDT, were rejected for use on this project.

2.5 Quantification of Pesticide Requirements

A geographical reconnaissance and logistics assessment is done to understand and map the area so as to appropriately plan for the operation. Secondly, a logistics assessment helps to quantify IRS materials (insecticides, pumps, PPE, etc) which will then be procured. In Zimbabwe, the contractor (Abt Associates) proposes to conduct the geographical reconnaissance, logistics

assessment and all the planning for the field operation in 17 Districts of the three target provinces (Manicaland, Mash East and Mash West Provinces).

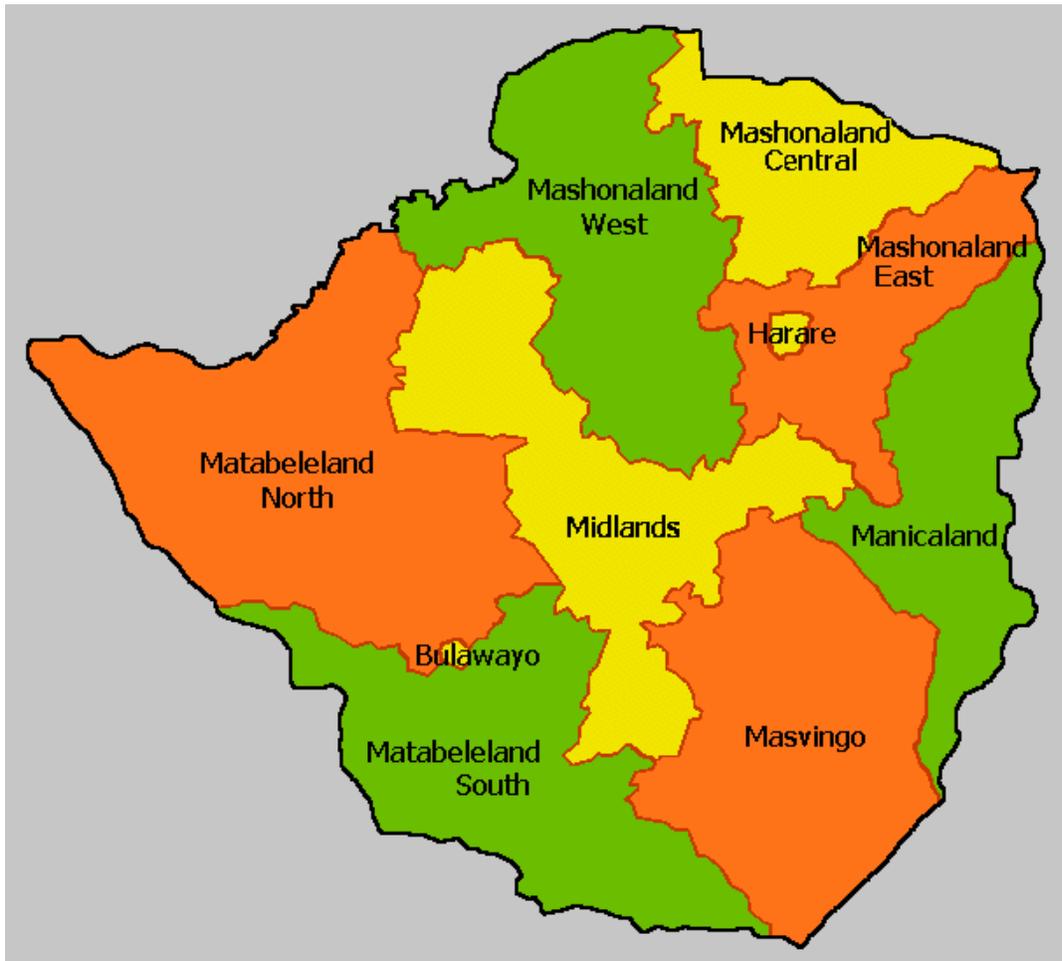


Figure 8: Map showing the all the provinces of Zimbabwe

The insecticides first will be freighted to Harare to the warehouse of the supplier. Zimbabwe Government Analyst Laboratory (ZGAL) will be requested by the Ministry of Health and Child Welfare (MOHCW), to take samples and perform ingredient analysis for quality control before transport to the provincial warehouse. The insecticides will then be transported directly to the principal warehouses at the provincial level before being dispatched to different districts where spray operations will be concentrated. Transportation of insecticides should be done in compliance with program and National environmental compliance requirements. During geographical reconnaissance and logistics assessments, the need for rehabilitation of principal warehouses at province level and district level to meet PMI BMP requirements for pesticide storage will be assessed.

2.5.3 Qualification of warehouses (Storage Facilities)

The procured pesticides are categorized as hazardous and toxic and can potentially cause adverse impacts to human health, animals, and the natural environment if not properly stored according

to the international guidelines and USAID/BMP (2011) for storing insecticides. Before insecticides are procured or transported to the spray areas, suitable warehouse(s) must be assessed and ensure that they meet the FAO or USAID/BMP standards for insecticides storage. Those standards include among others;

- Spacious enough to store insecticides in bulk
- Located as far as possible from; flood plains, wetlands, markets, schools and residential areas
- Well ventilated and allowing for air circulation
- Built of concrete or other solid material
- Adequate roofing that is not susceptible to leaks
- Adequately secured
- At least 2 exits for emergency purposes
- Guarded 24 hrs/day
- Fire extinguishers are available.
- Double locking padlocks are provided.
- Pallets are available for proper storage of insecticides

During the logistical needs assessment, the contractor (Abt Associates), working with Provincial Environmental Health Officers (PEHOs) will identify appropriate warehouses at the province level and at the districts level that meet the above mentioned requirements. They may require minor rehabilitation especially aimed at enhancing security by verifying locking system, floor, roof, doors, ventilation system etc.

In the three provinces of Manicaland, Mash East and Mash West, IRS insecticides and IRS material and equipment are stored with other provincial commodities. It is necessary to separate insecticides from others commodities to avoid risks of contamination.



Figure 9: Chinhoyi Provincial Warehouse (Mash West) Figure 10 : Mutoko District Warehouse (Mash East)

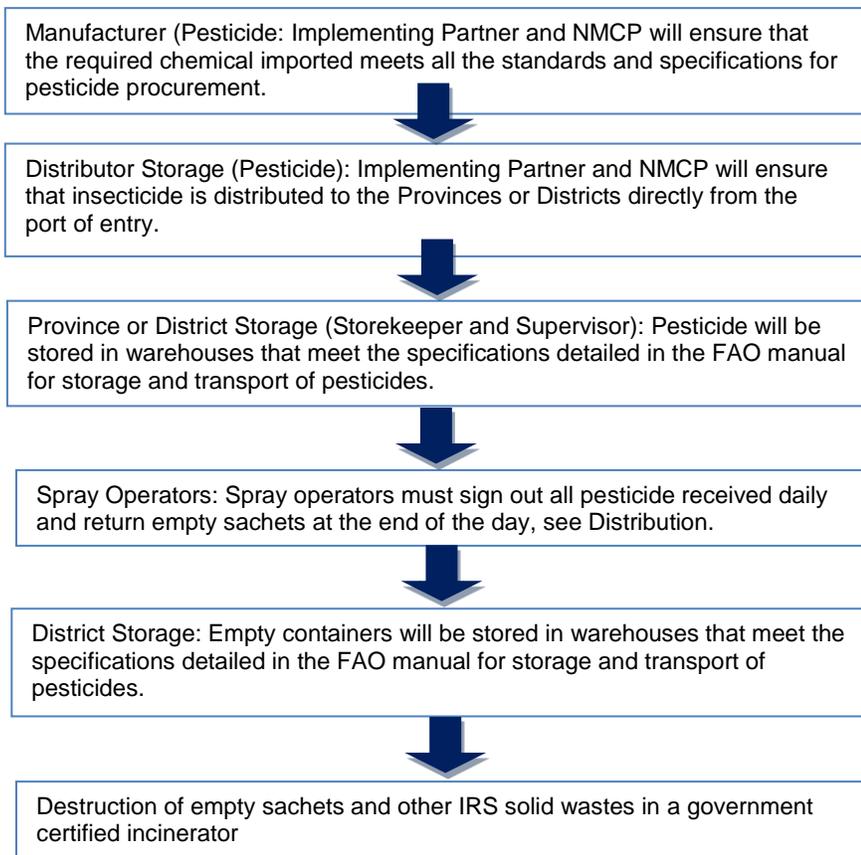
All facilities used for storage, distribution, and transportation of insecticide products should comply with relevant requirements of the Workers Safety and Social Services for employees,

Environmental Act, Agriculture Act, and any other relevant Zimbabwe standards on pesticides use and management. To that end, the following section and the EMMP describe the program requirements for storage, distribution, and transportation.

2.5.4 Supply Chain and Disposal Options

Abt Associates will work with the relevant authorities and will employ the following pesticide chain management in its Zimbabwe IRS programs to ensure control.

Figure 11: Pesticide Chain of Custody and Management



2.5.5 Health and Safety in the Warehouse

The following measures are required in all warehouses in order to reduce cases of pilferage, exposure through leakages and theft, and to ensure the health and safety of those accessing these facilities:

- Warehouse must be double-padlocked and guarded at all times.
- All the storage facilities must have thermometers installed for temperature recording.
- Soap and clean water for washing must be available at all times.

- Trained storekeepers must be present and wear appropriate PPE when in the pesticide area of storage.
- Pesticide stacking position and height in the warehouses must not be above 2 metres in height.
- The central warehouses must have at least two exit access routes in case of fire outbreak.
- Fire extinguishers must be available in the storage facilities and all workers trained on how to use them.
- Hazard warning notices must be placed in the outside of the store in pictorial form (skull and crossbones).
- First-aid kits must be available in all the central warehouses and secondary stores

2.5.6 Insecticide Distribution and Management Process at District and Lower Levels

Contractor (Abt Associates) will develop standard requisition, tracking, and monitoring forms to be used for inventory, record, and track all the insecticides distributed and returned. These forms will be used in the program at all levels, and the store managers will receive training on how to use these forms. The steps below highlight the insecticide distribution process proposed including recording and tracking methods:

- At reception at the provincial warehouse, lot numbers of insecticide and quantities are registered on shelf inventory card.
- District requisitions are approved at the program office, where copies are maintained.
- Requisition goes to district warehouses where distribution takes place and is signed for, based on sachet numbers. Insecticides are distributed on a “first-in, first-out” system, so the insecticide that arrived first is distributed first. This avoids accumulation of expired stock.
- On reception at lower storage levels, all sachets are counted and stamped with the relevant stamp and registered on a stock card.
- Every morning before the spray operations begin, spray operators receive from the store manager only enough sachets for the day’s work (between 8–10 sachets), and must sign for all pesticide received daily in a log book.
- At the end of the day, empty and full sachets are returned and numbers checked against what was signed out. Returned empty and full sachets are logged into the log book by the store keeper or supervisor.
- Supervisor examines spray operator performance by comparing number of structures sprayed to sachets used to determine whether there is an over or under application.

- Store keeper must submit the following to the central office for data entry on a daily basis: 1) insecticide stock balances; 2) sign-in/sign-out results; and 3) structures sprayed per spray operator.
- The next day, all previously signed for but unused sachets are reissued and signed for by the relevant spray operator.
- At the end of each day and at the end of the spray round, stock remaining must equal the stock at start of the day minus the number of sachets distributed. Number of sachets distributed should be equal to number of sachets used if there is no returned full sachet.

2.5.7 Personal Protective Equipment (PPE)

Each spray team will consist of sixteen spray operators. Each spray operator will be provided with the following safety equipment (figure 11) to be used during the spraying, in accordance with WHO and FAO specifications:

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

Figure 12: Operators dressed in PPE



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

For spray operators, safety precautions will depend on the proper use of PPE, and personal hygiene, including washing and daily changing of spray clothes. A schedule for carrying out and supervising personal hygiene, regular washing of protective clothes and cleaning of equipment will be organized along the following lines (WHO 2006):

- Spraying staff will be provided with at least two uniforms to allow for frequent changes.
- Washing facilities with sufficient water and soap will be made available in the field at appropriate locations.
- All working clothes must be removed at the end of each day's operations and a shower or bath taken—in circumstances where a full-body shower or bath is not feasible, face/neck and hands must be washed with soap and water.
- Working clothes will be washed daily.
- Particular attention will be paid to washing gloves, and avoiding contamination of the inside of the gloves.
- Spray operators will wash before eating, drinking or smoking at the end of the daily spray operation.
- Eating, drinking and smoking during work will be strictly forbidden at all times during the operation. If spray operators need to drink water in the course of the operation, they must clean their hands thoroughly to avoid any exposure, or receive assistance from the homeowner, such that they do not need to handle water containers with gloves or other PPE that has been exposed to pesticides during spray or make-up activities.

2.5.8 Procurement of Other IRS Equipment

The following IRS equipment will be procured alongside with the insecticides and PPEs including:-

- **Spray Nozzles**
The program in Zimbabwe will procure 8002E nozzles for the spray pumps which are the standard size recommended by World Health Organization for mud wall.
- **Spray pumps**
Spray operators use compression sprayers with shoulder-suspended tanks to apply a measured amount of insecticide on the interior walls of houses and structures. A water-soluble insecticide is added to the sprayer containing a pre-measured amount of water, the sprayer is pressurized, and the material is then applied to the interior walls of targeted house (Structure). After the day's spraying is complete, spray operators must clean the sprayer following the manufacturer's recommendations to ensure their proper operation and calibration.

Currently in Zimbabwe, two type of spray pumps are used, MICRONAIR and HUDSON X-PERT. From information provided by technical staff of different provinces during Kadoma national malaria conference (as of 28-30 March 2012, MICRONAIR pumps are not performing very well and the nozzles clog and leak. For that reason, it is recommended to procure Hudson X-PERT. All the spray pumps will be distributed to the districts based on the number of the spray operators. There will be reserve pumps used to replenish broken pumps that will need repairs.



Figure 13: Spray pumps used in IRS operations

2.5.9 Training

Training of Spray Operators

Spray operators will initially be chosen based on their completion of primary school and must pass written and practical tests of their ability to read, write and record critical spray information, and make calculations. They will then undergo medical exams to determine their physical capability for providing appropriate application of the insecticide. All the female spray operators and washers will be subjected to a mandatory pregnancy test before training and recruitment as spray operators or washers. Pregnant operators must not be included in the spray operations because of the possible effects the pesticides to the fetus. Every month until the operations are concluded, a pregnancy test must be obtained from the female candidates selected. The individuals recruited for IRS campaigns will receive intensive training on the use, operation, calibration and repair of the spray pumps, including practical exercises during a 5-day period prior to the beginning of the spraying campaign. They will also receive training to understand proper hygiene, to recognize the signs and symptoms of poisoning, and to understand the referral procedure for any incidents involving poisoning. This training is conducted in accordance with WHO's "Manual for Indoor Residual Spraying" (WHO 2002) and PMI IRS BMPs.

Due to the long experience of IRS in the country, NMCP has already trained a large number of spray operators using WHO Manual (Sect 1.5.1, table 2)

From the post IRS training test and on the basis of performance during training, graduates of this training will then be assigned to various categories of work including;

- Spray operators
- Supervisors

- Team leaders
- Washers
- District managers
- Pumps technicians
- Storekeepers
- Washers

The above teams will then receive additional specialized training in accordance with the area of assignment. This training will be conducted by the contractor’s staff in conjunction with MoHCW, MNCP and other partners (EMA, NIHR, etc.).

Clinician Training

The clinicians in the health center facilities at ward level will be given refresher courses on how to handle acute exposure incidents that is always likely to occur when using pesticides. Acute exposure can happen through dermal contact, which could lead to absorption into the blood stream as well as skin and eye irritation, or ingestion, which could also lead to poisoning. The health facilities must have relevant anti-dotes for poisoning incidences in their store (see Table 8).

Table 8 : Drugs Recommended for Treatment of Pyrethroid Exposure

Name of drug	Active ingredients
Promethazine	Promethazine Hydrochloride
Panadol	Paracetamol
Diazepam	Benzodiazapine/Diazepam
Lorazepam	Lorazepam
Calamine cream	Calamine, zinc oxide, glycerol, phenol, purified water, sodium citrate, betonite,
Vit E	Tocopherol, fragrance, mineral oil, deionized water, sodium hydroxide, stearic acid
Hydrocortisone cream	1% hydrocortisone
Salbutamol	Salbutamol 100 mcg, suspended inert aerosol
Salbutamol tablets	Salbutamol sulphate 4 mg
Activated Charcoal	Activated Charcoal

Driver Training

All the drivers recruited for the operations will also receive training on safe transport of pesticides, use of PPE, and steps to respond to spills or accidents.

2.5.10 Supervisory Actions during IRS

To ensure adequate supervision, the spray operators are organized into teams of five or six spray operators and a team leader to ensure strict supervision during the implementation phase. A team of six will be under the management of one supervisor. Supervisors will observe spray teams to ensure spraying occurs according to best practices. Supervisors will travel between spray teams and will observe spray operators and team leaders in pesticide preparation, spray technique, and

sprayer and PPE clean up during the IRS campaign, as well as compile all data collected by their respective teams. District teams will provide oversight to ensure the goal of day-to-day achievement of environmental compliance.

In general, districts will be divided into IRS Camping sites, where the progressive rinse occurs. These camping sites will be at identified health centers at ward level. At that site will be constructed soak pit and washing bays in an appropriate fenced area. The site will be identified during the logistical assessment phase and will be based on BMP recommendations, accessibility and access to water. It is preferable to be located near the Government health facility.

At District level, activities are coordinated by a District Environmental Health Officer. Each district will maintain an operational spray plan (progress calendar), produced during the micro-planning and validated by the health team at the district level, indicating all communities to be sprayed during the spray operations.

At the end of each day, spray leaders at each operational site will meet with their manager to discuss the day's events, challenges faced, and recommendations for resolving problems. At the end of each spraying month, IRS partners' coordination meetings will be held with the IRS project, IEC implementers, and the district health team, chaired by the District Chief Medical Officer or designate. During these meetings, the partners will assess the progress of spray operations, ensure that the planned work schedule is strictly adhered to, and make recommendations as necessary to the IRS project or IEC implementers.

The IRS district coordinator will hold a weekly meeting with the district chief medical officer and the IRS managers to discuss operational issues and their solutions. Abt Associates will maintain records of program performance reports which will be able to demonstrate adherence to WHO technical standards, quality of training and supervision, procurement activities, and environmental compliance. Such reports include the pre- and mid-spray environmental compliance report, reports on core IRS indicators and end-of-spray evaluation reports.

Supervisors will monitor the effectiveness on beneficiary populations of Information Education and Communication (IEC) campaigns by visiting sprayed houses to discuss beneficiary impressions, and visiting unsprayed houses to discuss with heads of families why spraying is important. Regarding spray technique and spray operator discipline, monitoring will involve visiting the sprayed compounds and interviewing beneficiaries to ensure that spray operators respect household members, spray all eligible rooms, record the essential data in the relevant form, mix and apply insecticides at the right dosage, and pass the relevant health information to the household.

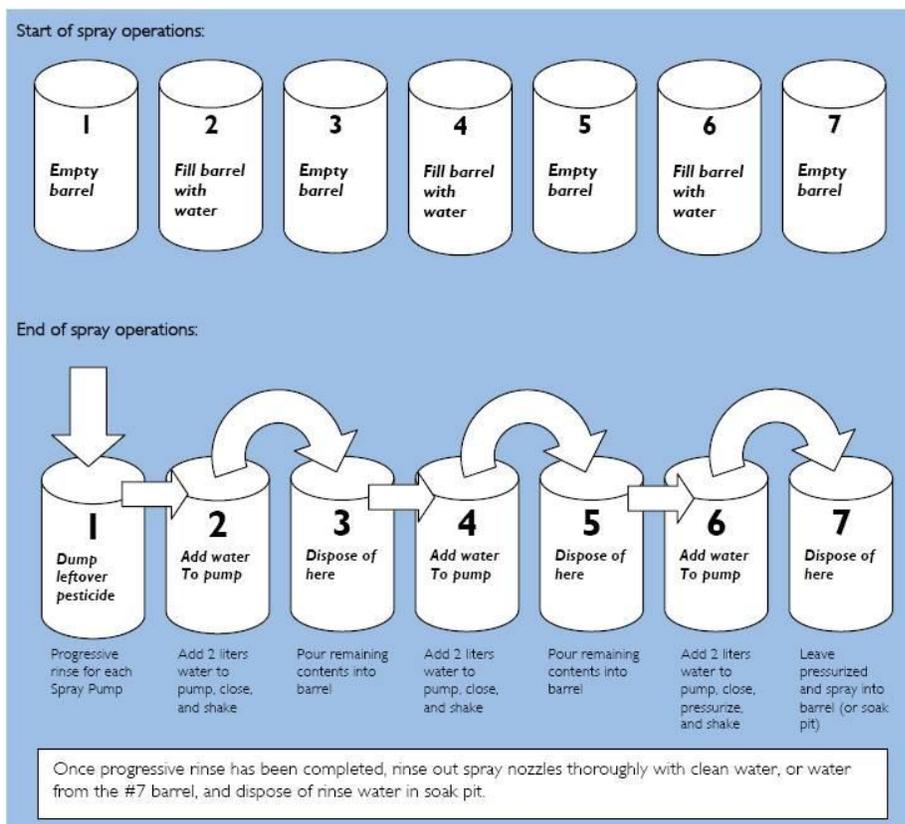
Good supervision will also require observing each spray group at work, spray group leaders, spray team leaders, and spray operators, and checking spray team habits to ensure best practices for insecticide storage and solid waste management. Since the reports of the operators are the basis for all reporting and data collection, supervisors will ensure that they are completed accurately and promptly at the end of the spraying day.

2.5.11 Equipment for decontamination

USAID's IRS BMP Manual recommends that water used to rinse out spray pumps at the end of each day must be re-used at the beginning of the next day's work to save water and reduce the potential for pollution from leftover pesticide or contaminated rinse-water. The best practice for rinse-water re-use is called "progressive rinse." With this rinse method, seven barrels/drums/containers of approximately 200-litres each are placed in a line. Every other container is filled with water (e.g. the first container is empty, the second is filled with water, the third is empty, fourth is filled with water, fifth is empty, sixth is filled with water and the seventh container is empty) (Figure 10). During the end-of-day cleanup, the remnants of a pump charge from the field are emptied into the first container. This will be a limited volume, which should be much less than half of this container, as most sprayers will be returned empty from the field. It is important to train operators to manage this goal of minimizing leftover at the end of the day. The spray operator will then fill the sprayer less than half-full with a cup of water from the second container, close and shake the sprayer, and dump the sprayer water in the third container. The spray operator will repeat those steps with the fourth and fifth containers, then with the sixth and seventh containers, making sure to rinse the outside of the sprayer only at the sixth container (although not in the sixth container). The following day, spray pumps are filled with liquid from containers in the same sequential order: container one, then container three, then container five. Any remaining liquid in the fifth and seventh containers are quite dilute and will be disposed in a soak pit.

The spray operator will repeat those steps with the fourth and fifth containers, then with the sixth and seventh containers, making sure to rinse the outside of the sprayer only at the sixth container (although not in the sixth container). The following day, spray pumps are filled with liquid from containers in the same sequential order: container one, then container three, then container five. Any remaining liquid in the fifth and seventh containers are quite dilute and will be disposed in a soak pit.

Figure 14: Progressive rinsing (BMP Manual)

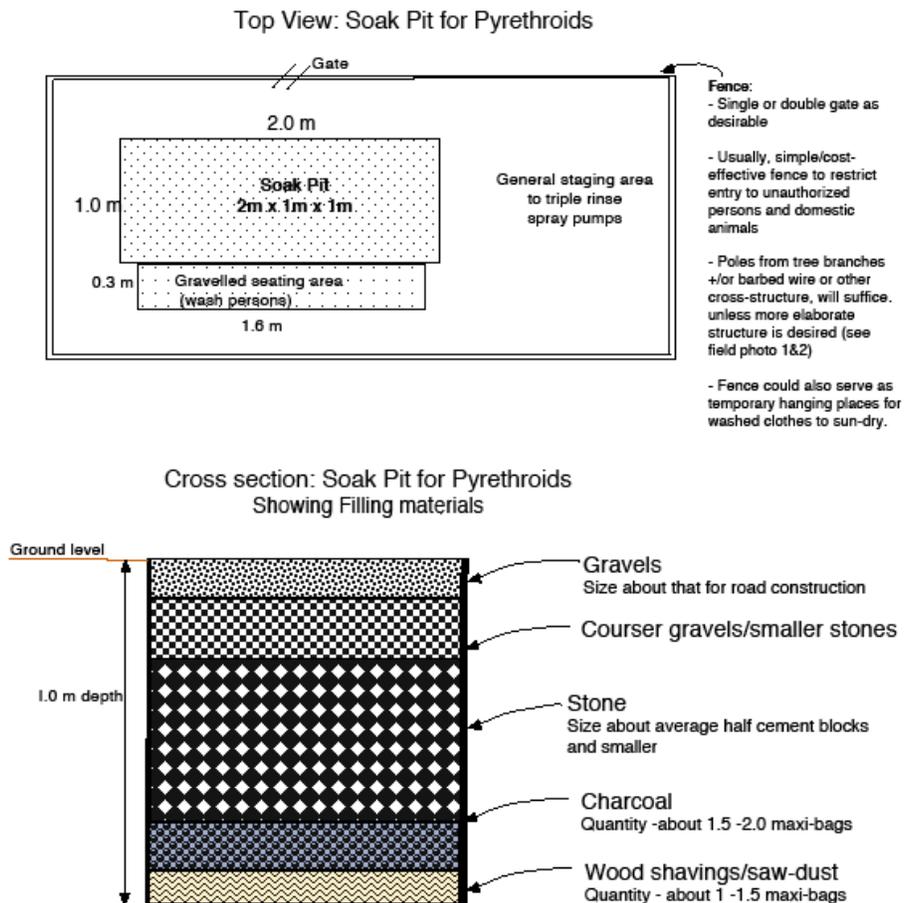


Effluent disposal facility: soak pits and washing areas

The site for the soak pits in each camping site will be selected jointly with the assistance of the representative of EMA and Environmental Health Department at the district level. In Zimbabwe, the camping site will be at the health center at ward level. The soak pit site must be away from water bodies, bore holes and schools wherever possible. The size of the soak pit depends on the number of spray operators that the soak pit supports. On average, and according to the USAID/BMP Manual, the soak pits are 2 meters by 1 meter, excavated to a depth of one meter. What is important is that the bottom of the pit is packed with hard coal or charcoal, followed by saw dust (where this is feasible) and stone aggregates and covered by gravels (Figure 11). The area is then fenced off to keep animals and children out of the soak pit area. The entire soak pit area is fenced complete with a lockable access door to prevent unauthorized entry by children or animals.

The overall principle of the soak pit, also referred to as a bio-bed, is to absorb the toxic chemicals in the pesticide through a filtration process so that the waste water that finally reaches the underground has been purified and no longer contains the chemical components. The organic chemical contaminants (pesticides) are held by the charcoal, where they are acted upon by environmental forces, including bacterial action. Research has shown that pesticides are destroyed within three months in the soak pit.

Figure 15: Outline of Soak Pits design (BMP Manual)



In order to minimize possible ground contamination from washing spray equipment and PPE, all staging areas are required to have an impervious wash area that drains to the soak pit. This will ensure that all contaminated washwater is properly treated in the soak pit.

Wash-persons will be hired and provided with protective gear. Wash persons will wash overalls at a central location in tubs used exclusively for overall washing. Spray operators must completely wash themselves after each day’s operations using wash basins or shower areas constructed near the soak pits. Spray operators should never wash themselves, their overalls, or their PPE in any water bodies, or delay washing until they are home. Washing must be performed at designated sites, and all wash-water must be disposed of in a soak pit. Where necessary, construction of infrastructure for proper disposal of contaminated water will be financed by PMI.

In PMI support provinces, soak pit and washing area will be constructed at each of the 81 camping sites (Table 9).



Figure 16: Type of soak pits and washing areas

Table 9 : Number of camps by province and district

Province	Districts	Numbers of camps
Mash East	Mudzi	4
	UMP	4
	Mutoko	4
	Murerwa	4
S/Total		16
MANICALAND	Buhera	7
	Chamanimani	4
	Chipinge	4
	Makoni	7
	Mutare	7
	Mutasa	4
	Nyanga	7

S/Total		40
Mash West	Kariba	5
	Harungwe	8
	Mukonde	4
	Zvimba	2
	Chegutu	2
	Kadoma	4
S/total		25
Total		81

2.5.12 IRS Solid Wastes Disposal

IRS solid wastes, which include empty insecticide sachets and contaminated gloves, masks and covering sheets will be collected from the field and brought back to the central warehouse. All require disposal in an environmentally and internationally accepted manner as prescribed by FAO/WHO with regards to disposal of pesticide wastes. Incineration under specific conditions is highly recommended by the United Nations Environment Program (UNEP) and WHO/FAO in relation to pesticide waste disposal, especially for primary and secondary packaging materials and contaminated single use clothing (dust masks).

Generally, according to WHO/FAO², incinerators recommended for disposal of non-DDT wastes meet the following key requirements:

- The recommended combustion temperature is between 1,100°C and 1,300°C.
- An after-burner is required, with a residence time of at least two seconds.
- The incinerator should have emission control, including particulate matter filters.
- Ash and slag produced by high-temperature incineration of pesticides are, in principle, considered inert, unless determined otherwise and can be disposed as normal waste, preferably in a dug out pit.
- An alternative disposal method is using a Sanitary Landfill which has impermeable lining underneath and a system of leachate collection.

In the three provinces (Manicaland, Mashonaland East and Mashonaland West), there are incinerators that meet requirements for incineration of non-DDT IRS solid wastes. Mutare Provincial hospital in Manicaland has a good incinerator using coal as source of energy, Chinhoyi provincial hospital in Mash West has two big incinerators using gasoil and electricity and Mutoko District Hospital in Mashonaland East has an appropriate incinerator using coal as source of energy. At the end of the campaign, the solid wastes will be transported to the nearest incinerator facility for appropriate disposal. A representative of EMA will be requested to

² Food and Agriculture Organization of the United Nations (2008). International Code of Conduct on the Distribution and Use of Pesticides: Guidelines on Management Options for Empty Pesticide Containers. Rome: FAO. Accessed June 2, 2008
http://www.who.int/whopes/recommendations/Management_options_empty_pesticide_containers.pdf

supervise the incineration and prepare a report for the accomplishment that will be filed at the province level.

Figure 17: Mutare Provincial Hospital Incinerator (Manicaland Province)



2.6 Alternative IRS Geographical Sites Considered

This SEA covers all the 8 provinces in Zimbabwe for the period of 5 years. Areas considered as malaria risks following entomological studies conducted by NMCP include all 8 provinces of the country. In Zimbabwe, 45 of the total 62 districts that constitute the country are considered as malaria risk districts, and some districts are located in each of the 8 rural provinces. However, for 2012, the proposed activities will focus on three provinces (Manicaland, Mash West, Mash East Provinces) of PMI intervention. Over 5 years, IRS implementation will depend on the malaria status of each area as determined by entomological studies. According to entomological resistance results, NMCP can decide to change insecticides or overall strategy. Unauthorized areas, however, including all special habitats such as wetlands, within 30 m of water bodies, and areas of sensitive habitats such as bee keeping areas, national forests, parks and other all protected habitats, may not be sprayed.

2.7 No Action Alternative

IRS is a critical intervention in the control of malaria because it attacks the malaria vector and drastically reduces the vector population. As a result, it prevents or reduces transmission, hence minimizing morbidity that would need to be addressed through a curative approach.

In Zimbabwe, malaria is ranked second amongst the top ten causes of OPD attendance, accounting for 20-30% of out-patients attendance, 12% of inpatients, and it is the second highest cause of death for inpatients per annum. The malaria incidence rate in the twenty most affected districts ranged between 158-700 cases per 1000 per annum in 1999. In year 2000, 15% of outpatient attendance and approximately 20% of inpatient admission to public health facilities were due to malaria.

According to MoHCW, IRS has demonstrated efficiency on malaria transmission reduction. Outpatient department malaria cases decreased from 14% in 2005 to 9% in 2009; inpatient

malaria cases declined from 10% to 8% between 2005 and 2008. Malaria deaths as a proportion of all inpatient deaths decreased from 7% in 2003 to 3% 2008.

As described above, a no IRS program scenario/alternative will mean a resurgence of malaria morbidity and mortality. Households targeted under the IRS program would not have the benefit of IRS as an intervention. The No Action alternative does not meet the PMI's overall goal: to reduce burden of malaria (morbidity and mortality) in 70% of the at-risk populations in expanded Africa PMI countries, including Zimbabwe.

2.8 Environmental Management Alternative

Environmental management for mosquito control aims to induce changes in the environment to disrupt the mosquito life cycle and reduce its propagation, principally 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 mainly used in urban environments to reverse or eliminate man-made changes that result in standing water. Larviciding and environment management cannot be used as an alternative to IRS but rather as part of an integrated vector control program.

2.9 Larviciding

Larviciding is not a developed component of the malaria control program in Zimbabwe; however, it is implemented in a few areas where transmission is low. Larviciding is undesirable because the addition of chemical to water bodies may have unintended side effects.

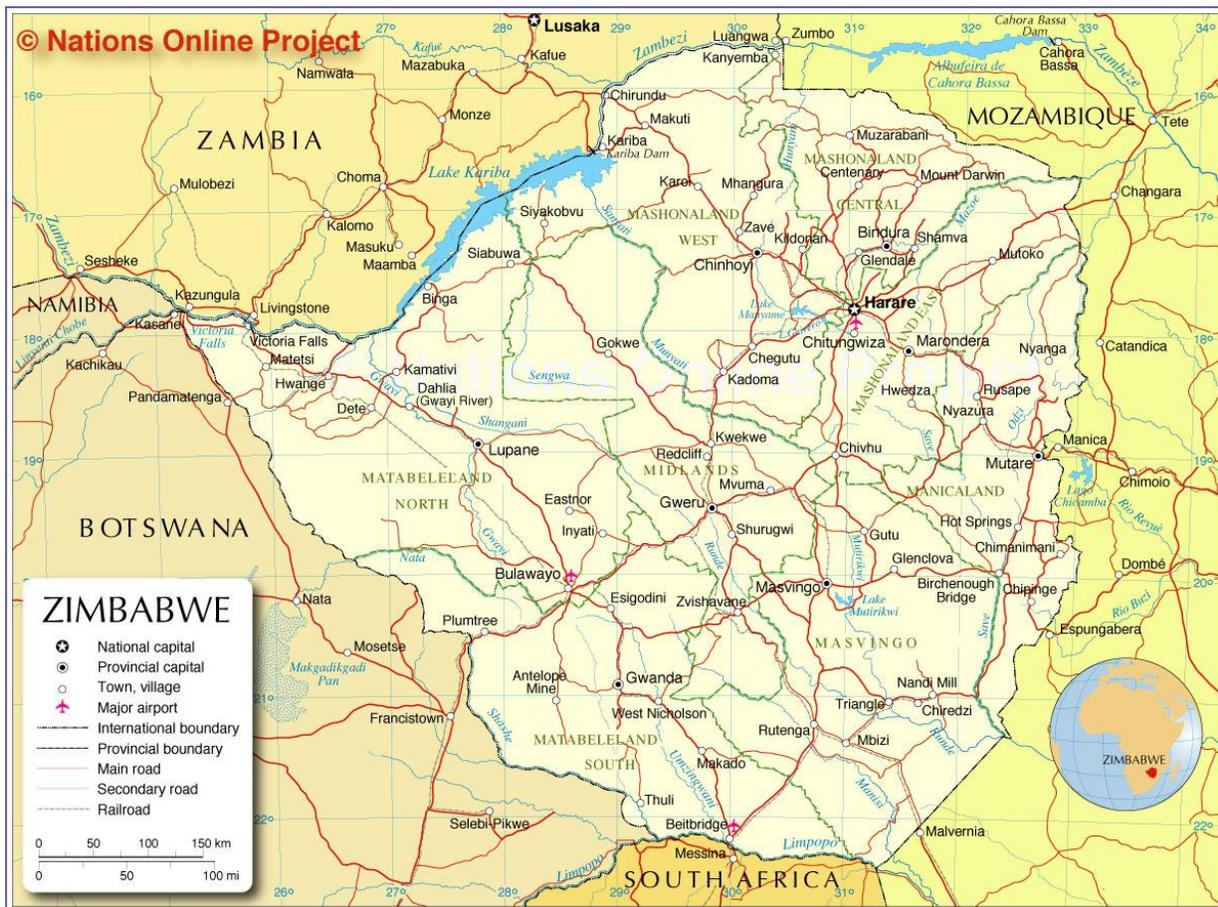
3.0 AFFECTED ENVIRONMENT- ZIMBABWE

This chapter will describe the critical environments and ecosystems that may be adversely affected during IRS program implementation by using pesticides as method for vector control. This will help to determine the mitigation measure to be implemented to address negative impact of IRS implementation.

For FY 2012, PMI IRS activity will focus on 17 Districts in the three provinces of Manicaland, Mashonaland East and Mashonaland West with possibilities of scaling up in future. In the present chapter, critical ecosystems or activities (surface water bodies, national parks and game reserves, apiculture, fisheries and organic farming, etc.) throughout Zimbabwe that can be negatively affected by implementation of IRS will be highlighted and mitigation measures or alternatives proposed.

3.1 Geography and Administrative Subdivisions

Figure 18: Zimbabwe Administrative Map



Zimbabwe is a landlocked country in southern Africa lying well within the tropics. It straddles an extensive high inland plateau that drops northwards to the Zambezi valley where the border with Zambia is and similarly drops southwards to the Limpopo valley and the border with South

Africa. The country has borders with Botswana 813 km, Mozambique 1,231 km, South_Africa 225 km, Zambia 797 km and meets Namibia at its westernmost point. The population is estimated to 12,5M (extrapolation from the 2002 census).

3.2 Climate

The Zimbabwe general climate is tropical, although moderated by altitude. There is a dry season, including a short cool season during the period May to September when the whole country has very little rain. The rainy season is typically a time of heavy rainfall from November to March. The whole country is influenced by the Inter-tropical Convergence Zone during January. In years when it is poorly defined there is below average rainfall and a likelihood of serious drought in the country (as happened in 1983 and 1992). When it is well-defined rainfall is average or well above average, as in 1981 and 1985.

Zimbabwe is generally dry and warm. The diurnal average surface temperatures vary from 15°C in July to 22°C in January. Average summer precipitation varies from 400 mm in the south to about 900 mm in the mountainous north-east. In winter the average precipitation is less than 70 mm. Annual average rainfall is between 400 and 700 mm.

Like the rest of southern Africa, Zimbabwe is strongly influenced by fluctuations in rainfall. An improvement in the water balance as a result of climate change would be a great benefit; increase water stress, on the other hand, would be a substantial development challenge.

1 QDS record(s) extracted from the Zimbabwe flora website (<http://www.zimbabweflora.co.zw>) on 08 Mar 2012.

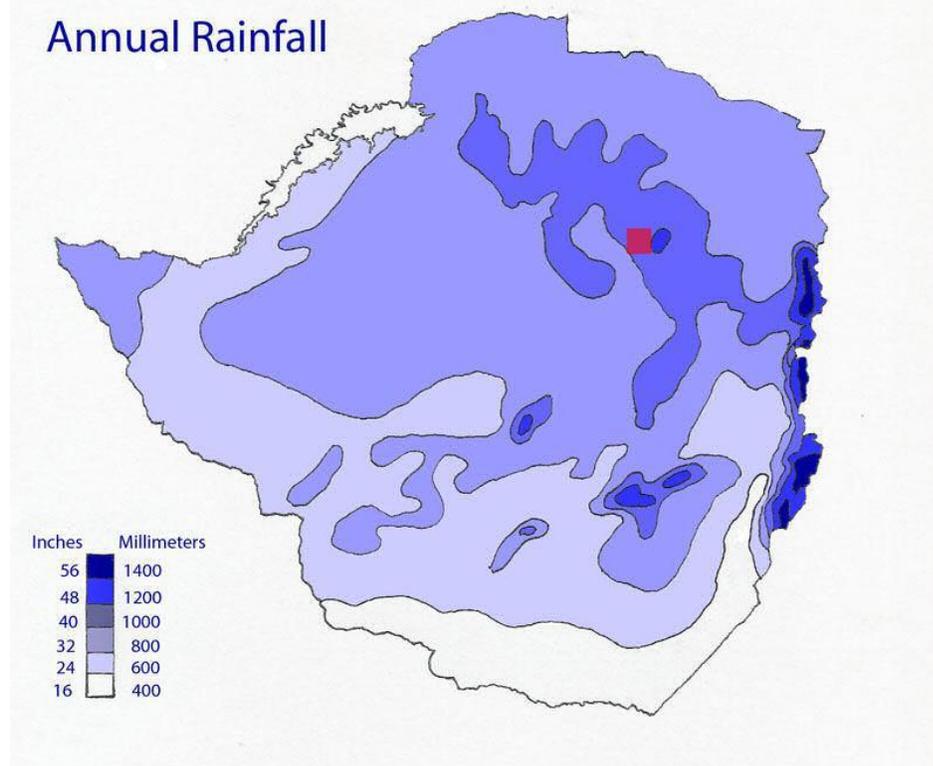


Figure 19 : Annual Rainfall in Zimbabwe

3.3 Topography

Zimbabwe lies within the tropics and covers an area of 396 000 km² extending from 15°30'S to 22°30'S and from 25°E to 33°E. The country has three major regions distinguished on the basis of elevation: Low altitude (below 900 m above sea level), Middle altitude (900-1 200 m) and High altitude (above 1 200 m). According to its relief, Zimbabwe is considered as a high plateau with higher central plateau which constitutes a watershed between the Zambezi and Limpopo river systems. The Limpopo and the lower Zambezi valleys are broad and relatively flat plains. The eastern end of the watershed terminates in a north-south mountain spine, called the Eastern Highlands (Figure 16).

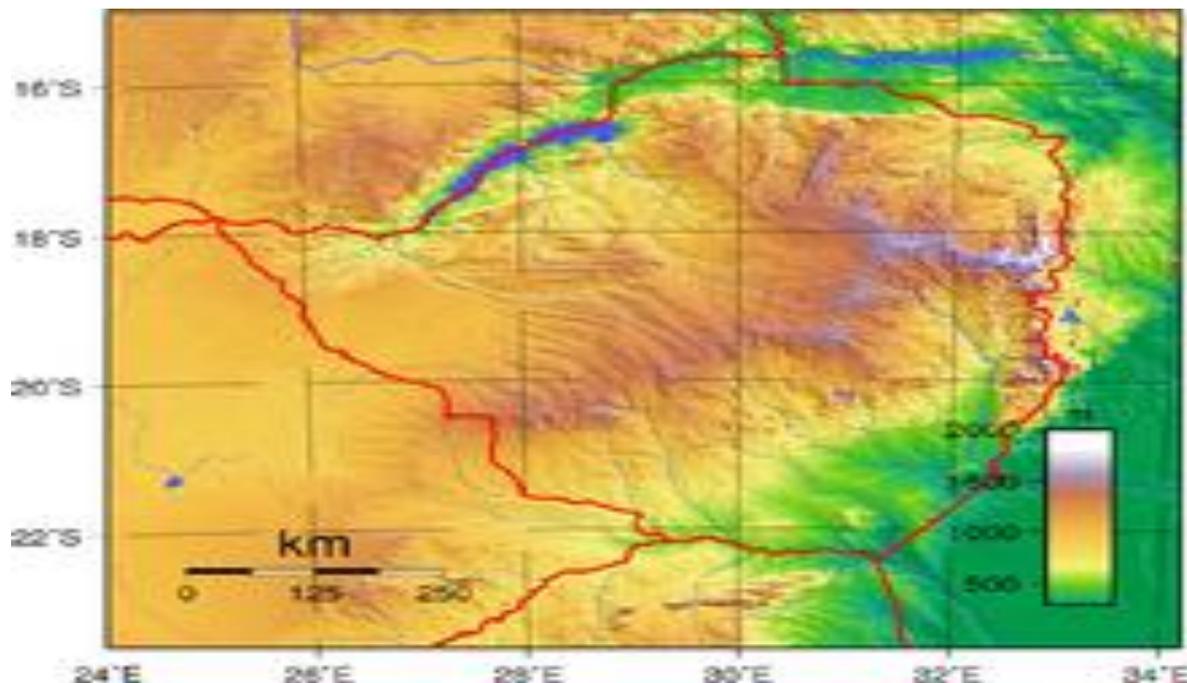


Figure 20: Zimbabwe Satellite map

3.4 Hydrology

The country is divided into six drainage basins. The largest are the Zambezi in north and west to the border with Zambia and the Limpopo in the south bordering with South Africa and Botswana. The Zambezi River in the north is one of the largest rivers in Africa, but does not currently supply water to the rest of the country, which is water-scarce in most parts. The geology is generally not conducive to large groundwater supplies.

Western parts of Matabeleland connect to the Okavango inland drainage basin through the Nata river. Most of the southern Mashonaland and adjacent parts of Masvingo drain through the Save river into the Indian ocean through Mozambique. Two smaller drainage basins cover parts of Manicaland, and drain into the Indian Ocean through Mozambique. These are the Pungwe River to the north and the Buzi River to the south.

Lake Kariba. Zimbabwe man-made waterway, covering an area of over 6500 sq kms, Lake Kariba was completed in 1958, for the purpose of providing the country with much needed hydro-electricity. The lake has since developed into one of Zimbabwe's greatest water playgrounds with water skiing, sailing and fishing being big sports.

In addition, throughout the country there are a lot water bodies (dams) created by the farmers to be used for irrigation, water for animals and also for fish farming.



Figure 21: Man-made water body in Mash East

3.5 Vegetation

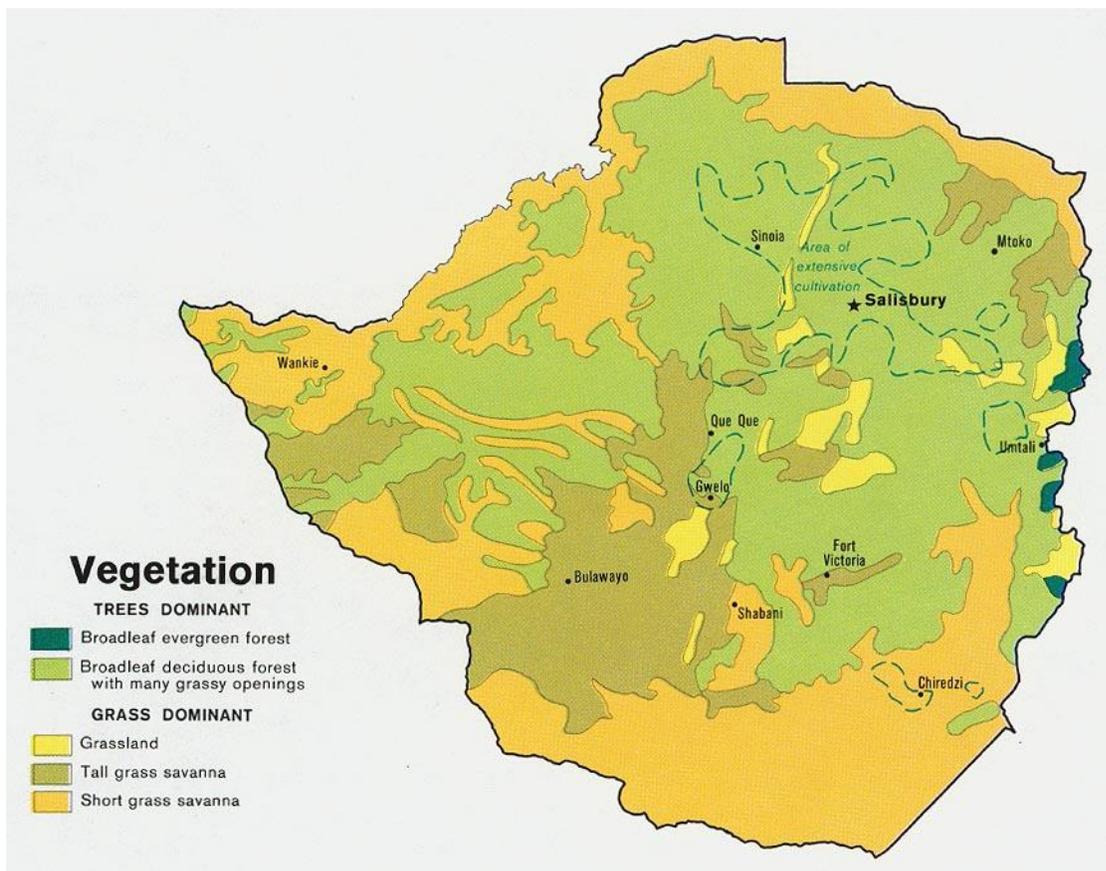
Savanna covers most of Zimbabwe, with the country's rainy summers giving generous assistance to the growth of trees on the plains, which is dominated by *Brachystegia*.

In the Miombo Woodland, natural vegetation is dominated by *Brachystegia spiciformis*, *B. glaucescens*, *Julbernardia globiflora*, *Pericopsis angolensis*. In the high altitudes, Riverine vegetation is dominated by *Rhus lancea*, *Englerophytum magalismsontanum*, *Olea europea* subsp. *africana*, and *Combretum erythrophylum* along the river.

In Lower Zambezi Valley considered as semi-arid in the north of country, vegetation is dominated by Zambezi teak (*Baikiaea plurijuga*), manketti-nut (*Schinziophyton rautanenii*), tick tree (*Sterculia africana*), jesse bush (Combretaceae), false mopanes (*Guibortia coleosperma* and *G. conjugata*), and torch-wood (*Balanites maughanii*).

In Lower Save-Limpopo Valley in the south of the country, considered as semi-arid, the vegetation is similar to the Zambezi Valley area. In that area there are some specimens of the baobab (*Adansonia digitata*), as well as tamboti (*Spirostachys africana*) and mopane (*Colophospermum mopane*). Along the river, there is riverine vegetation dominated by *Hyphaene pertesiana*, natal mahogany (*Trichilia emetica*), and ebony (*Diospyros mespiliformis*).

Figure 22: Zimbabwe Vegetation Map



In East Highlands of Zimbabwe (Haron-Mukurupini forest), vegetation is characteristic of rainforest dominated by giant red mahogany (*Khaya anthotheca*), *Erythrophleum suaveolens*, and *Newtonia buchananii*. The medium highland is occupied by *Anthocleista grandiflora*, *Chrysophyllum gorungosum*, and *Ficus rook*. The high altitude is dominated by big trees including albizia (*Albizia schimperana*), the parasol tree (*Polyscias fulva*), and yellowwood (*Podocarpus latifolia*). In the margin of the Eastern forest, dominant vegetation includes muranga (*Warburgia salutaris*), bivia (*Bivia jalberincludintii*), pink dombeya (*Dombeya burgessiae*), and the rare northern mountain bamboo (*Oreombambos buchwaldii*).

3.6 Agro-Ecological Zones

Zimbabwe is divided into five main natural regions according to differences in effective rainfall (Vincent and Thomas, 1960), and crop production progressively deteriorates from Region I to V (Figure 3). Annual rainfall is highest in Natural region I which covers approximately 2% of the land area. It is a specialized and diversified farming region with plantation forestry, fruit and intensive livestock production. Tea, coffee and macadamia nuts are grown in frost-free areas. Natural region II covering 15% of the land area, and receives lower rainfall than region I, but is nevertheless suitable for intensive farming based on crops or livestock production.

Natural region III is a semi-intensive farming region covering 19% of Zimbabwe. Although rainfall in this region is moderate in total amount, severe mid-season dry spells make it marginal for maize, tobacco and cotton, or for enterprises based on crop production alone. The farming systems are therefore based on both livestock (assisted by the production of fodder crops) and cash crops.

Natural region IV is a semi-extensive farming region covering about 38% of Zimbabwe. Rainfall is low and periodic seasonal droughts and severe dry spells during the rainy season are common. Crop production is therefore risky except in certain very favorable localities, where limited drought resistant crops are grown as a sideline. The farming is based on livestock and drought resistant fodder crops.

Natural region V is an extensive farming region covering about 27% of Zimbabwe. Rainfall in this region is too low and erratic for the reliable production of even drought resistant fodder and grain crops, and farming is based on grazing natural pasture. Extensive cattle or game ranching is the only sound farming system for this region.

Table 10 : Zimbabwe Ecoregions (Vincent and Thomas, 1960).

Natural Region	Area (km ²)	Rainfall (mm yr ⁻¹)	Farming system
I	7 000	>1 000	Specialized and diversified farming
II	58 600	750 – 1 000	Intensive farming
III	72 900	650 - 800	Semi-intensive farming
IV	147 800	450 - 650	Semi-extensive farming
V	104 400	<450	Extensive farming

Source: MLARS, 2000.

3.7 Agriculture

Rainfall is the major determinant of the agricultural production patterns in Zimbabwe. Most crops are planted in November/December at the beginning of the rains and harvested between April and June. Winter wheat, barley and various horticultural products are grown in the dry season under irrigation. Irrigation schemes are also important in supplementing the production of wheat, tobacco, maize, cotton, soybeans, groundnuts and coffee.

The proportion of land allocated to food crops varies with the AEZ, availability or size of land, and farm productivity. In general, farm households in NRs II and III allocate 40-50 percent of the arable land under cultivation to food crops. The proportion rises to 60-70 percent in NRs IV and V.

Cropping patterns and land allocation to various crops within the communal area subsector:

- Maize is a dominant crop across all AEZs, occupying 50-70 percent of the cropped area in NRs I, IIA, and IIB, and 40-50 percent of the cropped area in NRs III, IV and V
- Cotton is dominant in NR III.
- Small grains, particularly sorghum and pearl millet, are dominant in NRs IV and V
- Finger millet and sunflowers are widely grown in all NRs, except that the area of sunflower in NR I is relatively small, accounting for 2-4 percent of the cropped area. Finger millet is grown for home use while sunflowers are essentially a cash crop.

The principal agricultural export commodities are tobacco, horticulture, beef, cotton, maize and sugar. In addition to exports, these commodities provide raw materials that sustain the manufacturing sector. The performance of the agriculture sector is important for the economic performance of the whole economy of Zimbabwe.

Soya bean production and processing

In Zimbabwe Soya beans contribute 30% of all the cooking oil production while cottonseed contributes 50%.

Tea and coffee production and processing

Tea is one crop that can be grown on a very small scale because of the productivity and its resistance to pests and diseases. Some farmers even plant it at the backyard of their homes.

Floriculture

Zimbabwe is the second largest producer in Africa after Kenya and is the fifth producer in the world. There is a potential to expand the industry to three or four times larger and still remain profitable.

Livestock

Zimbabwe is one of a few sub-Saharan African countries allowed to export beef to the European Union. Exports began in 1985; however, Zimbabwe could not keep up with its quota, and exports have dwindled over the years. Total exports were 9,500 metric tons in 1996. Sheep, goats, pigs, and poultry are also extensively farmed. Beef animals are developed at small and large scale. The pig industry also is very important.

Honey production and processing

In Makoni District of Manicaland Province, there are over 600 registered beekeepers, each with a minimum of four beehives. One beehive can yield 20 liters of honey per harvest. Harvesting is done three times a year for well managed hives. After harvesting, honey can be further processed into clear syrup. Zimbabwe is well placed to not only produce its own honey but to explore the export potential of honey. Apiculture is a positive program that not only contributes to uplifting the livelihoods of rural communities but protects the trees and ultimately contributes to protecting the Earth.

3.8 National Parks and Wildlife

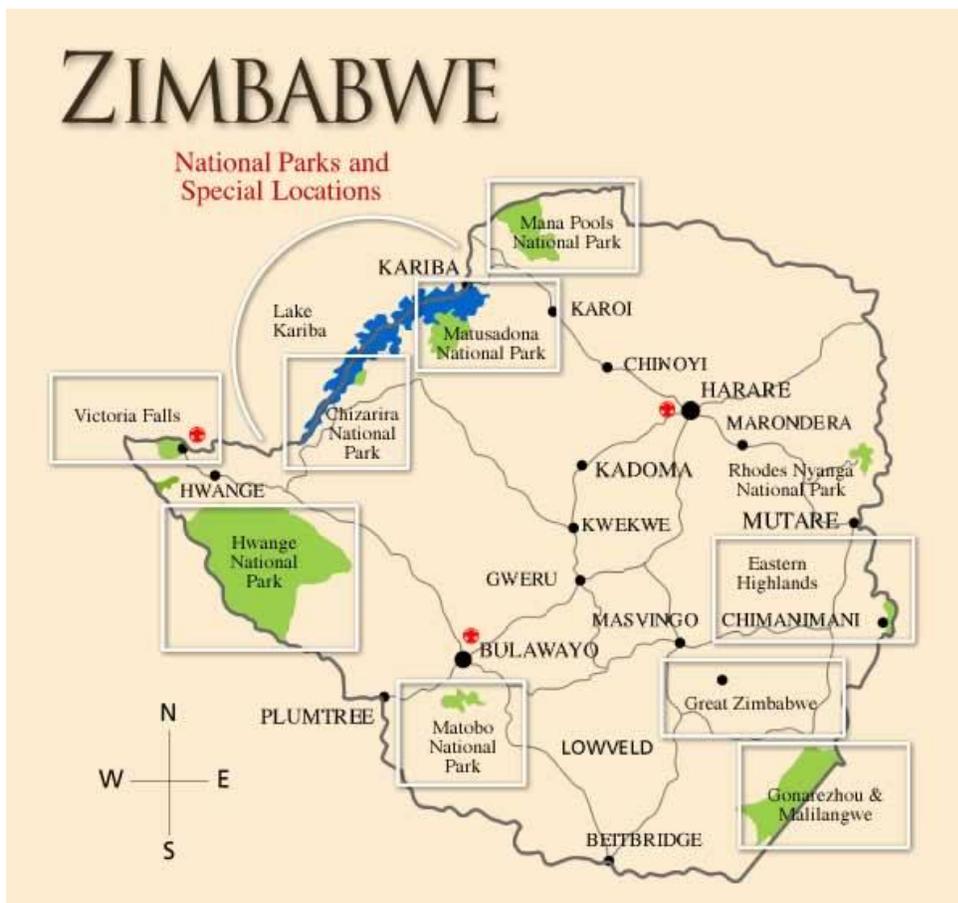


Figure 23: Zimbabwe National Parks Map

National Parks and wildlife in Zimbabwe are protected according to the legislation 'Parks and Wildlife Act of 1975' amended and consolidated in 1982. At that time, certain animals were protected and a list established to comply to CITES convention. Taking of animals has been prohibited except under special permit issued by the authority for scientific or educational purposes or for captive breeding of falcons, live export, and re-stocking, wildlife management, or defense of property. Provision also includes taking of indigenous plants, hunting of animals and regulation of fishing.

Chimanimani National Park is located on the eastern side of Zimbabwe and borders with Mozambique. The main focal point of this park is the Chimanimani mountain range, superb for walkers and hikers and one of the only national parks in the country where you can walk unaccompanied. It is characterized by a diverse landscape of steep sandstone peaks and towers, savanna valleys, rivers and pools that are safe for swimming. It is also rich in botanic endemic species like Orchideae, Hibiscus, L Lobelia, Aloea and many other species.

Chizarira National Park lies astride the Zambezi Escarpment and known as Zimbabwe's most scenic park with its steep gorges, high plateau region and Busi flood plain all offering panoramic views. The park is rich in wildlife; mammals found in this park include elephant, leopards, lions, warthogs and a numerous species of antelope.

Gonorezhou National Park is located in the south eastern part of the country and is an extension of South Africa's Kruger National Park which covers an area of 5,000 sq. kms. The park's landscapes are impressive and are located in the areas around the Mwanezi, Save and Runde rivers where most game can be found. The name of the park originates from the local language of Shona and means "abode of elephants"

Hwange is Zimbabwe's largest national park covering an area of over 14,500 sq. kms located on the west, bordering with Botswana. The park holds the largest variety of animals and over 400 species of birds including elephant, giraffe, zebra, buffalo, hyena, lion, leopard, cheetah, a variety of antelope such as Sable, Kudu and Impala.

Mana Pools lies in the northern tip of the country bordering with Zambia. The name "Mana" means four which is reference to the parks four pools situated around the parks headquarters. This park is a designated World Heritage site, and supports numerous species of bird life and a large variety of game including elephant, buffalo, zebra, kudu, waterbuck, hippos and crocodiles. The rare black rhino can also be found here.

The Motopos National Park lies in the south western part of the country, just 40 km from Bulawayo. Throughout the park are numerous caves, with paintings by ancient bushmen, depicting the life that existed in the area many thousands of years ago. Most of the animals can be found in the small Whovi Game Park which holds dense population of wildlife including white rhino, giraffe, ostrich, wildebeest, leopards and a number of different antelope and the rare black rhino.

Matusadona is located in the southern shores of Lake Kariba. The Zambezi Escarpment runs along the Park, providing a combination of flat plains rising high and wild mountain country.

The park has a fair amount of wildlife including large herds of buffalo and elephants as well as a large number of fish eagles.

Nyanga National Park adjoins with the Mtarazi Falls National Park and is a favorite with visitors from Harare becoming a popular weekend destination. It's located in the Eastern Highlands and provides some beautiful scenes, plenty of waterfalls and Zimbabwe's highest mountain, Mt. Nyangani.

Victoria National Park, one of the worlds' most spectacular natural wonders, Victoria Falls spreads 1,700 m wide and is an awesome sight as it falls into the gorge below. There are lots of tracks around the rim that lead to good viewing spots. The most dramatic spot is Cataract View. Danger Point is also superb, but the trek to it can be extremely slippery. By far the best view to be had of the falls is from the air, and if your budget allows - it's not to be missed.

Bordering with Zambia the **Zambezi National Park** has 40kms of the impressive Zambezi River running through it, making the park rich in wildlife, mopane forest and savannah. Game found within the park consists of hippo, elephant, giraffe, sable and other species of antelope, zebra, buffalo amongst others. Game drives, game walks and horseback riding is available.

Lake Kariba

An enormous man-made waterway, covering an area of over 6500 sq kms, Lake Kariba was completed in 1958, for the purpose of providing the country with much needed hydro-electricity. The lake has since developed into one of Zimbabwe's greatest water playground with water skiing, sailing and fishing being big sports. A large number of crocodiles and elephants abound the lake and shores.

There is plenty of wildlife to be seen on the banks of the lake such as buffalo, rhino, elephant, many other smaller species of mammal and host to prolific birdlife including the Goliath heron, white egrets, grey heron, fish eagle and open-bill storks. Game viewing can also be seen by cruising the lake. The Mavhuradona National Park borders with the lake.

4.0 PESTICIDE PROCEDURES

a. The United States Environmental Protection Agency's Registration Status of the Requested Pesticide

Pesticides registered for IRS in Zimbabwe and the United States, and recommended by WHO, will be preferred in this IRS project. However, some of the pesticides on the WHO list are not registered with the USEPA, for economic reasons rather than technical ones. Because this is an economic issue rather than a technical one, and because there is widespread use of these chemicals around the world, with a good database attesting to the safety of the chemicals, USAID and USEPA has chosen to allow the use of all WHO-recommended pesticides under the Africa IRS program. Annex 4 presents toxicity data for these chemicals.

According to the US regulation 22 CFR 216.3 (b), when dealing with a project that uses pesticides, it is also a fundamental requirement that the pesticides be registered by the host governments. All 12 WHOPEs approved pesticides are registered for public health use in Zimbabwe. The Department of Agricultural Regulatory Services (DARS) of the Ministry of Agriculture has procedures for registration of pesticides in Zimbabwe. A pesticide registration certificate is issued to the supplier of the pesticides by DARS after compliance to the requirements in summarized in Annex1. According to Environment and Management Act, registration certificate must be renewed every ten years, but this regulation is under review to renew registration every three years. For insecticides to be used in public health, National Institute for Health Research (NIHR) proposes to the MOHCW the type of insecticides to be registered after test of efficiency.

b. The Basis for Selection of the Requested Pesticides

Insecticide selection for any PMI supported program is subject to international procurement requirements of the US Federal laws. Requests to purchase public health insecticides used in IRS must be initiated at class level, rather than for a particular insecticide (compound). The insecticide class to be used in IRS is selected each season based on a number of considerations.

Primary Criteria for choosing pesticides:

- a) **Approval by the World Health Organization Pesticide Evaluation Scheme:** Only insecticides approved by WHO can be used in IRS. Organophosphates, carbamates, and pyrethroids are WHOPEs approved classes of pesticides for use in IRS and thus any can be used based on entomological data and host country registration status.
- b) **Registration for use in the country:** According to the Department of Agriculture Registration Services (DARS) all of the 12 insecticides approved are registered for use in Zimbabwe.
- c) **Residual effect for a period longer than, or at least equal to, the average duration of the malaria transmission season in the area:** According to WHO, all pyrethroids, carbamates, and organophosphates are expected to have duration of 3 to 6 months in terms of effectiveness; however, the duration of effectiveness varies under different climatic

conditions. Three pyrethroids, known as longer-lasting pyrethroids, can last up to eleven months based on various field trials. For this reason, pyrethroids make the best choice during insecticide selection due to the longer residual effect. Technical information on duration of effectiveness on the primary wall surface types will continue to be considered when selecting insecticide class(es).

- d) **Pesticide must be appropriate for use on the wall surfaces of the selected location:** Structures in the targeted regions are mostly from mud walls or burnt bricks. Near major towns and commercial centers, cement and brick walled houses are predominant. Pyrethroids, carbamates and organophosphates are known to function well on mud and cement walled houses and are therefore appropriate.



Figure 24: Type of rural mud habitats in Mash West and Mash East of Zimbabwe

- e) **Local vector susceptibility to the insecticide:-** One of the major concerns when implementing IRS campaign is to prevent resistance to insecticide among vectors. Resistance to insecticide develops when a hereditary feature is selected in an insect population that reduces the population's sensitiveness to a given insecticide. In Zimbabwe, vector susceptibility is monitored by National Institute for Health Research. For the moment, NIHR considered that in the three PMI provinces (Manicaland, Mashonaland East and Mashonaland West), Lambda-Cyhalothrin and Deltamethrin are considered as appropriate and no resistance has been noted yet from the result of resistance tests. A nationwide susceptibility study is underway by NMCP with the support of Abt Associates. The results will be available at the end of April 2012 and will provide support for definitive insecticide selection for 2012 IRS campaign.
- f) **Ecological impact:** The PEA for IVM assessed the toxicity of IRS insecticides to non-target organisms, including mammals, birds, fish, bees, and 'other aquatic' organisms. In summary, pyrethroids and carbamates are similar in toxicity to non-target organisms. Apart from propoxur, which has a low toxicity for fish and other aquatic organisms, the rest of the insecticides are all highly toxic to the same. Similarly all the insecticides from the approved classes are highly toxic to bees, apart from pirimiphos methyl. In mammals, all the insecticides approved by WHO for IRS carry low-to medium toxicity, with the exception of lambda cyhalothrin and propoxur, that are categorized as highly toxic to mammals. In avifauna, only propoxur is categorized as highly toxic with the rest categorized as low-medium

in toxicity. It is important to note that in Zimbabwe, wildlife thrives throughout the country due to the favorable ecological conditions. It is extremely important to maintain this biodiversity.

Table 11: Pesticide Toxicity

IRS Insecticide	Mammal	Bird	Fish	Other Aquatic	Bee	Persistence	Bioaccumulate
Alpha-cypermethrin (P)	High Toxicity	Medium to High Toxicity	High Toxicity				
Bendiocarb (C)	Medium to High Toxicity	High Toxicity	Medium to High Toxicity	Medium to High Toxicity			
Bifenthrin (P)	Medium to High Toxicity	Medium to High Toxicity	High Toxicity	High Toxicity	High Toxicity	Data Not Found	High Toxicity
Cyfluthrin (P)	Medium to High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	Medium to High Toxicity
DDT (OC)	Low to Medium Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity
Deltamethrin (P)	Medium to High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	Medium to High Toxicity	High Toxicity
Etofenprox (P)	High Toxicity						
Fenitrothion (OP)	High Toxicity	Medium to High Toxicity					
Lambda-cyhalothrin (P)	High Toxicity	Medium to High Toxicity	High Toxicity				
Malathion (OP)	Low to Medium Toxicity	Medium to High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity	High Toxicity
Pirimiphos-methyl (OP)	Medium to High Toxicity	High Toxicity	High Toxicity	High Toxicity	Medium to High Toxicity	High Toxicity	High Toxicity
Propoxur (C)	High Toxicity	Low to Medium Toxicity	Low to Medium Toxicity				

Source: IVM PEA

Key	
High Toxicity	High Toxicity
Medium to High Toxicity	Medium to High Toxicity
Medium Toxicity	Medium Toxicity
Low to Medium Toxicity	Low to Medium Toxicity
Low Toxicity	Low Toxicity
Data Not Found	Data Not Found

- g) **Human health impact:** The PEA for IVM also assessed cancer and non-cancer risks associated with all WHOPEs-approved insecticides by process (e.g., mixing insecticide, spraying, residing in sprayed house, etc.) and pathway (e.g. inhalation, dermal, ingestion, etc.), and cancer risks by process and pathway where available (mainly for DDT and select pyrethroids). In general, pyrethroids and carbamates pose less non-cancer risks than organophosphates when risks are assessed via any pathway. If organophosphates are used, then decisions on insecticide type should be informed in part by the human health toxicity and risk associated with each compound and formulation.

Secondary Selection Criteria:

Once the local selection committee, including NMCP, approves the analysis of these factors, then the criteria is updated to include international procurement language in which the criteria is clearly stipulated and then tendered out in accordance with international open competitive procurement rules. Once there are responses to the call for bids, the resulting proposals are subjected to secondary criteria including:

- Appropriate packaging for safety and standard delivery tools
- Unit cost of insecticide
- Timely delivery of the insecticide to the preferred point of delivery
- Local representation of supplier in host country
- Technical assistance with training and troubleshooting by supplier

Once a winning bid is selected, it is then submitted to PMI for approval and the local selection committee (including the NMCP), is informed of the now-named insecticide that has been selected and the reasons for its selection for the current IRS round. Once PMI/USAID, grants its approval, then procurement of the insecticide starts.

c. The Extent to Which the Proposed Pesticide Use Is Part of an Integrated Pest Management (IPM) Program

IPM is defined³ as:

“Integrated pest management (IPM) is an ecosystem-based strategy that focuses on long-term prevention of pests or their damage through a combination of techniques such as biological control, habitat manipulation, modification of cultural practices, and use of resistant varieties. Pesticides are used only after monitoring indicates they are needed according to established guidelines, and treatments are made with the goal of removing only the target organism. Pest control materials [pesticides] are selected and applied in a manner that minimizes risks to human health, beneficial and non-target organisms, and the environment.”

In Zimbabwe, pyrethroids are being used in agricultural contexts, and may be responsible for the increased resistance that has been shown for some of these compounds.

Use of IPM for the control of the vector population responsible for malaria is limited to some common sense safeguards, such as limiting standing water which can serve as a breeding ground for mosquitoes. However, because of the life-cycle requirements and the adaptability shown by these vectors, integrated practices have not demonstrated effectiveness.

IPM is often used in an agricultural context, but similar in nature is the concept of Integrated Vector Management (IVM). The major characteristics of IVM include:

³ (<http://www.ipm.ucdavis.edu/IPMPROJECT/about.html>)

- *Methods based on knowledge of factors influencing local vector biology, disease transmission, and morbidity;*
- *Use of a range of interventions, often in combination and synergistically;*
- *Collaboration within the health sector and with other public and private sectors that impact vectors;*
- *A public health regulatory and legislative framework.*

USAID strategy has been that IRS will be implemented as a component of IVM for malaria control, along with ITNs and environmental management. These interventions are described in a preceding section on *Malaria Control in Zimbabwe*.

There is a deliberate effort by NMCP to use eco-epidemiological criteria in the selection of local interventions. For example, IRS has largely targeted epidemic prone areas, while ITNs have been deployed largely in areas of perennial transmission. The FY12 PMI/MOP however indicates IRS will be implemented in epidemic-prone areas, as well as selected endemic districts.

d. The Proposed Method or Methods of Application, Including Availability of Appropriate Application and Safety Equipment

IRS involves spraying a liquid insecticide with long lasting residual activity on the indoor wall surfaces where mosquitoes usually rest. The pesticide then dries up and leaves a crystalline deposit on the sprayed surface. A lethal dose of the insecticide is absorbed when the mosquito rests on the surface, which kills the mosquito.

Pesticide will only be applied using pressurized spray equipment approved for the pesticide in use, by trained spray operators wearing gloves, overalls, hard hats with face shields, boots, and goggles. Spray operators will be trained in and use spray patterns designed by experienced program operators which have proven effective for providing long-lasting toxicity toward the malaria vector mosquito.

The following IRS equipment will be used:

- **Spray Nozzles**

The program in Zimbabwe will procure 8002E nozzles for the spray pumps which are the standard size recommended by World Health Organization for mud wall.

- **Spray pumps**

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

Currently in Zimbabwe, two type of spray pumps are used, MICRONAIR and HUDSON X-PERT. From information of technical staff of different provinces during Kadoma national malaria conference (28-30 March 2012), MICRONAIR pumps were reportedly not performing very well and the nozzles are subject to clogging. For that reason, it is recommended to procure Hudson X-PERT.



Figure 25: Spray pumps used in IRS operations

e. Any Acute and Long-Term Toxicological Hazards, either Human or Environmental, Associated with the Proposed Use and Measures Available to Minimize Such Hazards

The two broad categories of hazard are release and exposure to humans and domestic animals, and releases causing environmental damage. Release and exposure may occur at any point, from the production or importation of the pesticide through transportation, storage, distribution, pesticide make-up, spray application, clean-up, and final disposal, as well as post-spray due to improper spray deposition on household articles, or improper behavior of beneficiaries regarding sprayed surfaces. Hazards are examined in detail in the Environmental Mitigation and Monitoring Plan (EMMP) in Chapter 6 and Annex 1. The EMMP also includes mitigative strategies for each of the risks. The consequences of release and exposure are found in the toxicological profiles and in Table 9. The acute and long-term toxicological hazards of pyrethroids, carbamate and organophosphate-based pesticides are detailed in Annex 4: Toxicological Profiles.

Major hazards include exposure during handling (transporting or spraying), environmental release through vehicular accidents during transportation, and the possibility of fire causing combustion of pesticides, in storage or in transportation. These hazards are discussed in more detail in Chapter 6, and have been addressed in the Environmental Mitigation and Monitoring Plan (Annex 1). In addition, the *Pesticide Storage and Stock Control* (Annex 6) by the Food and Agriculture Organization of the United Nations (FAO) provides detailed guidance on proper storage management practices, as well as remedial measures in case of spillage and incidents brought on by natural disasters including flooding. These guidelines therefore provide a sound basis for minimizing the risk of human, animal, or environmental exposure.

Exposure treatment for carbamates, pyrethroids, and organophosphate-based pesticides are detailed in Table 12 and Annex 2. Training for supervisors, spray team leaders, spray operators, washpersons, storeroom managers, and health officials include recognition of the symptoms of poisoning, incident response elevation protocol, and, for the medical professionals, the treatment protocols for each pesticide.

Specific measures to mitigate transportation-related exposure will include:

1. Training drivers before they transport insecticides from the customs warehouse or central storage facility to the local storage facility.
2. Ensuring that drivers are thoroughly knowledgeable about the toxicity of insecticides, and that training includes opportunities for drivers to respond to scenarios related to the transport of specified insecticides:

Drivers must prevent pesticide contamination in vehicles rented for the project in order to avoid negative consequences when the vehicles are used for other purposes, such as food transport. To prevent pesticide runoff from vehicle washing, drivers are responsible for wiping the vehicle bed with a damp cloth before washing the exterior of the vehicle

Under existing legislation, it is a legal requirement for major incidents resulting in spillage to be reported. However, a general observation is that in most developing countries, a lack of clarity on what constitutes a reportable chemical incident results in under-reporting (e.g., reporting a traffic accident involving a spillage as a traditional road accident, omitting the spillage aspect). Often, the reportable amount is dependent on the actual chemical, but this may be a degree of knowledge that transporters cannot manage.

Other than transporters, storage area personnel, and spray teams, the people at risk of exposure are primarily the beneficiary population in the targeted communities. Acceptability of the pesticide and IRS intervention among the targeted households is a primary external factor and critical for compliance. The IEC program is of critical importance toward gaining this acceptability. It is important that the targeted community and households are adequately educated on safety, including procedures for removing personal belongings prior to spraying, observing the required exclusion period, and avoiding contact with sprayed surfaces on an indefinite basis.

Information, Education, and Communication (IEC) programs are currently being implemented in targeted communities under the ongoing IRS operation. The campaign includes radio spots for mass media announcements and also direct communication through the spray operators. Communities are mobilized by each local administration. Clear instructions are provided on what to do before and after the house is sprayed, including the removal of all foodstuffs and cooking utensils, barring of entry into the sprayed rooms for at least two hours, preventing the re-entry of children until the floors have been swept clean or washed, and targeted training of selected health care providers at the region, district, and community levels on the management of pesticide poisoning.

f. The Effectiveness of the Requested Pesticide for the Proposed Use

Pesticides are selected for IRS based on efficacy in the intended use, and other extrinsic variables. Selection criteria have been expounded in Chapter 2, Alternatives, and in Factor B of this PERSUAP.

Once the program is established, it is necessary to monitor vector resistance prior to the initiation of spray activities, to ensure that acceptable kill levels will be achieved. A resistance monitoring program has been established and is operating, and the results from this ongoing program will be a primary determinant of the choice of pesticide and other supplementary actions.

Pesticide efficacy is also affected by vector behavior, insecticide quality, and the residual action of the pesticide. The probability of vector-pesticide contact depends on whether the targeted vector feeds indoors (endophagic) and rests indoors (endophilic), as this increases the likelihood of the vector resting on the sprayed wall. The efficacy of the pesticide to kill may be either compromised if the vector exits after feeding without resting on the wall, or absent if the vector feeds outdoors (exophagic) and rests outdoors (exophilic). *An. arabiensis* and *An. funestus*, the major malaria vectors in Zimbabwe, are mainly endophagic and endophilic. This makes them suitable targets for IRS.

Knowledge of vector susceptibility is critical to planning and evaluating the effectiveness of the IRS program. It enables timely forward planning to (i) manage the development of the resistance and (ii) evaluate new or alternative insecticides for possible future introduction should a change of pesticide be required. Resistance testing is done to (i) establish a baseline susceptibility of the local vectors for future reference, (ii) monitor changes that occur as time progresses, (iii) identify the mechanisms of resistance and cross-resistance to inform the resistance management strategy that will be adopted, and (iv) evaluate the susceptibility of the local vectors to potential alternative insecticides, should there be a need to change pesticide.

Vector resistance may differ in origin, intensity, type, and significance for vector/disease control in a given population. The evaluation of the significance of resistance to vector control should therefore consider the biochemical and genetic characteristics of the resistance, as well as the eco-epidemiology of the disease and operational characteristics.^{4, 5} Resistance also tends to be highly focal (i.e., limited to a definite area). It is therefore important to ascertain the spatial distribution of the observed resistance to better inform the resistance management strategy to be employed and the geographical extent to which it will apply (e.g., what geographical area a possible change in pesticides for IRS will cover).

⁴ WHO (1986) Resistance of vectors and reservoirs of disease to pesticides: tenth report of the WHO Expert Committee on Vector Biology and Control. World Health Organization, Geneva.

⁵ Brogdon, W.G. and McAllister, J.C. (1998). Insecticide Resistance and Vector Control *Emerging Infectious Diseases* 4(4): 605-613.

The operational criterion for vector resistance is having 20% or more survival rate in the number tested using standardized methods of the WHO.⁶ Irrespective of the pesticides used for IRS, national capacity has been developed to enable systematic evaluation of the mechanisms for resistance development and the gene frequencies among the local malaria vector populations. There is also a need to evaluate other pesticides and non-chemical alternatives to facilitate the evolution of a full-fledged IVM for malaria.

The residual efficacy of the pesticide being used for IRS is crucial to evaluating the implication of vector resistance. Generally, a positive correlation between observed vector resistance and a decline in pesticide efficacy is an important criterion in determining the need for a change of the pesticide in a local area. It is important that wall bioassays be carried out at specified intervals after the IRS operation in order to determine the period and level of residual activity in a given locality and the sprayed surface.

The third major factor affecting the effectiveness of the pesticides is their quality (specification). If the active ingredient, for example, is not up to the recommended specification and concentration, it may lead to under-dosage of deposited pesticide, which then contributes to intervention failure. Storage of pesticide for too long a time, or in extremely hot warehouses can lead to breakdown of the active ingredient. Poor pesticide quality may present additional risks to the pesticide handlers and spray operators who may be exposed. For this reason, samples of the pesticide should be taken prior to use, and analyzed for the concentration of the active ingredient.

g. Compatibility of the Proposed Pesticide with Target and Non-Target Ecosystems

The WHOPEs recommended pesticides are incompatible with the non-target ecosystems (humans, animals, and the environment), in that, if they are released to the non-target environment in large quantities, they would have negative effects on land and water based flora and fauna. However, the IRS implementation process is designed to ensure that to the maximum extent possible, pesticides are deliberately and carefully applied to the walls, ceilings, and roofs of dwellings, and do not come in contact with humans, animals, or the environment. IRS implementation is also planned to minimize and responsibly manage the liquid wastes through the reuse of leftover pesticides, the triple rinsing of equipment, and the daily washing of PPE. In addition, contaminated solid wastes are incinerated in an approved incinerator that will destroy the pesticide and prevent environmental contamination. The Environmental Mitigation and Monitoring Plan in Chapter 6 and Annex 1 details the measures that will be enacted to prevent contamination of ecosystems.

The pesticides are compatible with the target environment (walls, ceilings, eaves) in that they dry on these surfaces, and are not released to any great extent. The dried pesticide remains on the sprayed surfaces, and performs as designed, killing vector mosquitos that rest on them.

⁶ WHO (1998). *Test procedures for insecticide resistance monitoring in malaria vectors, bio-efficacy and persistence of insecticides on treated surfaces*. World Health Organization, Geneva, WHO/CDS/CPC/MAL/98.12

h. The Conditions under Which the Pesticide Is To Be Used, Including Climate, Flora, Fauna, Geography, Hydrology, and Soils

A carbamates, pyrethroids and organophosphate-based IRS program is proposed. In general, these classes of chemicals have the potential to cause harm to bees, birds, fish, and other aquatic organisms. Chapter 3 of this SEA discusses the conditions that exist in Zimbabwe relative to the implementation of IRS.

In addition, the reader is referred to a useful Web site on “Seasonal Climate Suitability for Malaria Transmission” created by the Columbia University International Research Institute on Climate and Society for graphic depictions that are useful in visualizing the range of conditions found across Zimbabwe:

<http://iridl.ldeo.columbia.edu/maproom/Health/Regional/Africa/Malaria/CSMT/>.

Particular attention will be paid to any areas where bee-keeping or natural bee habitats are established. In addition, bird-nesting habitat will be protected, and all insecticides will be kept away from all water habitats and resources. IRS will be prohibited within protected areas or sensitive ecosystems. Prior to spraying, contractor will identify households in sensitive areas, and train sprayers to identify houses that should not be sprayed. Abt Associates will consult with the Environment Management Agency regarding the application of pesticides near ecologically sensitive areas, such as wetlands, lake shore, river edge and protected areas and follow their policies and guidelines.

Strict supervisory control will also be established to prevent contamination of agricultural products.

i. The Availability and Effectiveness of Other Pesticides or Non-Chemical Control Methods

This IRS program is limited to using those pesticides that are on the WHO list of recommended pesticides. WHO currently recommends twelve insecticides from four chemical groups for IRS, each with a specific dosage regime, duration of effectiveness, and safety rating.⁷ Each of these agents has been evaluated for effectiveness within the program, and continuing monitoring for resistance and susceptibility will be employed to allow up-to-date decisions prior to each spray campaign. The goal of this SEA is to broaden the options for pesticide use to combat periodic resistance development.

The approved insecticides are effective for differing periods (see Table 5), generally categorized as 2-3 months, 3-6 or 4-6 months, and >6 months. Within this range, the effective period depends on local circumstances, including dosage actually applied, wall type, climate (temperature and humidity), and resistance to that chemical in the mosquito population.

⁷ Najera JA, Zaim M (2002). Malaria vector control – Decision-making criteria and procedures for judicious use of insecticides. WHO, Geneva, WHO/CDS/ WHOPES/2002.5. (Document available at: www.who.int/ctd/whopes/docs/JudiciousUseRev.pdf)

For IRS to be effective, the NMCP must either use a chemical that lasts longer than the average malaria transmission season or conduct multiple rounds of spraying to achieve continuous control with a shorter-lived chemical. Thus, current formulations of carbamates that are effective for 3-6 or 4-6 months may be sufficiently effective with one application per year in the northeast arid zone, but would require two applications per year if used in zones with perennial transmission.

Non-chemical means of malaria vector control are generally not effective. For example, while elimination of standing water breeding habitats is a logical and sensible concept, the malaria mosquitoes only need the smallest of aquatic habitats to successfully reproduce, and it is nearly impossible to eliminate all of these minute breeding habitats. Alternative means of achieving the goals of IRS are discussed in Chapter 2, Alternatives.

j. The Requesting Country's Ability to Regulate or Control the Distribution, Storage, Use, and Disposal of the Requested Pesticide

Zimbabwe has regulations for the control and distribution of pesticides. The Ministry of Agriculture of Zimbabwe, Department of Agriculture Regulatory Services (DARS) is solely responsible for the registration, control and management of pesticides in the country. Under the Environment Management Act, and statutory instrument 12 of 2007, Environment Management (Hazardous substances, pesticides and other Toxic Substances) Regulation, 2007 and Statutory Instrument 10 of 2007; Environment Management (hazardous wastes management) Regulation, 2007, there are detailed guidelines and frameworks governing the procurement, packaging and storage, as well as transport and disposal of pesticides.

Acts relating to the environment are enforced by a number of different ministries. There are almost twenty acts and twice as many statutory instruments for the environment. They include the Natural Resources Act, Forest Act, Parks and Wildlife Act, Trapping and Animals Control Act, Hazardous Substances and Articles Act, Atmospheric Pollution Prevention Act, Noxious Weeds Act, Plant, Pests and Diseases Act, Mines and Minerals Act, Water Act, Regional Town and Country Planning Act, Rural District Councils Act, Communal Land Act, and Communal Forest Product Act.⁸

Generally, the enforcement of some of these acts is difficult due to the provision of exemptions, which allow companies to pollute. In some cases, the various pieces of legislation are conflicting, which leads to further problems of implementation. Furthermore, poor management and under-funding has severely weakened the effectiveness of the government to ensure compliance.

Although a legislative framework for managing waste is in place in the country, concern is raised about the non-enforcement of the legislation. In terms of specific laws bearing on the management of waste in the country, there are inter alia: the Environmental Management Act

⁸ African Development Bank African Development Fund Country Environmental Profile Zimbabwe Environment and Social Policy Working Paper Series Working Paper No. 2

(CAP 20:27), the Urban Council Act (CAP 29:15), and the Public Health Act (CAP 15:09). In addition, a number of policies have been drafted to improve the management of waste in the country, including the Environmental Impact Assessment Policy (1994), the draft Waste Management Strategy (2006), and the National Environmental Policy (2003).

Waste management has emerged as one of the greatest challenges facing local authorities throughout Zimbabwe. The volume of waste being generated continues to increase at a faster rate than the ability of authorities to improve the financial and technical resources needed to parallel this growth. Waste management services have increasingly become inadequate, as evidenced by the rise in illegal dumping and proliferation of the now seemingly permanent piles of rubbish in some commercial, industrial, and residential areas of urban settings. Some Provincial hospitals have high temperature incinerators that reach a maximum of 1200 degrees Celsius, and are suitable for the destruction of non-DDT IRS waste.

k. The Provisions Made for Training of Users and Applicators

The effectiveness of the IRS program depends on the availability of adequately trained spraying personnel, well-maintained equipment, and competent supervision, as well as end-user acceptability and compliance. USAID has developed guidelines for IRS operations (“*PMI IRS Best Management Practices*”), and WHO provides a training manual “*Manual for Indoor Residual Spraying*”⁹. Other resources include the *WHO-UNEP Manual on Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning*,¹⁰ the PEA-IVM of USAID, as well as this SEA, all of which provide precise precautions and recommendations on many aspects of IRS operations.

PMI will support the training of spray operators and supervisors, and provide overall guidance and logistical support to the IRS operations in Zimbabwe. Abt Associates will continue to provide technical support for environmental compliance, with a medium-term goal of building national capacity to progressively transfer responsibilities. Preparations will include the following:

- A training of trainers program, in which potential supervisors¹¹ and team leaders are trained on all aspects of IRS operation in collaboration with the MOH and the District Health Service. Areas of training shall include planning of IRS, household preparations, record keeping, community mobilization, rational/judicious use of insecticides including sprayer and PPE cleaning, personnel management, environmental aspects of IRS – including geographical reconnaissance, and data recording and analysis.

⁹ World Health Organization (WHO). 2002. *Manual for Indoor Residual Spraying: Application of Residual Sprays for Vector Control* (WHO/CDS/WHOPES/GCDPP/2000.3).

¹⁰ WHO (2007). *WHO-UNEP Manual on Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning: A Resource Tool*. World Health Organization, Geneva. 332 Pages. (Document also accessible at: www.who.int/ipcs/en/a)

¹¹ These are usually health-related government staff within the targeted district (health assistants/educators/ inspectors, nursing assistants, and community development assistants).

- The identification of temporary workers recruited from local areas and trained as spray operators and wash persons. New operators will receive five to seven days of training prior to the spray operations. Priority areas of training will include:
 - How to properly mix the wettable powder and filling of the sprayer
 - Correct spraying (maintaining 35-55 psi pressure, spray nozzle at 45 cm from the sprayable surface, swath overlap, etc.)
 - The correct use of protective materials and related safety precautions
 - Support to households on safety issues
 - Personal safety relating to the different pesticides used for IRS (carbamate and organophosphate-based pesticides, as well as the pyrethroids which are currently in use)
 - Environmental safety in relation to pesticides, including management of the empty pesticide sachets
 - The use of daily spray cards and data entry

I. The Provisions Made for Monitoring the Use and Effectiveness of the Pesticide

Two kinds of measurements are needed to provide a complete understanding of the effectiveness of pesticide that is being used for IRS. The immediate (output) level relates to the efficacy of the pesticide, that is, the degree to which the pesticide is able to kill the targeted mosquito vectors, and involves direct entomological evaluations on pesticide contact bioassays and related pesticide resistance methodologies as recommended by WHO.¹² The second broad level of measuring the effectiveness of the pesticides relates to the general goal of reducing the local disease burden. This will require specialized entomological and epidemiological skills and the assessment of the impact of vector control operations, and possibly the assignment of the contributory impact of the IRS operations. This latter measurement is usually done through a combination of methodologies such as measuring the changes in parasite inoculation rates, passive case detection at health centers, and periodic community fever and parasite surveys (active case detection).

Another key characteristic of pesticide effectiveness is the longevity of the treatment. This characteristic has important economic and health implications: the program must adjust its spray schedule to make sure that there is active pesticide on the walls of homes during critical breeding periods. Unfortunately, the guidance that is provided with regard to effective period for each pesticide is very broad (e.g. 3-6 months), and the effective period is probably subject to complex environmental factors such as heat, humidity, and substrate (wall) composition. This area is ripe for research, and any contributions that could be made towards increasing the knowledge of the relationship between these variables and the resultant effectiveness of the pesticide would be very valuable.

¹² WHO (1998). Test procedures for insecticide resistance monitoring in malaria vectors, bio-efficacy and persistence of insecticides on treated surfaces WHO/HQ, Geneva, World Health Organization, WHO/CDS/CPC/MAL/98.12

5.0 PUBLIC CONSULTATIONS

During the preparation of the present SEA, consultation was organized at national, provincial, district and ward level, to understand the status of IRS implementation, and, together with NMCP and provincial and district staff, identify the gaps and share propositions for improvement of the IRS program.

5.1 Ward Level

At ward level, the consultation was organized during the visits to camping sites in Mutare District of Manicaland Province, Murewa and Mutoko Districts in Mashonaland East and Makonde District of Mashonaland West Province.

Figure 26: Community Health Workers of Nyagundi Figure 27: Kadoma IRS conference



At the ward level, meetings were organized with community health workers in charge of health education at the village level to ensure that the environmental and health aspects of IRS will be taken into account (Figure 22). In the wards visited, it was confirmed that community health workers are trained in IRS key messages to be used for community mobilization. At that meeting, the community health workers informed us that beneficiaries prefer Lambda-Cyhalothrin because for them it is efficient and it kills all pests in the house, including cockroaches and rats.

5.2 Provincial Level

At the provincial level, in addition to the meetings organized with the three PMI provinces (Manicaland, Mashonaland East and Mashonaland West), the consultant participated in the Kadoma IRS conference (Photo 34) where the representatives of all 8 provinces reviewed the 2011 IRS implementation report, including challenges encountered. This conference also allowed us to meet representatives of the provinces not visited. From the meeting information, it was clear that environment compliance was not considered essential to IRS implementation. PPE used in the program, in particular leather boots and gloves with lining are considered as inappropriate for IRS. From the discussion, the MICRONAIR spray pumps were not appreciated by the technical staff because they leak. It was noted also that IRS wastes were not disposed according to WHO requirement.

After discussion with the technical team, they expressed the need of support to include environment compliance in the implementation of the program.

5.3 National level

At the national level, NMCP organized a debriefing meeting for the consultant and NMCP to present the findings of the field visit for SEA preparation. NMCP invited key partners including, representative of Ministry of Environment and Natural Resources (EMA and Directorate of Environment), Director of Zambia Analyst Laboratory, National institute for Health Research, Procurement Service of Ministry of Health and Child Welfare, Representative of Ministry of Agriculture (Department of Agricultural Registration Services), USAID/PMI, representative of Abt Associates and private sector representatives (2 Insecticide suppliers companies: Net of Africa and Chemplex Corporation).

Figure 28: Debriefing meeting in NMCP/MOHCW



In the meeting, the needs for the involvement of the Environment Management Agency, and the adoption of environment compliance in IRS program implementation were highlighted. The SEA will be an important tool for Zimbabwe IRS program, and the NMCP Manager is ready to ensure that the EMMP is implemented.

6.0 ENVIRONMENTAL IMPACTS AND THE MITIGATION AND MONITORING PLAN

This section addresses the potential direct and indirect impacts of the IRS program in Zimbabwe, and also discusses mitigation and monitoring measures. The Environmental Mitigation and Monitoring Plan (EMMP) presents the Best Management Practices (BMP) and mitigation measures identified for the project, responsibilities for the implementation of the Plan, and monitoring and reporting measures. This EMMP is the guiding document for IRS management team in Zimbabwe which will be used as the tool for ensuring environment compliance for the program.

The EMMP summary (Annex 1) presents a program by which the contractor and NMCP will assure initial and ongoing compliance with environmental requirements and guidelines. The plan also includes descriptions of activities proposed for mitigating environmental and social impacts.

6.1 Potential Positive Effects of the IRS Program

6.1.1 Direct Positive Effects

The direct positive impacts of the IRS program are generally the reduction in malaria morbidity and mortality that will result in a reduction in human suffering, and will lead economic growth. Other positive impacts include reduced incidence of adult morbidity, miscarriages, low birth-weight, and adverse effects on malaria-induced fetal neurodevelopment; and reduced incidence of malaria-related childhood anemia, complications, organ failure. There is also the benefit of elimination of household pests, including other bugs, as well as vermin in some cases.

6.1.2 Indirect Positive Effects

The IRS program will also indirectly contribute in the enhancement of the local economy in the following indirect ways: spray operators, washers, mobilizers, supervisors will all receive a daily payment for their work. There will also be capacity building in the form of training of a large number of people associated with IRS operations. A reduction in household pests may result in a reduction in other diseases carried by the pests.

6.2 Potential Adverse Impacts

Adverse impacts of IRS project are those unintended effects of the project that can compromise the well-being of the environment and human health.

6.2.1 Indirect Adverse Effects

After completion of the IRS program, USAID will leave remaining IRS equipment in the hands of the provinces and district health offices; and will no longer supervise its use. IRS equipment left to Zimbabwe government officials includes backpack compression sprayers, unused chemicals, and used, cleansed boots that are still in operable condition. The action of leaving behind IRS equipment may temporarily, and in a minor way increase the total pesticide load on the environment.

6.2.2 Direct Potential Adverse Effects

Contamination of surface water courses and underground water

During IRS implementation, it will be possible to accidentally release insecticides into water bodies during the transportation and storage of pesticides, application of insecticides to walls, and clean-up of IRS equipment and PPE. It is also possible to have a deliberate release through washing in areas other than the soak pit, or improper disposal of leftover pesticide.

A spill into surface water bodies is a key concern in IRS because it could not only lead to contamination of water routinely used for domestic purposes but could cause a fishkill, possibly causing loss of a food supply. Other aquatic organisms that are vital to a healthy ecosystem could also be wiped out.

Contamination of underground water resources is possible through improper disposal of left over pesticide on the ground, especially if there is a high water table. However, the impacts of this risk are likely to be insignificant because pyrethroids, organophosphates and carbamates degrade very quickly when exposed to sunlight and in the soil. If wash areas and soak pits are properly constructed and used, liquid pesticide waste will be captured in the charcoal layer of the soak pit and held until it breaks down by natural processes.

Impacts to Birds, Fishes, and other organisms from pesticides:

The degree of toxicity of the four World Health Organization (WHO) approved pesticide classes to birdlife, aquatic life and insects especially bees including the degree of persistence and bio-accumulation is well-documented and very important to remember. See Table 9 for details.

Impacts on Bees

Beekeeping is one of the important farming activities in PMI provinces, in particularly Manicaland Province, (section 4.2.6) and honey is produced for both local consumption and for exportation. Spraying in areas where bees are kept can lead to the death of the bees, which are vulnerable mostly to pyrethroids. The hives in the province are generally, though not exclusively, located far away from the spray houses thereby minimizing interaction of the bees with the pesticide. However, spraying remains a concern as it can cause death if the drift goes to the direction of the hives and this should be mitigated at all times. The project should make continuous effort to map any locations where bee-keeping is kept.

Summary of Toxicity of pesticides to Avifauna, Aquatic life, mammals and insects by Class

Pyrethroids:

- All pyrethroids are highly toxic to bees and highly toxic to fish and other aquatic organisms except Deltamethrin which has low toxicity to other aquatic organisms¹³.
- Birds, if exposed, are most affected by bifenthrin (low to medium toxicity). All other pyrethroids have very low toxicity to birds.

¹³ USAID's IVM PEA

- In mammals, only lambda cyhalothrin is highly toxic to mammals. Alpha-cypermethrin and etofenprox have very low toxicity to mammals while bifenthrin, cyfluthrin and deltamethrin have low to medium toxicity.
- In terms of persistency in the environment, only cyfluthrin has more characteristics of persistency. The rest of the pyrethroids have low to medium toxicity.
- Bifenthrin does not accumulate in the environment. Potential for bio-accumulation in aquatic organisms for deltamethrin and cyfluthrin is relatively low while lambda-cyhalothrin is medium and alpha-cypermethrin is high.

Carbamates: (Bendiocarb and Propoxur)

- Carbamates are highly toxic to bees, and have the potential to cause cholinesterase depression in humans. Care must be taken to avoid skin contact with carbamates, especially by spray operators. All spray personnel should be trained to recognize the symptoms of cholinesterase depression, and know the protocol for obtaining medical assistance.
- In addition to other aquatic organisms Propoxur is also highly toxic to mammals and birds. 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. On the other hand this insecticide has very low toxic properties on fish.
- Bendiocarb has low to medium toxicity on mammals and birds.
- In general both carbamates have low to medium indications for persistency in the environment and bioaccumulation in organisms

Organophosphates

- Organophosphates have different characteristics and impacts on different organisms depending on the type of insecticide. However, all three WHO-approved organophosphates have the potential to cause cholinesterase depression in humans and other organisms, and skin contact with these pesticides must be strictly avoided, especially by spray personnel. All spray personnel should be trained to recognize the symptoms of cholinesterase depression, and know the protocol for obtaining medical assistance.
- Fenitrothion has low toxicity on mammals and fish and is not persistent in the environment. However it is highly toxic to bees, birds and other aquatic organisms, like crustaceans and aquatic insects and has a medium toxicity to aquatic worms. It has moderate to medium potential to bioaccumulate in organisms.
- Malathion is only highly toxic to bees. It has very low impacts on fish and other aquatic organisms, and has a very low potential to bioaccumulate in organisms or persist in the environment. Its toxicity on mammals and birds is low to medium.
- Pirimiphos-methyl is highly toxic to fish and other aquatic organisms and has a high potential to persist in the environment. It has low to medium toxic effects on mammals and bees. It does not bioaccumulate in organisms.

6.3 Human Exposure Risks/Impacts

Exposure risks of all WHO approved pesticides in relation to cancer and non-cancer endpoints, and with respect to exposure dosage, Hazard Quotient and the Life Time Average Daily Dose (LADD) are presented in *USAID's IVM Programmatic Environmental Assessment 2007*. There is a draft update to this document under revision as of April 2012. The exposure risk for cancer and non-cancer endpoints is presented at different stages of the pesticide application including mixing, spraying, post spraying, dermal risk, etc.

Inhalation exposure and risk during mixing

- Of the proposed pesticides, only etofenprox (pyrethroid) and propoxur (carbamate) have carcinogenic properties once threshold levels are exceeded.

Dermal exposure and risk during mixing

- On the list of insecticides to be used in IRS only three (DDT, etofenprox (pyrethroid) and propoxur (carbamate)) have been determined to be carcinogenic at dermal exposure levels of $8E-07$ mg/kg-day for etofenprox and $4E-06$ mg/kg-day for propoxur.

Inhalation exposure and risk during spraying

- Of the proposed pesticides, only etofenprox (pyrethroid) and propoxur (carbamate) have carcinogenic properties once threshold levels are exceeded.

Dermal exposure and risk during spraying

- Of the proposed pesticides, fenitrothion and pirimiphos-methyl have non-cancer risks due to dermal exposure.

Resident dermal exposure and ingestion risk after spraying

- The only concerns are to adults when using cyfluthrin and etofenprox (pyrethroids) and propoxur (carbamate). The risk is however very low.

Resident exposure and risk due to chronic ingestion after spraying

- There are four insecticides with potential impact due to chronic ingestion by drinking insecticide contaminated water. These are Cyfluthrin, Permethrin and Etofenprox (pyrethroids) and propoxur (carbamate). Best management practices are recommended.

Resident dermal exposure and risk due to bathing using contaminated groundwater

- Cyfluthrin and etofenprox (pyrethroids) have potential impact for dermal exposure using contaminated groundwater. When best management practices are applied in IRS, this risk is significantly reduced.

Resident exposure and risk due to reuse of pesticide containers

- Only deltamethrin is registered to have potential for acute ingestion from using pesticide containers. However, residents will have no access to pesticide containers used in IRS. The pesticide containers are only available in IRS storage facilities which are securely double locked and must be disposed by incineration at high temperature.

Worker exposure and risk due to inhalation during spillage

- According to information presented in the Programmatic Environmental Assessment, etofenprox and propoxur have potential to impact workers through inhalation during spillage. The workers are trained on how to handle spillage and must be equipped with appropriate PPE.

1. Worker and Resident Exposure Pathway

During the IRS spraying process, spray personnel are at risk of un-intentional or deliberate exposure through accidents or poor and improper handling of the spray chemical. Worker exposure to the chemical could arise during the pre-spraying, spraying and post-spraying phase of the IRS operations. Beneficiaries can also be exposed during each of these phases, and additionally over the life of the pesticide on the wall.

a. Pre Spraying Exposure Pathway

Preparing pesticide solutions during the IRS requires pouring the pesticide in the spray pump to ensure ample mix with the water. The process of mixing the pesticide can lead to exposures via inhalation, dermal contact, and incidental ingestion, mostly from releases of pesticide vapors, and solutions. Vapor releases can occur when liquid concentrated emulsions are diluted. Workers or residents can inhale the vapors or the particulates or be exposed through dermal contact. Spills could also pose significant risk, especially for children who ingest the resulting residues that are left on surfaces such as food, floors, soil, as well as absorbing additional doses from eating plants and animals contaminated during the preparation for spraying.

b. Exposure during Spraying

Inhalation of aerosol vapors during spraying is the main process for worker exposure during IRS, however, dermal exposure through spills or absorption onto cotton overalls is also a significant risk. Especially in the case of organophosphates, the dermal hazard is significant, and can cause cholinesterase depression. Residents are mainly exposed through dermal contact with sprayed surfaces and incidental ingestion of insecticide after their houses have been sprayed, especially when food or drink are left in the house during spraying. Leaky equipment can also lead to insecticide exposure through dermal contact with the floors and incidental ingestion by children who may come in contact with the spills before they are cleaned up.

c. Exposure during Disposal (including Progressive Rinsing)

Disposal is a key issue with IRS intervention that utilizes pesticides especially during the decontamination process and disposal of the liquid effluent that will arise from washing and progressive rinse. Both burying and dumping can lead to dermal exposure to residents who come in contact with the soil or water in which the pesticide was disposed. Ingestion exposure can occur from drinking contaminated surface water. Once the excess formulation gets into the soil, the pesticide can reach the groundwater, which may be used as a water supply via household wells. Residents may then be exposed to this contaminated water by ingestion or by dermal contact when it is used for cleaning or drinking purposes.

d. Occupant long-term exposure from residue

Residents of sprayed structures, especially crawling babies and children, will have a finite exposure risk due to physical contact with sprayed surfaces, as well as small amounts released from substrate walls, ceilings, and eaves, due to physical surface breakdown.

6.4 Cumulative Impact

The combined, incremental effects of human activity, referred to as cumulative impacts, pose a serious threat to the environment. Cumulative impacts develop over time, from one or more sources, and can result in the degradation of important resources.

The critical resources or ecosystems that can be affected by the IRS program over a period of time especially with regards to pesticide application include water supply, food supply, waste assimilation/disposal capacity, river, lake, and stream quality, agriculture, aquaculture, apiculture, human and animal health, biodiversity resources, environmental services, and others. Pesticide run off and accumulation in the rivers, streams and other water bodies, can lead to the progressive contamination of the water resources and reduction of aquatic biodiversity. However, using the IRS BMPs reduces the likelihood of releases, and the chances of a series of releases within the pesticides half-life is extremely unlikely, except in the case of willful malfeasance.

Continuous human exposure to pesticides over time can lead to health risks or complications, especially among spray operators and others in close contact with pesticides. This is particularly true in the case of organophosphates. However, the risk assessment performed in the PEA indicates minimal exposure with the use of proper technique and appropriate personal protective equipment (PPE), i.e. dust masks, helmet, face shield, gloves, overalls and boots that minimize exposure by dermal absorption or inhalation, and a great reduction in the potential for harm.

The sprayed pesticides solidify on the walls, ceilings, and eaves of the structures, and become largely immobile and significantly less harmful. Exposure to the occupants will be further reduced by the procedures and safety measures described in this Environmental Mitigation and Monitoring Plan and Annex 1.

Pyrethroids, organophosphates and carbamates degrade very quickly when exposed to light and to the external environment, thus the cumulative and residual adverse impacts of their use will be insignificant. The soak pits used for waste disposal are designed to break down influent pesticides wastes within about three months, while the pesticides are held by the charcoal used in pit construction.

The long term use of any pesticide could lead to insecticide resistance. To minimize this cumulative impact, insecticide resistance is actively monitored. The proposed action is designed with the concept of vector monitoring, insecticide rotation and mosaicking which will reduce the future incidence of vector resistance.

6.5 Mitigation Measures

This section outlines the various mitigation measures proposed for any of the potential adverse impacts likely to occur as outlined above. The primary mitigation measures include delivery of a

mix of Information Education and Communication (IEC) approaches targeting the residents and spray operators and all IRS personnel. The mitigation measures also include provision of Personal Protective Equipment (PPE), training of spray operators and strengthen supervision and monitoring.

6.5.1. Residential Exposure

Provincial and District authorities, implementing partners and IRS staff will work with relevant institutions at all levels to carry out an IEC campaign to sensitize residents to IRS activities, in accordance with WHO guidelines and also Zimbabwe Malaria strategy 2008-2013. The IEC campaign (as well as IRS Project team leaders and supervisors who will also instruct residents on best practices prior to spraying) should focus on the following elements of residential safety during an IRS program:

- Clear homes of mats or rugs, furniture, cooking implements and foodstuffs prior to spraying; if furniture cannot be moved out of the home, then move it to the center of the room and covered with impermeable material
- Stay outside the home during spraying for two hours after spraying
- Move and keep all animals outside the home during spraying, and for two hours after spraying
- Sweep up any insects killed from the spraying and drop them in latrine pits
- Sweep floors free of any residual insecticide that may remain from the spraying
- Do not re-plaster or paint over the sprayed walls after spraying
- Keep using bed-nets for protection against malaria
- If skin itches after re-entrance into home, wash with soap and water; for eye irritation, flush eyes with water; for respiratory irritation, leave the home for fresh air; for ingestion, if soap and water are unavailable, or if symptoms persist, contact program staff or go to nearest health facility which has the appropriate medical intervention.
- If spraying during the rainy season, the teams should follow the following Contingency Plan which will minimize exposure of household effects

During the rainy season;

- Each spray operator must be given adequate covering material (3m by 3m minimum) which should be used to cover household effects not removed from the houses.
- Adopt a system of moving household effects to the center of the room and covering them with impermeable material before spraying
- Materials can also be moved into structures which may not be sprayed e.g. an isolated kitchen or other domestic animal shelter.
- Move the household effects to one room which should not be sprayed on that particular day but the next day.
- The spray teams should pay close attention to any signs of potential rains so that they prepare the communities accordingly.

When it rains in the mid of spraying;

- Stop the spraying activities. After the rains stop and the weather is considered good, spraying can continue.
- Cover the household effects with an impermeable material. These materials should have already been procured by the program and given to each operator.

6.5.2 Pesticide Transport

After the procurement of the insecticides for use in the 2012 IRS campaign, insecticides are expected to move to the provincial warehouses by road. During transportation, there is a risk of vehicle accidents and consequently insecticide spillage. The transport must comply with environment management regulation, statutory instrument 12 of 2007 section 14, regarding hazardous substances, pesticides and other toxic substances and the guidelines of NEMA on transport of pesticides.

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

- Purpose of the insecticide
- Toxicity of the insecticide
- Security issues, including implications of the insecticide getting into the public
- Hazardous places along the routes to be taken, and mitigation measures
- Steps to take in case of an accident or emergency (according to FAO standards)
- Combustibility and combustion byproducts of insecticide

Drivers hired specifically for the spray campaign period will receive:

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

The vehicles to transport insecticides must be in good condition and preferably a lockable box truck. If the pesticides are to be left unattended for any period of time, including lunch breaks or overnight stops, a lockable box truck is essential.

Figure 29 : Emergency Response to Insecticide Spills

In case of Insecticide Spills

1. Control, contain and clean up the spill
2. Protective clothing should be donned prior to attempting to clean the spills.
3. It is imperative to avoid fire as a result of the accident and a fire extinguisher should be deployed just in case. The engine should be shut off and smoking in the area strictly prohibited.
4. Onlookers and bystanders should be cautioned against approaching the accident site.
5. If the crew has come in contact with the pesticides, they should remove contaminated clothing immediately and wash the pesticide off their skin.
6. For major spills send for help immediately; drivers should have cell phones and an emergency number for use in such cases.
7. People should be kept away and the spill covered with earth, sand, etc.; no attempt should be made to wash away the spill with water or other substances.
8. Vehicles that are used for transporting large quantities of pesticides should be equipped with a bucket of sand, sawdust or soil, a shovel, and fire extinguisher.

Because vehicles used for insecticides transportation can be used for the transport of other goods including food, it is important to ensure that vehicles are decontaminated. The drivers will be responsible for cleaning and decontaminating the interior of the vehicle and exterior bed at the end of the spray campaign. Drivers will be provided with gloves and rubber boots to wear for cleaning the vehicle. All cloths used in wiping down the interior and bed of the vehicle will be washed with soap.

6.5.3 Accidental Warehouse Fires

Human inhalation of toxic fumes in the event of a storehouse fire is also an unavoidable risk. The risk can be minimized, however, by following BMPs for storage, including prohibiting lighted materials in the warehouse and in the vicinity of pesticides, proper ventilation, etc.

Information on the combustion byproducts of pyrethroids can be found below (taken from USAID's *Integrated Vector Management Programs for Malaria Vector Control: Programmatic Environmental Assessment (IVM/PEA)*), as well as fire-fighting instructions from Material Safety Data Sheets.

Table 12: Insecticide, Combustion byproduct, and Extinguishing Instructions

Pesticide	Combustion Byproduct	Extinguishing Instructions
Alpha-cypermethrine	Open burning of lambda-cyhalothrin creates nitrogen oxides, hydrogen chloride, and hydrogen fluoride (WHO, 1997)	<p>Extinguishing media: For small fires use water spray, alcohol-resistant foam, dry chemical or carbon dioxide. For large fires, use Alcohol-resistant foam, Water spray. Extinguishing media which must not be used for safety reasons: Do not use solid water stream as it may scatter and spread fire. Specific hazards during firefighting: As the product contains combustible organic components, fire will produce dense black smoke containing hazardous products of combustion. Exposure to decomposition products may be a hazard to health.</p> <p>Special protective equipment for firefighters: Wear full protective clothing and self-contained breathing apparatus. Further information: Do not allow run-off from fire-fighting to enter drains or water courses. Cool closed containers exposed to fire with water spray.</p>
Bendiocarb	Fine dust may form explosive mixtures in air. The product is not flammable, but when heated above 125° C will evolve toxic fumes of methyl isocyanate. Water is the preferred extinguishing medium as it decomposes any methyl isocyanate.	<p>Water fog or fine spray, carbon dioxide, dry chemical, foam.</p> <p>Fire fighters should wear full protective gear, including self-contained breathing apparatus (AS/NZS 1715/1716). Keep unnecessary people away and move all other personnel to windward side of fire. Bund area with sand or earth to prevent contamination of drains or waterways. Dispose of fire control water or other extinguishing agent and spillage safely later.</p>
Delta-methrine	Combustion and/or pyrolysis of deltamethrin can lead potentially to the production of compounds such as formaldehyde, acrolein, hydrogen cyanide, and hydrogen bromide (UK PID, 2006)	<p>Suitable extinguishing media: Water spray jet, carbon dioxide (CO₂), dry powder, foam.</p> <p>Extinguishing media which should Product itself is non-combustible not be used for safety reasons: Fire extinguishing measures to suit surroundings.</p>

Pesticide	Combustion Byproduct	Extinguishing Instructions
Bifenthrin	Not available	<p><u>Suitable extinguishing media:</u> Carbon dioxide (CO₂), Foam; Powders</p> <p><u>Not suitable extinguishing media:</u> Water (the product is hazardous for the environment - do not dilute it)</p> <p><u>Specific fire-fighting methods:</u> Isolate fire area. Evacuate downwind. Contain the extinguishing fluids by bunding (the product is hazardous for the environment). Do not attempt to fight the fire without suitable protective equipment. Do not breathe fumes</p> <p><u>Protection of fire-fighters:</u> Self-contained breathing apparatus and complete protective clothing</p>
Cyfluthrin	Combustion and/or pyrolysis of cyfluthrin can lead potentially to the production of compounds such as formaldehyde, acrolein, hydrogen cyanide, hydrogen chloride, and hydrogen fluoride (UK PID, 2006)	Not available to-date.

(Source: IVM PEA, USAID, Jan 2007)

6.5.4 Fetal Exposure (Pregnancy Testing)

All the potential female candidates as spray operators will be tested for pregnancy before being recruited into the spray operations and every thirty days until operations end. Females found to be pregnant should be re-assigned to positions that do not require exposure to insecticides. The same applies to breastfeeding spray operators.

6.5.5 Spray Operator Exposure

Each spray operator will be provided with safety equipment (PPE, see section 2.5.7) in accordance with WHO and FAO specifications.

Workers should be closely monitored for acute symptoms, because there will always be some level of exposure. In addition, work-day duration should be monitored to limit exposure as required by safety recommendations.

Monitoring of acute exposure of the spray operators will be undertaken by reviewing of the Incident Report Forms that are made available to every spray team and filled daily by supervisors. Any exposure incident is normally recorded as a form of best practice and action taken i.e. immediate treatment following guidance given, or referral to the health facilities for further treatment.

Similarly, residential exposure will be monitored. During the IEC campaign, residents are made aware of the steps to take if exposed and especially if acute symptoms are encountered the advice is to report to the nearest health facility. Thus reported cases at health facilities or by IEC mobilizers will serve as the principal monitoring strategy for exposure incidents.

The individuals recruited for IRS campaigns will receive intensive training on the use, operation, calibration and repair of the spray pumps and practical exercises during a five-days training period prior to the beginning of the spraying campaign. They will also receive training to understand proper hygiene, to recognize the signs and symptoms of poisoning, and to understand the referral procedure for any incidents involving poisoning. This training will be conducted in accordance with WHO's "Manual for Indoor Residual Spraying" (WHO 2002 and the USAID/PMI Best Practices Manual. Potential spray operators must also pass written and practical tests at the end of training.

Pesticide Exposure and Treatment.

The following drugs are recommended for use in case of exposure to the insecticides. The project will ensure that all the health facilities around the spray sites have in their store these recommended drugs and that all the staff responsible receives appropriate training on emergency treatment to pesticide exposure.

Table 13 : Antidotes for Pesticide Classes

Organochlorine (DDT):	Activated Charcoal (priority) Diazepam or Lorazepam (for seizure) Phenobarbital Cholestyramine resin	
Organophosphates:	Atropine sulfate or Glycopyrolate (priority treatment) Furosemide (less critical) Diazepam or Lorazepam (for seizure)	
Carbamates:	Cholestyramine Atropine (priority) Furosemide (less critical) Diazepam (for seizure)	
Pyrethroids:	<i>Name of Drug</i>	<i>Active Ingredient(s)</i>
	Promethazine	Promethazine Hydrochloride
	Panadol	Paracetamol
	Diazepam	Benzodiazapine/Diazepam
	Lorazepam	Lorazepam
	Calamine cream	Calamine, zinc oxide, glycerol, phenol, purified water, sodium citrate, betonite,
	Vit E	Tocopherol, fragrance, mineral oil, deionized water, sodium hydroxide, stearic acid
	Hydrocortisone cream	1% hydrocortisone
	Salbutamol	Salbutamol 100 mcg, suspended inert aerosol
	Salbutamol tablets	Salbutamol sulphate 4 mg
	Activated Charcoal	Activated Charcoal

All the spray operators including the supervisors will receive detailed training on the emergency steps to take if accidental exposure of the chemical occurs including ingestion, eye or dermal

contact with the chemical. This training will be conducted by the district health officers and will include drills to test knowledge of the operators.

6.5.6 Warehouse/Storage Risks

In order to mitigate risks associated with pesticide storage, the following key points will serve as key mitigation steps:

- All primary pesticide storage facilities will be double-padlocked and guarded on a 24 hour basis
- All the storage facilities will be located away from nearby water courses, domestic wells, markets, schools, hospitals, etc.
- Soap and clean water will be available at all times in all the facilities
- A trained storekeeper will be hired to manage each facility
- Recommended pesticide stacking position and height in the warehouse as provided in the FAO Storage and Stock Control Manual will be followed
- All the warehouses will have at least two exit access routes in case of fire outbreak
- A fire extinguisher will be available in the storage facilities and all workers will be trained on how to use this device.
- Warning notices will be placed outside of the store with skull and crossbones and the local language (Ndebele and Shona)
- All pesticides waiting to be used and any remnants will be stored under lock and key until the next rounds of spraying.

6.5.7 Solid and Liquid Contaminated Wastes

Mitigation measures are described in section 2.5.11 and 2.5.12 and in the EMMP Summary (Annex I)

6.6 Pesticide Quality Assurance

The procurement and use of pesticides that do not meet the necessary quality assurance standards can compromise the overall spray quality and desired vector action while at the same time could expose the residents and spray operators to hazards related to altered toxicological characteristics. In Zimbabwe, quality assurance of pesticides is provided by the Zimbabwe Analyst Laboratory (ZAL) and it is one step of the procurement process. Before reception of insecticides in the government warehouse, ZAL must perform sampling and analysis of chemical ingredient according to the specification presented in the binding contract. This is done to ensure the quality of insecticides before use.

6.7 Conclusion

The table below is a decision criteria matrix showing that if all the factors are considered in combination i.e. (diseases management effect, environmental effect, health risk and cost effectiveness etc), pyrethroids are the most cost effective, have beneficiary and government preference, and are considered less detrimental to human health and the environment. Organophosphates have the disadvantage of higher human health risk and higher cost, with lower beneficiary preference. At the same time, it is important to note that all three pesticide classes, when used with all the compliance and mitigation measures, have acceptable risk to human health and the environment and therefore are considered part of the proposed action.

Table 14: Decision Criteria Matrix

Criteria	Pesticide choice	Susceptibility	Socio-economic Impact	Cost	Country preferences	Human and ecological impacts	Total
IRS in Zimbabwe							
	Pyrethroids	+++	+++	+++	+++	-	11
	Carbamates	+++	+++	++	++	-	9
	Organo Phosphates	+++	+++	++	+	--	7
No Action		0	---	--	---	0	-8

Key/Legend 0= net zero effect
 -=net negative effect +=positive effect
 --=moderate negative effect ++=moderate positive effect
 ---=significant negative effect +++=significant positive effect

7.0 EMMP Implementation

The EMMP will be implemented by NMCP with the support of Abt Associates, a USAID/PMI contractor operating in the 17 Districts of three provinces supported by PMI. However, at the province and districts levels, IRS is directly implemented by the Province and Districts staff in particularly provincial and Districts Environment Health Officers. The staff in charge of implementation of EMMP will be trained to ensure effectiveness of the mitigation measures during spray operation. EMA will nominate IRS focal persons at national, province and district levels for monitoring environmental compliance of IRS campaign. Abt Associates will provide necessary support to facilitate EMA involvement in implementation of EMMP during spray operation. At the end of spray operation, EMA will prepare a report on wastes disposal and the environment compliance in general and propose recommendation for improvement for the 2013 IRS campaign.

The contractor and NMCP will undertake monitoring of the activities to ensure environment compliance during spray operation. Abt Associates will ensure that a specific environmental compliance inspection is conducted during spray operations, and a report prepared and submitted to PMI and shared with NMCP and EMA. The inspection will endeavor to ensure that all the mitigation measures highlighted in the EMMP are being implemented and propose measures for improvement for the next IRS campaign.

In addition PMI will conduct an independent environment compliance audit to ensure that all the mitigation measures are implemented during the spray campaign. This activity must be in the work plan and budget of the year 2012.

ANNEX 1: ENVIRONMENTAL MITIGATION AND MONITORING PLAN (EMMP)

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
Driver and/or community exposure, or environmental contamination due to improper transport of pesticide	<p>Driver training according to FAO recommendations</p> <p>Provision of appropriate equipment (reliable vehicle with side walls capable of negotiating rugged roads, tie-downs, packing materials, tarps, spill clean-up kit)</p> <p>Cautious driving while transporting chemicals</p> <p>Checking for and repairing leaks from spray equipment prior to transport</p> <p>In case of accident, completion of accident and corrective action report</p>	<p>Once prior to campaign, reinforcement as needed</p> <p>Continuous</p>	<p>Procedures being followed</p> <p>Demonstrated knowledge</p> <p>Existence of training materials</p> <p>Absence of vehicle accidents</p> <p>Vehicle condition</p> <p>Absence of spills during insecticide transport</p>	Drivers, Implementing partners, Pesticide distributors, spray team leaders
Environmental contamination due to improper siting or construction of storage and wash facilities	<p>Use site qualification checklist. Locate storage and wash facilities on high ground, above floodplains, away from sensitive receptors (water bodies, birds, bees, fish, children, etc.).</p> <p>Use appropriate construction materials as specified in FAO recommendations</p>	Once prior to campaign	<p>Storage and wash facilities outside of floodplain and away from sensitive receptors (birds, bees fish, children, etc.)</p> <p>Constructed of suitable material</p> <p>Adequately ventilated</p> <p>Adequate storage space</p>	District Environmental Officers, Implementing partner
Storekeeper and/or community exposure or environmental contamination due to improper storage or pilferage	<p>Provision of secure storage facilities</p> <p>Training of storekeepers, team leaders and supervisors according to FAO recommendations</p> <p>Daily tracking of insecticide sachets issued, used, and returned</p> <p>Storage procedures according to</p>	<p>Once prior to campaign</p> <p>Continuous</p>	<p>Dedicated and trained storekeeper who demonstrates knowledge and uses correct procedures</p> <p>Stock records up-to-date</p> <p>Stocks orderly, rotation system in place</p>	Storekeeper, spray team supervisors, spray team leaders, Implementing partners

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
<p>Cont.</p> <p>Storekeeper and/or community exposure or environmental contamination due to improper storage or pilferage</p>	<p>BMPs</p> <p>Storekeepers trained to not issue pesticides for agricultural or any other unauthorized use</p>	<p>Continuous</p>	<p>Expiration dates observed</p> <p>Empty sachets collected, counted and reconciled with amounts issued</p> <p>Ratio of structures sprayed to sachets issued</p> <p>Storehouse temperature measured and recorded</p> <p>No leaks or spills evident</p> <p>Insecticides not stored in same room with food, or medicine, or in inhabited spaces</p> <p>Facility physically secure, padlocked and guarded when not in use</p> <p>No fire, flame, smoking or eating allowed in storage areas</p>	
<p>Personnel handling OPs or carbamates experience cholinesterase inhibition (CI) due to exposure. (Symptoms include tiredness, weakness, dizziness, nausea and blurred vision, headache, sweating, tearing, drooling, vomiting, tunnel vision, and twitching, abdominal cramps, muscular tremors, staggering gait)</p>	<p>For all pesticides, all storage, spray, and wash teams receive training in recognizing effects of pesticide poisoning, remain alert to symptoms amongst their co-workers and respond appropriately.</p> <p>If using OPs other than pirimiphos-methyl (PM), CI testing will be performed on the all workers teams to determine base level of cholinesterase, then monitor for CI during the spray program.</p>	<p>Training: Included in pre-campaign orientation, and in training for new personnel.</p> <p>CI Testing: For OPs other than PM, once prior to the campaign and then weekly. Immediate testing upon display of symptoms.</p> <p>PM and carbamates only require CI testing if symptoms are displayed</p>	<p>Demonstrated knowledge of symptoms of poisoning, emergency treatment, and referral protocol by supervisors, team leaders, SWS members</p> <p>CI test results</p> <p>Antidotes available at health facilities</p>	<p>MOH, District Health Officers, Implementing partners</p>

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
<p>Acute effects of pesticide toxicity go untreated (Symptoms include tiredness, weakness, dizziness, nausea, blurred vision, headache, sweating, tearing, drooling, vomiting, tunnel vision, twitching, abdominal cramps, muscular tremors, staggering gait)</p>	<p>Employ CI testing as needed</p> <p>Team leaders, storekeepers trained to recognize symptoms and enforce treatment</p> <p>Ensure treatment medicines are available at District health centers.</p> <p>If skin itches after re-entrance into home, wash with soap and water, for eye irritation, flush eyes with water.</p> <p>For respiratory irritation, leave the home for fresh air.</p> <p>For ingestion, or if symptoms persist, contact program staff or go to nearest health facility.</p>	<p>Training on symptoms and responses prior to each campaign</p> <p>Continuous observation, reinforcement and enforcement of treatment protocols</p>	<p>Demonstrated knowledge of signs and symptoms of poisoning, emergency treatment, and referral protocol by supervisors, team leaders, storekeepers, spray operators, washpersons (SSW), and residents</p> <p>CI test results</p> <p>Antidotes and treatment medicines available at health facilities</p>	<p>Spray team supervisors, spray team leaders. District health officials, and Implementing partners</p>
<p>Exposure of SSW members and/or community during spray operations due to improper spray procedures</p> <p>Failure to realize/receive the benefits of IRS due to improper spray procedures</p>	<p>Training of SSW members, team leaders supervisors, and health workers according to MOH and WHOPES recommendations</p> <p>Proper assembly and calibration of spray equipment</p> <p>Proper spray patterns</p> <p>Proper cleanup and equipment storage procedures</p> <p>Discipline SSW members that do not follow proper procedure in all aspects of operations (handling, spraying, hygiene, cleanup)</p>	<p>Once prior to campaign</p> <p>Continuous</p>	<p>Spray operators, team leaders supervisors and health workers display knowledge by following procedures at all times</p> <p>Frequently agitate spray can</p> <p>Hold pump such that compression gage can be seen</p> <p>Stands parallel to wall being sprayed</p> <p>Stands 45 cm from wall</p> <p>1m/2.5 sec spray rate</p> <p>75 cm swatch width and 5 cm overlap</p> <p>All eaves and interior surfaces sprayed except dedicated kitchens</p>	<p>Spray team supervisors, spray team leaders, Implementing partners</p>

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
SSW member or community exposure, or environmental contamination due to equipment or PPE issues	<p>Use of sprayers manufactured and maintained according to WHOPES specifications</p> <p>Proper assembly and calibration of spray equipment</p> <p>Procurement and proper use of PPE by all persons in contact with pesticides</p>	Continuous	<p>All PPE as specified in WHOPES recommendations in good condition and worn by all personnel in contact with pesticides</p> <p>Condition of spray equipment</p> <p>Spray nozzle not dripping during spraying or transportation</p> <p>CI levels</p>	Spray team supervisors, spray team leaders, Implementing partners
Residential Exposure from contaminated household goods	<p>Training of spray operators to refuse to spray houses that are not properly prepared</p> <p>IEC Campaign, instruct residents to:</p> <p>Clear homes of mats or rugs, furniture, cooking implements and foodstuffs prior to spraying</p> <p>If furniture cannot be moved out of the home, then move it to the center of the room and cover with drop cloth</p> <p>Stay outside the home during spraying and for two to four hours after spraying</p> <p>Move and keep (tie-up or cage) all animals outside the home during spraying, and for four hours after spraying</p> <p>Sweep up any insects killed from the spraying or any residual insecticide and drop waste in latrine pits</p>	<p>Training and communication program prior to campaign,</p> <p>Spray operators require household goods removal prior to spraying domicile</p>	<p>IEC materials developed and include specific instructions</p> <p>IEC materials delivered in appropriate fashion</p> <p>Residents outside house during spraying</p> <p>Food and goods outside house during spraying</p> <p>Furniture covered during spraying</p> <p>Residents stay outside for four hours after spraying</p> <p>Residents sweep floor and dispose of waste properly</p> <p>Occurrence of skin/eye/throat irritation</p> <p>Houses not sprayed for lack of preparation</p>	District Environment Office, NEMA, EPA, Implementing partners USAID

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
Failure to realize benefits of spraying due to post-spray behavior change	Train residents to continue using bed nets for protection against malaria, and to refrain from re-plastering or painting over the sprayed walls after spraying, re-plaster prior to spraying if necessary	Prior to each campaign	Continued bed net use Walls not plastered after spraying	Village and district leaders
Staff and community exposure in vehicle used to transport spray team and/or pesticides	Frequent washing interior and exterior of program vehicles after pesticide transport using soap and water and PPE	Continuous	Vehicle condition	Cooper, Spray team supervisors, spray team leaders, Implementing partners
SSW personnel exposure due to poor personal hygiene	<p>Training and enforcement in good personal hygiene, daily washing of protective clothes and cleaning of equipment</p> <p>Prohibition of eating, drinking and smoking during travel, work or before decontamination</p> <p>Discipline SSW personnel that do not follow proper procedures in all aspects of operations (handling, spraying, hygiene, cleanup)</p>	Training once prior to campaign, continuous reinforcement and enforcement of good personal hygiene	<p>Two uniforms and PPE issued to each spray operator and one set cleaned each day</p> <p>No eating, drinking or smoking witnessed during operations or prior to washing</p> <p>Adequate numbers of shower/bathing facilities available</p> <p>Shower or bath taken, face/neck and hands washed with soap and water.</p>	Spray team supervisors, spray team leaders, Implementing partners
SSW personnel and/or community exposure due to poor waste management procedures	<p>Procurement of barrels for progressive rinse, and wash-tubs for personal hygiene; equipment labeled as District Health Office property to deter sale and domestic use in event of pilferage</p> <p>Collection, counting, and comparing number of empty sachets to disbursement records, collection of worn/torn gloves and masks</p> <p>Shipment of all wastes to authorized incinerator, destruction witnessed by Ministry of Health Official</p>	<p>Once prior to campaign</p> <p>Continuous</p>	Purchase records, inspection reports, waste disposal records from incinerator	District health officials, Implementing partners

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
Exposure of residents needing physical assistance during spray operations	<p>Communities establish system to assist the elderly and disabled in removing self and goods from the household.</p> <p>Spray operators enforce removal of household goods</p>	<p>Train operators once prior to campaign</p> <p>Continuous enforcement</p>	IEC campaign adequately addresses issues surrounding the elderly and disabled	District, County, Parish, and Village leaders
<p>Fetal/Infant Exposure due to maternal exposure on spray team</p> <p>Fetal Exposure – Pregnant women in contact with pesticides</p>	<p>Training of stockroom, spray, and wash, (SSW) teams.</p> <p>Pregnancy tests as eligibility criteria for SSW teams;</p> <p>Prohibition of breastfeeding women on SSW teams;</p> <p>Education of women regarding risks of exposure</p> <p>Completion of consent forms</p> <p>Assign pregnant women to tasks that have no occupational exposure to insecticides.</p>	Once prior to campaign, during campaign as necessary	<p>Pregnancy test results</p> <p>Written confirmation from all female SWS workers that they are not breastfeeding</p> <p>Signed consent forms from all female SSW workers</p> <p>Number of females reassigned</p>	Spray team supervisors, spray team leaders, District health officials, Implementing partners
Exposure of aged, infirm, pregnant women or fetus, due to inability to leave the home during spraying	Prohibition of spraying in homes where seriously infirm or immobile persons, or pregnant women are living who cannot move outside the home and stay outside the home during, and 4 hours after spraying	Continuous	<p>Residents outside house during spraying</p> <p>Residents stay outside for four hours after spraying</p> <p>Number of houses not sprayed due to resident immobility</p>	Spray team leaders and supervisors, residents, spray personnel
Pesticide contamination of water resources, (groundwater, rivers, streams, lakes)	<p>Do not spray any residences within 100 meters of principle water resources (other interventions should be implemented such as LLINs or wall lining)</p> <p>Do not dispose of any pesticides anywhere other than IRS triple rinse wash system</p>	Continuous	Evidence of environmental contamination (fish, bird, or bee kills), discoloration or turbidity of water	Spray team leaders, supervisors, district environmental officers, Implementing partners environmental compliance officer

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
Loss of biodiversity due to pesticide contamination	Do not spray or wash near sensitive areas or critical habitat (sensitive areas and critical habitats must be identified before activities commence)	Continuous	Individual organism fatalities or impairment	Spray team leaders, supervisors, district environmental officers, Implementing partners environmental compliance officer
Farm, aquaculture or apiary contamination	Train farmers, fish farmers and beekeepers in target areas to guard against contamination of agri/aquaculture or apiary equipment, and to ensure sweeping and disposal of floor residue and dead after IRS in pit latrines prior to storing equipment in home. Train SSW workers on the dangers of pesticides to food, fish, birds, and bees	Once prior to campaign	Number of post-spraying complaints from agri-aquaculture or apiary practitioners in target area Reports of fish or bee kills	Spray team leaders and supervisors, spray personnel, Implementing partners
Spray operations have no/reduced impact on vector due to pesticide quality	Collect insecticide samples and test to ensure quality control Supervise and monitor pesticide make-up procedures	Periodic spot sampling Continuous monitoring by spray team leaders and supervisors	Pesticide meets specifications Spray operator usage reports reflect proper house/sachet ratio	Implementing partners, team leaders and supervisors
Loss of efficacy of pesticides due to continuous or inappropriate use	Use pesticide rotation or mosaicing protocol to minimize development of resistance to insecticides. Avoid agricultural use of health-based pesticides.	Continuously re-assess pesticide to be used based on entomological monitoring	Protocol developed	Implementing partners.
Vector develops resistance to insecticide used	Change pesticide used	Monitoring resistance before, during, and after each campaign.	Monitoring results presented in end-of-round report	Implementing partners

Negative Impact	Mitigation Activities	Monitoring Frequency	Monitoring Indicators	Implementation Responsibility
SSW worker or community exposure, or environmental contamination due to negligence	Take disciplinary action against SSW workers that do not follow proper procedure in all aspects of operations (handling, spraying, hygiene, cleanup) up to and including discharge from duties	Continuous monitoring throughout campaign, immediate action upon discovery of non-conformance with procedures	Good hiring and management practices Adequate supervisor to team leader to spray operator ratio Number and severity of incidents reported	Spray team supervisors, spray team leaders, Implementing partners, District Officials
Community exposure, or environmental contamination post- campaign due to inadequate de-mobilization	Spray equipment, uniforms, PPE, wash equipment, , etc. get a final cleaning at end of campaign and are securely stored Check expiration dates on all leftover pesticide. Transfer any unused pesticide to District secured warehouse for disposal if expired, or use in subsequent spray round(s).	Once at end of campaign	Presence of adequate facilities for end of campaign cleaning and storage Visual observance of proper de-mobilization All equipment cleaned and properly stored	District health teams, Implementing partners
Community exposure due to residuals in vehicles used for pesticide transport	End-of-program cleaning/decontamination of interior and exterior of vehicles	Once after campaign	Interiors and exteriors of vehicles cleaned	Drivers/Rental company

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

Skin Decontamination

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

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

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

Airway Protection

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

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

Gastrointestinal Decontamination

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

- 1. **Gastric Lavage.** If the patient presents within 60 minutes of ingestion, lavage may be **considered**. Insert an orogastric tube and follow with fluid, usually normal saline. Aspirate back the fluid in an attempt to remove any toxicant. If the patient is neurologically impaired,

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

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

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

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

Dosage of Activated Charcoal:

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

Many activated charcoal formulations come premixed with sorbitol. Avoid giving more than one dose of sorbitol as a cathartic in infants and children due to the risk of rapid shifts of intravascular fluid. Encourage the victim to swallow the adsorbent even though spontaneous vomiting continues. Antiemetic therapy may help control vomiting in adults or older children. As an alternative, activated charcoal may be administered through an orogastric tube or diluted with water and administered slowly through a nasogastric tube. Repeated administration of charcoal or other absorbent every 2-4 hours may be beneficial in both children and adults, but use of a cathartic such as sorbitol should be avoided after the first dose. Repeated doses of activated charcoal should not be administered if the gut is atonic. The use of charcoal without airway protection is contraindicated in the neurologically impaired patient.

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

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

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

Dosage of Diazepam:

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

Dosage of Lorazepam:

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

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

Phenobarbital is an additional treatment option for seizure control. Dosage for **infants, children, and adults** is 15-20 mg/kg as an IV loading dose. An additional 5 mg/kg IV may be given every 15-30 minutes to a maximum of 30 mg/kg. The drug should be pushed no faster than 1 mg/kg/minute.

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

Annex 3: USA Regulation 22cfr 216.3.(b)

(b) Pesticide Procedures

(1) **Project Assistance.** Except as provided in §216.3 (b)(2), 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)(1)(i) through (v). These procedures shall also apply, to the extent permitted by agreements entered into by A.I.D. before the effective date of these pesticide procedures, to such projects that have been authorized but for which pesticides have not been procured as of the effective date of these pesticide procedures.

(i) When a project includes assistance for procurement or use, or both, of pesticides registered for the same or similar uses by USEPA without restriction, 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. Factors to be considered in such an evaluation shall include, but not be limited to the following:

- (a) The 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 nontarget 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 nonchemical 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; and
- (l) The provisions made for monitoring the use and effectiveness of the pesticide.

In those cases where the evaluation of the proposed pesticide use in the Initial Environmental Examination indicates that the use will significantly effect the human environment, the Threshold Decision will include a recommendation for the preparation of an Environmental Assessment or Environmental Impact Statement, as appropriate. In the event a decision is made to approve the planned pesticide use, the Project Paper shall include to the extent practicable, provisions designed to mitigate potential adverse effects of the pesticide. When the pesticide evaluation section of the Initial Environmental Examination does not indicate a potentially unreasonable risk arising from the pesticide use, an Environmental Assessment or Environmental Impact Statement shall nevertheless be prepared if the environmental effects of the project otherwise require further assessment.

(ii) When a project includes assistance for the procurement or use, or both, of any pesticide registered for the same or similar uses in the United States but the proposed use is restricted by the USEPA on the basis of user hazard, the procedures set forth in §216.3(b)(1)(i) above will be followed. In addition, the Initial Environmental Examination will include an evaluation of the user

hazards associated with the proposed USEPA restricted uses to ensure that the implementation plan which is contained in the Project Paper incorporates provisions for making the recipient government aware of these risks and providing, if necessary, such technical assistance as may be required to mitigate these risks. If the proposed pesticide use is also restricted on a basis other than user hazard, the procedures in §216.3(b)(1)(iii) shall be followed in lieu of the procedures in this section.

(iii) If the project includes assistance for the procurement or use, or both of:

(a) Any pesticide other than one registered for the same or similar uses by USEPA without restriction or for restricted use on the basis of user hazard; or

(b) Any pesticide for which a notice of rebuttable presumption against reregistration, notice of intent to cancel, or notice of intent to suspend has been issued by USEPA,

The Threshold Decision will provide for the preparation of an Environmental Assessment or Environmental Impact Statement, as appropriate (§216.6(a)). The EA or EIS shall include, but not be limited to, an analysis of the factors identified in §216.3(b)(1)(i) above.

(iv) Notwithstanding the provisions of §216.3(b)(1)(i) through (iii) above, if the project includes assistance for the procurement or use, or both, of a pesticide against which USEPA has initiated a regulatory action for cause, or for which it has issued a notice of rebuttable presumption against reregistration, the nature of the action or notice, including the relevant technical and scientific factors will be discussed with the requesting government and considered in the IEE and, if prepared, in the EA or EIS. If USEPA initiates any of the regulatory actions above against a pesticide subsequent to its evaluation in an IEE, EA or EIS, the nature of the action will be discussed with the recipient government and considered in an amended IEE or amended EA or EIS, as appropriate.

(v) If the project includes assistance for the procurement or use, or both of pesticides but the specific pesticides to be procured or used cannot be identified at the time the IEE is prepared, the procedures outlined in §216.3(b)(i) through (iv) will be followed when the specific pesticides are identified and before procurement or use is authorized. Where identification of the pesticides to be procured or used does not occur until after Project Paper approval, neither the procurement nor the use of the pesticides shall be undertaken unless approved, in writing, by the Assistant Administrator (or in the case of projects authorized at the Mission level, the Mission Director) who approved the Project Paper.

(2) **Exceptions to Pesticide Procedures.** The procedures set forth in §216.3 (b)(1) shall not apply to the following projects including assistance for the procurement or use, or both, of pesticides.

(i) Projects under emergency conditions.

Emergency conditions shall be deemed to exist when it is determined by the Administrator, A.I.D., in writing that:

(a) A pest outbreak has occurred or is imminent; and

(b) Significant health problems (either human or animal) or significant economic problems will occur without the prompt use of the proposed pesticide; and

(c) Insufficient time is available before the pesticide must be used to evaluate the proposed use in accordance with the provisions of this regulation.

(ii) Projects where A.I.D. is a minor donor, as defined in §216.1(c)(12) above, to a multidonor project.

(iii) Projects including assistance for procurement or use, or both, of pesticides for research or limited field evaluation purposes by or under the supervision of project personnel. In such instances, however, A.I.D. will ensure that the manufacturers of the pesticides provide toxicological and environmental data necessary to safeguard the health of research personnel and the quality of the

local environment in which the pesticides will be used. Furthermore, treated crops will not be used for human or animal consumption unless appropriate tolerances have been established by EPA or recommended by FAO/WHO, and the rates and frequency of application, together with the prescribed preharvest intervals, do not result in residues exceeding such tolerances. This prohibition does not apply to the feeding of such crops to animals for research purposes.

(3) **Non-Project Assistance.** In a very few limited number of circumstances A.I.D. may provide nonproject assistance for the procurement and use of pesticides. Assistance in such cases shall be provided if the A.I.D. Administrator determines in writing that

(i) emergency conditions, as defined in §216.3(b)(2)(i) above exist; or

(ii) that compelling circumstances exist such that failure to provide the proposed assistance would seriously impede the attainment of U.S. foreign policy objectives or the objectives of the foreign assistance program. In the latter case, a decision to provide the assistance will be based to the maximum extent practicable, upon a consideration of the factors set forth in §216.3(b)(1)(i) and, to the extent available, the history of efficacy and safety covering the past use of the pesticide in the recipient country.

Annex 4: Pesticides Profiles

Profile for Bendiocarb:

CAS Registry Number 22781-23-3

Summary of Insecticide

Chemical History

Bendiocarb is a broad spectrum carbamate insecticide first registered in the United States in 1980 for use to control a wide variety of nuisance and disease vector insects, such as mosquitoes, flies, wasps, ants, fleas, cockroaches, silverfish, and ticks. It is also effective against a variety of agricultural insects and to treat seeds against pests (U.S. EPA, 1999a, 1999b; EXTOXNET, 1996). The registration for bendiocarb was voluntarily canceled in 1999 (U.S. EPA, 1999a).

Bendiocarb exhibits its toxic effects through fast-acting, but reversible, cholinesterase inhibition. It has moderate toxicity in mammals (WHO/FAO, 1982), moderate toxicity in birds, and moderate to high toxicity in fish (EXTOXNET, 1996). In humans, symptoms of poisoning are neurological and include headache, blurred vision, nausea, vomiting, giddiness, slurred speech, excessive sweating and salivation, chest tightness, and twitching muscles (WHO/FAO, 1982). Bendiocarb pesticides were formulated as dusts, granules, wettable powders, pellets, and ultra low volume (ULV) sprays (U.S. EPA, 1999a; EXTOXNET, 1996).

Description of Data Quality and Quantity

Review data for bendiocarb are limited. Relevant resources include

Bendiocarb: Revised HED Chapter for the Reregistration Eligibility Decision (RED) Document (U.S. EPA, 1999b)

Data Sheet on Pesticides No. 52: Bendiocarb (WHO/FAO, 1982)

Pesticide Information Profile for Bendiocarb (EXTOXNET, 1996).

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

Summary Table

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute Intermediate, Chronic	Inhalation	0.002	mg/kg/day	Inhalation NOAEL (0.00018 mg/L) for neurological effects with UF of 100 applied	U.S. EPA (1999b)

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute, Intermediate, Chronic	Oral	0.00125	mg/kg/day	Acute and chronic oral RfDs based on neurological effects; adopt chronic for intermediate duration	U.S. EPA (1999b)
Acute	Dermal	0.5	mg/kg/day	Dermal NOAEL for neurological effects of 50 mg/kg/day with UF of 100 applied	U.S. EPA (1999b)
Intermediate	Dermal	0.2	mg/kg/day	Dermal LOAEL for neurological effects of 50 mg/kg/day with UF of 300 applied	U.S. EPA (1999b)
Chronic	Dermal	0.00125	mg/kg/day	Oral NOAEL for neurological effects of 0.125 mg/kg/day with UF of 100 applied	U.S. EPA (1999b)

For inhalation exposure, a NOAEL of 0.00018 mg/L (0.2 mg/kg/day)³ was identified for whole blood cholinesterase inhibition in rats exposed to bendiocarb via inhalation for 6 hours per day, 5 days per week, for 90 days (Coombs et al., 1995). An uncertainty factor of 100 to account for interspecies and intrahuman variation was applied, for an inhalation benchmark of 0.002 mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 1999b).

The acute and chronic oral RfDs of 0.00125 mg/kg/day were based on a NOAEL of 0.125 mg/kg for whole blood cholinesterase inhibition (about 25 percent) in rats exposed via gavage five days per week for two weeks (EPA MRID No. 00059269, no additional citation provided), with an uncertainty factor of 100 applied (10 each for interspecies and intrahuman variability). This value was also adopted for intermediate exposure (U.S. EPA, 1999b).

For acute dermal exposures, a NOAEL of 50 mg/kg/day in rats for whole blood cholinesterase inhibition from a single exposure was identified (EPA MRID No. 00122308, no additional citation provided) and an uncertainty factor of 100 was applied (10 each for interspecies and intrahuman variability). For intermediate dermal exposures, a LOAEL of 50 mg/kg/day for whole blood cholinesterase inhibition from repeated dermal exposures was identified (EPA MRID No. 00122308, no additional citation provided) and an uncertainty factor of 300 was applied (10 each for interspecies and intrahuman variability and 3 for the use of a LOAEL). For chronic dermal exposures, the NOAEL that was used to develop the oral RfDs was used with an uncertainty factor of 100 applied (10 each for interspecies and intrahuman variability) (U.S. EPA, 1999b).

³ Conversion between mg/m³ and mg/kg/day assumes, for Wistar rats, an average body weight of 0.187 kg and inhalation rate of 0.2 m³/day (U.S. EPA, 1988).

Insecticide Background

CAS #:	22781-23-3
Synonyms:	2,3-isopropylidenedioxyphenyl methylcarbamate (EXTOXNET, 1996), Ent-27695; OMS 1394; (WHO/FAO, 1982), 1,3-Benzodioxol-4-ol, 2,2-dimethyl-, methylcarbamate, 1,3-Benzodioxole, 2,2-dimethyl-4-(N-methylamino-carboxylato)-, 105201 (U.S. EPA PC Code), 1924 (CA DPR Chem Code), 2,2-Dimethyl-1,3-benzodioxol-4-yl methylcarbamate, Carbamic acid, methyl-, 2,3-(dimethylmethylenedioxy)-phenyl ester, Carbamic acid, methyl-, 2,3-(isopropylidenedioxy)phenyl ester (PAN, 2005), bencarbate, 1,3-benzodioxole, 2,2,-dimethyl-4(n-methylcarbamato), 2,2-dimethyl-1,3-benzodioxol-4-ol methcarbamate, 2,3-isopropylidenedioxyphenyl methylcarbamate, methylcarbamic acid 2,3,-(isopropylidenedioxy)phenyl ester (HSDB, 2005)
Chemical Group:	n-methyl carbamate (PAN, 2005)
Registered Trade Names:	Compounds containing bendiocarb: Ficam, Dycarb, Garvox, Multamat, Multimet, Niomil, Rotate, Seedox, Tattoo, Turcam (EXTOXNET, 1996), NC-6897, Ficam D, Ficam plus, Ficam W, Ficam ULV (HSDB, 2005).

Usage

Bendiocarb is a residual carbamate insecticide that has a variety of indoor and outdoor uses, including the control of mosquitoes, household and ornamental plant pests, and fire ants. It has no registered uses on either food or feed crops (U.S. EPA, 1999b). Most products containing bendiocarb are General Use Pesticides (EXTOXNET, 1996) and are meant for homeowner/residential use. However, some formulations (e.g., wettable powders) are recommended to be used only by pest control operators. Bendiocarb is not a Restricted Use Pesticide (U.S. EPA, 1999b); however, the formulations Turcam and Turcam 2.5 G are classified as restricted and may only be used by certified applicators (EXTOXNET, 1996).

Common bendiocarb formulations for both agricultural and public health program uses include wettable powders (800, 500 and 200 g active ingredient/kg [g a.i./kg]), granules for soil and turf treatment (30, 50, and 100 g a.i./kg), dust (10 g a.i./kg), suspension concentrate (500 g a.i./l) for spray or seed treatments, suspension in oil for ULV application (250 g a.i./l), residual sprays, and paint on and granular preparations with bait. The use patterns for bendiocarb in agricultural, horticultural, or forestry applications are reported as follows: soil treatment (300–2,000 g a.i./ha), seed treatment (1–10 g a.i./kg), residual spray (100–1,000 g a.i./ha), and ULV spray (50–500 g a.i./ha). In public health programs, it is reported that the 80 percent wettable powder should be applied only by a professional applicator (WHO/FAO, 1982).

Formulations and Concentrations

Common formulations of pesticides containing bendiocarb include technical grade, dusts, granules (for soil and turf treatment: 30, 50, and 100 g a.i./kg), wettable powders (800, 500, and 200 g a.i./kg), dust (10 g a.i./kg), suspension concentrate (for spray or seed treatment: 500 g a.i./L) and ULV sprays (in oil: 250 g, a.i./L) (WHO/FAO, 1982; EXTTOXNET, 1996). WHO (1999) indicated that the bendiocarb content in various preparations should be declared and contain the following:

Technical grade bendiocarb: not less than 940 g/kg

Wettable Powder: above 250 up to 500 g/kg \pm 5% of the declared content or above 500 g/kg \pm 25 g/kg

Dustable Powder: shall not differ from the declared content by more than -10% to + 35%.

ULV Liquid: Above 100 up to 200 g/kg \pm 6% of the declared content (WHO, 1999)

Shelf Life

Bendiocarb is reported to be stable below 40°C. Its half-life in aqueous solutions at 25°C is reported as 48 days at pH 5, 81 hours at pH 7, and 45 minutes at pH 9. Bendiocarb degrades slowly at pH 5. Bendiocarb is resistant to oxidation on nonabsorbant surfaces and at low humidity. In sunlight, bendiocarb photo-oxidizes (WHO/FAO, 1982).

Degradation Products

In moist soils and water, a major fate process for bendiocarb is hydrolysis. This is particularly true in neutral and alkaline environments. In neutral hydrolysis, the products are 2,3-isopropylidenedioxyphenol, methylamine, and carbon dioxide (HSDB, 2005). At pHs less than 5, bendiocarb slowly degrades into pyrogallol and acetone (WHO/FAO, 1982). The major degradation product of terrestrial field dissipation on turf is NC-7312 (U.S. EPA, 1999b).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Insecticidal carbamates that are applied to plants reach the soil both directly and indirectly. Degradation of carbamates in soil depends on volatility, leaching, soil moisture, absorption, pH, temperature, photodecomposition, microbial degradation, and soil type (IPCS, 1986). With a Koc range of 28 to 200, moderately to very high mobility is expected if bendiocarb is released in soil (HSDB, 2005). The major fate processes are hydrolysis in moist soils and biodegradation, with volatilization being an unimportant fate process for both dry and moist soils due to the low vapor pressure of bendiocarb. In moist soils, bendiocarb may undergo hydrolysis, and hydrolytic degradation depends on pH (HSDB, 2005; U.S. EPA, 1999b). Biodegradation of bendiocarb is expected to be rapid (HSDB, 2005). The half-life of bendiocarb in soil varies from less than 1 week up to 4 weeks, depending on the type of soil and the pH (EXTTOXNET, 1996). The estimated hydrolysis half-life of bendiocarb is 46.5 days at pH 5, 2 days at pH 7, and 0.33 days at pH 9 (U.S. EPA, 1999b). Soil photolysis is important in the photodegradation of bendiocarb in soil. In field dissipation studies on turf, bendiocarb and its degradate NC-7312 are not highly mobile, with intermediate half-lives of 20 days (bendiocarb) and 21 days (NC-7312) (U.S. EPA, 1999b). Bendiocarb degrades before leaching through soil, and degradates remain in the upper layers of soil in low concentrations (U.S. EPA, 1999a, 1999b). It is unlikely that bendiocarb will move

through soil to groundwater or to surface water through runoff (U.S. EPA, 1999a). Bendiocarb is of low persistence in soil (EXTOXNET, 1996).

Fate and Transport in Aquatic Systems

Water is an important factor in the transport of carbamates; however, the hazard posed by carbamates under these conditions is limited due to their rapid decomposition under aqueous conditions (IPCS, 1986). In water, bendiocarb is not expected to adsorb to suspended soils and sediments based on its K_{oc} range (28 to 200). The major fate processes in water are hydrolysis and biodegradation; volatilization is an unimportant fate process due to the low vapor pressure of bendiocarb. Additionally, direct photolysis is not a major degradation pathway in water (U.S. EPA, 1999b) and depends on the turbidity of the water (IPCS, 1986). In alkaline and neutral environments, hydrolysis is expected to be a major fate process. Half-lives have been reported of 48 days at pH 5, 4 days at pH 7, and 45 minutes at pH 9 (HSDB, 2005). Bendiocarb does not accumulate in water (EXTOXNET, 1996), and based on soil studies, biodegradation in water is expected to be rapid (HSDB, 2005). Because bendiocarb degrades rapidly in water, bioconcentration in fish is unlikely (U.S. EPA, 1999a). The estimated bioconcentration factor is 12 (HSDB, 2005).

Human Health Effects

Acute Exposure/Effects/Symptoms

Bendiocarb causes toxic effects by the rapid, but reversible, inhibition of cholinesterase in the blood. It is moderately toxic if absorbed through the skin or ingested (EXTOXNET, 1996). Typical signs of acute poisoning are neurological, and include weakness, excessive sweating and salivation, headache, blurred vision, nausea, vomiting, stomach pain, tightness in the chest, muscular twitching, giddiness, slurred speech, confusion, and muscular incoordination (WHO/FAO, 1982; EXTOXNET, 1996). Death from bendiocarb poisoning can result from paralysis of the respiratory system, severe constriction of the lung openings, or stopped breathing (EXTOXNET, 1996). Little data exist on the human health effects of acute exposure to bendiocarb. In humans, the threshold for mild symptoms and blood cholinesterase inhibition is 0.15–0.20 mg a.i./kg for ingestion. No symptoms were reported following repeated hourly doses of 0.1 mg a.i./kg. Studies in human volunteers have shown that both the onset and recovery from cholinesterase inhibition are very rapid (WHO/FAO, 1982). Case reports of accidental bendiocarb exposures report typical symptoms with reversible cholinesterase inhibition. In one case, cholinesterase was inhibited by 63 percent, and the exposed person recovered in less than 3 hours without any medical treatment. Cholinesterase levels returned to normal within 24 hours. In another case, recovery from symptoms occurred within 2 hours after being decontaminated and treated with atropine, with complete recovery by the next day. Bendiocarb is also a mild irritant to the skin and eyes (EXTOXNET, 1996).

In animals, bendiocarb is acutely toxic via the oral, inhalation, and dermal routes (U.S. EPA, 1999b). The oral LD₅₀ values of unformulated bendiocarb in various animal species include 34–156 mg/kg in rats, 35–40 mg/kg in rabbits, and 35 mg/kg in guinea pigs. The reported dermal LD₅₀ value in rats is greater than 566 mg/kg (EXTOXNET, 1996; IPCS, 1986; WHO/FAO, 1982) and the reported 4-hour LC₅₀ in rats is 0.55 mg/L (EXTOXNET, 1996). For formulated bendiocarb compounds, an LD₅₀ of 143–179 mg/kg was reported in rats for an 80 percent a.i. water dispersible powder. A dermal LD₅₀ of greater than 1,000 mg/kg was reported for an 80 percent a.i. liquid formulation (WHO/FAO, 1982).

As in humans, acute exposure to bendiocarb in animals causes symptoms typical of cholinesterase inhibition (U.S. EPA, 1999a, 1999b). No acute delayed neurotoxicity was observed in hens. Although bendiocarb causes slight eye irritation in animals, it is not considered a skin or eye irritant or a dermal sensitizer (U.S. EPA, 1999b).

Treatment

Exposure to bendiocarb may be determined through laboratory tests that determine cholinesterase levels in blood; however, the enzyme will only be inhibited for a few hours following exposure. Additionally, bendiocarb metabolites may be identified in urine (WHO/FAO, 1982). Bendiocarb poisoning should be treated in the same way as high-toxicity carbamate poisoning (PAN, 2005). First removing any contaminated clothing and wash affected areas with soap and water. If bendiocarb gets in the eyes, they should be rinsed immediately with isotonic saline or water. Oral exposure to bendiocarb should be treated by rapid gastric lavage with 5 percent sodium bicarbonate if the patient is not already vomiting. Medical attention should be sought. Adults showing signs of bendiocarb toxicity should be treated with 1–2 mg atropine sulfate given intramuscularly or intravenously as needed. Oxygen may be necessary for unconscious patients or those in respiratory distress. Pralidoxime is not effective in treating bendiocarb poisoning (WHO/FAO, 1982).

Chronic Exposure

Noncancer Endpoints

The effects of chronic exposure to bendiocarb in humans have not been well described in the literature, although it is not expected to be toxic at the levels applied to control mosquitoes. When used as a residual mosquito insecticide, few adverse effects were reported by occupationally exposed workers. Those effects that were reported were transient and mild. Additionally, no effects were reported by residents of villages where it was applied (WHO/FAO, 1982).

Subchronic and chronic exposure studies in rats, mice, and dogs have shown that bendiocarb inhibits cholinesterase activity in whole blood, plasma, red blood cells, and the brain (U.S. EPA, 1999a, 1999b; WHO/FAO, 1982). No macroscopic pathology or histological evidence of dermal irritation or treatment-related mortality was observed in a 21-day dermal study in rats. Rats exposed to bendiocarb for 90 days via inhalation showed whole-blood cholinesterase inhibition (U.S. EPA, 1999b). Additionally, bendiocarb does not accumulate in mammalian tissue. There was no evidence of cumulative toxicity in rats or dogs fed bendiocarb for 90 days (WHO/FAO, 1982). Bendiocarb is not expected to cause reproductive effects in humans. In rats, no effect on fertility and reproduction was seen in rats fed diets containing bendiocarb for three generations. However, very high doses were toxic to dams and pups, as indicated by decreased survival rate and decreased pup weight (EXTOXNET, 1996). No teratogenicity was seen in rats or rabbit fetuses or offspring following pre- and/or postnatal exposures to bendiocarb (U.S. EPA 1999a, 1999b; WHO/FAO, 1982). No evidence of mutagenicity was observed following in vivo or in vitro exposures to bendiocarb (U.S. EPA, 1999a, 1999b; EXTOXNET, 1996; WHO/FAO, 1982). No irreversible or delayed neurotoxicity has been reported in animals following long-term bendiocarb exposure (WHO/FAO, 1982).

Cancer Endpoints

EPA has classified bendiocarb as a Group E chemical, noncarcinogenic to humans (U.S. EPA, 1999b). The classification is based on the lack of increase in tumors in rat and mouse studies and is supported by the lack of mutagenicity in somatic cells (U.S. EPA, 1999b). No human data are available.

Toxicokinetics

Bendiocarb can be absorbed through oral, dermal, and inhalation pathways; dermal absorption is especially rapid and is the main route of absorption. Absorption from inhalation, except inhalation of airborne dusts or fine spray mists, is unlikely due to bendiocarb's low vapor pressure (EXTOXNET, 1996; WHO/FAO, 1982). Animal metabolism studies indicate that bendiocarb is rapidly absorbed following oral exposure (U.S. EPA, 1999b). Liver microsome enzymes readily conjugate and metabolize bendiocarb, and it is rapidly excreted. Because of its rapid metabolism and excretion, bendiocarb does not accumulate in mammalian tissues (WHO/FAO, 1982). The majority of an orally administered dose is eliminated in the urine (U.S. EPA, 1999b). In rats fed diets containing up to 10 mg/kg bendiocarb, 89 to 90 percent of the dose was excreted in the urine, 2 to 6 percent was excreted in the feces, and 2 to 6 percent was exhaled. A human subject orally exposed to bendiocarb exhibited a similar excretion pattern (EXTOXNET, 1996). Bendiocarb is excreted mainly as sulfate and beta-glucuronide conjugates of the phenol derivative (WHO/FAO, 1982).

Ecological Effects

Acute Exposure

When applied at the maximum registered application rate, bendiocarb poses acute risk to nontarget terrestrial organisms, such as mammals and birds (WHO/FAO, 1982; U.S. EPA, 1999a). Single broadcast applications on turf may result in high risk to birds, and multiple applications may result in repeated acute effects (U.S. EPA, 1999a). Oral LD50 values range from 3.1 mg a.i./kg body weight in mallard ducks to 137 mg a.i./kg body weight in domestic hens (WHO/FAO, 1982; U.S. EPA, 1999a). However, bendiocarb does not affect avian reproductive parameters (WHO/FAO, 1982). Additionally, bendiocarb has been found to be highly toxic to bees (WHO/FAO, 1982; EXTOXNET, 1996; U.S. EPA, 1999a), with an oral LD50 of 0.0001 mg/bee (EXTOXNET, 1996). Additionally, bendiocarb severely affects earthworms under treated turf (EXTOXNET, 1996). Bendiocarb poses acute risks to freshwater fish, and estuarine and marine animals (U.S. EPA, 1999a). It is moderately to highly toxic to fish, with LC50 values ranging from 0.7 to 1.76 mg a.i./L in various species (U.S. EPA, 1999a; WHO/FAO, 1982). The 96-hour LC50 for rainbow trout is 1.55 mg/L (EXTOXNET, 1996). When applied at the maximum registered rate, bendiocarb also poses acute risks to freshwater invertebrates (U.S. EPA, 1999a).

Chronic Exposure

Very little data exist for chronic exposure to bendiocarb in nonterrestrial target organisms. In birds, multiple applications of the maximum registered application rate to turf are expected to result in repeated acute effects. The reproductive effects of chronic exposures cannot be assessed due to limited data (U.S. EPA, 1999a).

Little data exist for chronic exposure to bendiocarb in marine or estuarine organisms. When applied at the maximum registered rate, bendiocarb poses chronic risks to freshwater invertebrates. However, it poses no chronic risk to freshwater fish (U.S. EPA, 1999a).

Profile for Fenitrothion:

CAS Registry Number 122-14-5

Summary

Chemical History

Fenitrothion is a general use organophosphate insecticide that is nonsystemic and nonpersistent. It is mostly used in the control of chewing and sucking insects on a wide variety of agricultural crops and in forests, as well as for public health purposes. It is also used as a residual contact spray against mosquitoes, flies, and cockroaches. Fenitrothion is used residentially to control household and nuisance insects (EXTOXNET, 1995; WHO, 2003). Fenitrothion was introduced in 1959 as a less toxic alternative to parathion, with which it shares similar insecticidal properties. Fenitrothion is used heavily in countries that have banned parathion (EXTOXNET, 1995). In the United States, the use of fenitrothion for mosquito control was voluntarily cancelled by the manufacturer in 1995 (U.S. EPA, 1995) and the only registered use is for containerized ant and roach baits (U.S. EPA, 2000b). The primary route of occupational exposure to fenitrothion is dermal, although inhalation exposures are also possible (U.S. EPA, 1995). Exposure to fenitrothion can cause overstimulation of the nervous system due to cholinesterase inhibition. This may result in nausea, dizziness, confusion, and respiratory paralysis and death at very high exposures (U.S. EPA, 2000b).

Description of Data Quality and Quantity

EPA has developed quantitative human health benchmarks (acute and chronic oral RfDs and inhalation and dermal benchmarks) for fenitrothion. Relevant review data resources include the following

Reregistration Eligibility Decision (RED) Fenitrothion (U.S. EPA, 1995)

Pesticide Information Profiles (PIP) for Fenitrothion (EXTOXNET, 1995)

Specifications for Pesticides Used in Public Health: Fenitrothion (WHO, 1999)

Pesticide Residues in Food 2000: Fenitrothion (IPCS, 2000).

Summary Table

<u>Duration</u>	<u>Route</u>	<u>Benchmark Value</u>	<u>Units</u>	<u>Endpoint</u>	<u>Reference</u>
<u>Acute, Intermediate, Chronic</u>	<u>Inhalation</u>	<u>0.0004</u>	<u>mg/kg/day</u>	<u>Inhalation NOAEL of 0.2 µg/L (0.2 mg/kg/day) for neurological effects in rats with UF of 100 applied and adjusted for intermittent exposure</u>	<u>U.S. EPA (1999a)</u>
<u>Acute</u>	<u>Oral</u>	<u>0.13</u>	<u>mg/kg/day</u>	<u>Acute oral RfD based on neurological effects in rats</u>	<u>U.S. EPA (1999a)</u>
<u>Intermediate</u>	<u>Oral</u>	<u>0.0013</u>	<u>mg/kg/day</u>	<u>Adopt chronic RfD for intermediate duration</u>	<u>U.S. EPA (1999a)</u>
<u>Chronic</u>	<u>Oral</u>	<u>0.0013</u>	<u>mg/kg/day</u>	<u>Chronic oral RfD for based on NOEL for systemic and neurological effects in dogs</u>	<u>U.S. EPA (1999a)</u>
<u>Acute, Intermediate, Chronic</u>	<u>Dermal</u>	<u>0.01</u>	<u>mg/kg/day</u>	<u>Dermal LOAEL of 3 mg/kg/day for dermal effects in rabbits</u>	<u>U.S. EPA (1999a)</u>

For inhalation exposure, a NOAEL of 0.2 µg/L (0.2 mg/kg/day)⁴ was identified in rats (Coombs et al., 1988) exposed to fenitrothion via inhalation for 6 hours per day, 5 days per week, for 90 days (U.S. EPA, 1999a; IPCS, 2000). The concentration was adjusted for intermittent exposure⁵ (0.04 mg/kg/day) and an uncertainty factor of 100 was applied to account for interspecies and intrahuman variation, for an inhalation benchmark of 0.0004 mg/kg/day. This value is appropriate for all exposure durations.

For oral exposure, an acute oral RfD was estimated at 0.13 mg/kg/day based on a NOAEL of 12.5 mg/kg/day for acute neurotoxicity in rats (Beyrouy et al, 1992). An uncertainty factor of 100 was applied to account for interspecies and intrahuman variability (U.S. EPA, 1999a). A chronic oral RfD of 0.0013 mg/kg/day was developed by EPA (1995, 1999a) based on a NOAEL of 0.125 mg/kg/day for systemic effects and plasma acetylcholinesterase inhibition in a long-term feeding study in dogs (Spicer, 1986). An uncertainty factor of 100 was applied to account for interspecies and intrahuman variability (U.S. EPA, 1995, 1999a). The chronic RfD was adopted to represent intermediate-term exposures.

For dermal exposure, a LOAEL of 3 mg/kg/day for dermal irritation and desquamation of the epidermis was identified from 21-day dermal rabbit study (Suetake, 1991); no neurological effects were observed at this concentration (U.S. EPA, 1995). An uncertainty factor of 300 was applied to account for interspecies and intrahuman variability and the use of a less serious LOAEL, resulting in a dermal benchmark of 0.01 mg/kg/day. This value is appropriate for all exposure durations.

Insecticide Background

⁴ Conversion between mg/m³ and mg/kg/day assumes, for female Wistar rats, an average body weight of 0.156 kg and inhalation rate of 0.17 m³/day (U.S. EPA, 1988).

⁵ Adjustment for intermittent exposure is the product of air concentration and exposure of 6/24 hours/day and 5/7 days/week.

CAS#	122-14-5
Synonyms:	O,O-dimethyl O-(4-nitro-m-tolyl) phosphorothioate (U.S. EPA, 1995) methylnitrophos (Eastern Europe) (EXTOXNET, 1995)
Chemical Group:	Organophosphate (EXTOXNET, 1995; U.S. EPA, 2000a)
Registered Trade Names:	Accothion, Agrothion, Bay 41831, Bayer 41831, Bayer S 5660, Cyfen, Cytel, Dicofen, Dybar, Fenitox, Fenstan, Folithion, Kaleit, Mep, Metathion, Micromite, Novathion, Nuvanol, Pestroy, Sumanone, Sumithion, and Verthion (U.S. EPA, 1995; EXTOXNET, 1995)

Usage

Fenitrothion is a broad spectrum organophosphate insecticide and acaricide (IPCS, 2000) most commonly used in agriculture to control chewing and sucking insects on crops such as rice, cereals, fruits, vegetables, stored grains, and cotton. It is also used in forested areas and to control flies, mosquitoes, and cockroaches, and in public health programs (WHO, 2004). In the United States, fenitrothion is only registered for use as a containerized ant and roach bait. In Australia, it is used on stored wheat (U.S. EPA, 2000b).

Formulations and Concentrations

There are several formulations for fenitrothion, each containing varying amounts of the active ingredient. The typical formulations for fenitrothion are dusts (2 percent, 2.5 percent, 3 percent, or 5 percent), emulsifiable concentrate (50 percent), flowable, fogging concentrate (95 percent), and wettable powder (40 or 50 percent). It is also available in granules and ultra-low-volume, oil-based liquid spray (EXTOXNET, 1995). Registered formulation types include 0.01563 percent and 1 percent pellets and granular baits. Emulsifiable concentrates are not registered in the United States (U.S. EPA, 2000b). The fenitrothion content for various formulations should be declared as follows: technical grade fenitrothion (no less than 910 g/kg), fenitrothion emulsifiable concentrate and wettable powder (above 250 up to 500 g/kg + 5% of declared content, above 500 g/kg + 25 g/kg) (WHO, 1999).

Shelf-Life

Like many insecticides, fenitrothion should be stored in a locked, well-ventilated facility, preferably one designated only for insecticide storage. It should not be exposed to sunlight and should be stored away from animal feed and foodstuffs (IPCS, 1991).

Fenitrothion is stable for up to two years if stored between 20 and 25°C; storage temperatures should not exceed 40°C. Fenitrothion is unstable when heated above 100°C and may undergo Pishchemuka isomerization and decompose explosively. Decomposition of fenitrothion is promoted by iron. Therefore, fenitrothion should be stored in enamel, aluminum, or glass containers. Fenitrothion is not stable in alkaline environments (EXTOXNET, 1995). Residues of fenitrothion are stable for up to 147 days in wheat and 174 days in wheat gluten when frozen (-18°C) (U.S. EPA, 1995).

Degradation Products

In water, fenitrothion is degraded through photolysis and hydrolysis, with degradation accelerated in the presence of microflora. In soil, fenitrothion is primarily broken down by biodegradation with photolysis also playing a role (WHO, 2003, 2004). Carbon monoxide is the major degradate for aerobic soil metabolism and photolysis. The major nonvolatile degradates for aerobic soil metabolism, anaerobic aquatic metabolism, and photolysis include 3-methyl-4-nitrophenol (approximately 1 to 22 percent of applied); aminofenitrothion (approximately 13 percent of applied); acetyl-aminofenitrothion (approximately 13 percent of applied); formylaminofenitrothion (4.9 percent of applied); o,o-dimethyl o-(3-carboxy-4-nitrophenyl)phosphorothionate (12.4 percent of applied); fenitrooxon (\leq 4.3 percent of applied); demethylate fenitrothion (approximately 1 percent of applied); and desmethylfenitrooxon (\leq 4.3 percent of applied). Other degradates are present at concentrations less than or equal to 2 percent and include o,o-dimethyl o-(3-methyl-4-nitrophenyl)phosphorothioate-3-methyl-4-nitrophenol; o-methyl (5-methyl o-(3-methyl-4-nitrophenyl)phen-phorothioate; o-methyl o-hydrogen o-(3-methyl-4-nitro-phenyl)phosphate; o,o-dimethyl o-(3-carboxy-4-nitrophenyl)phosphate; 5-methylfenitrothion; and carboxyfenitrooxon. The major degradates in pH 5 and pH 9 solutions are demethylated fenitrothion (10.3 percent of applied) and 3-methyl-4-nitrophenol (1.7 percent of applied). In pH 9 solution, the major degradate is 3-methyl-4-nitrophenol (15.1 percent of the applied), while demethylated fenitrothion accounts for up to 5.6 percent of applied. The major degradate from hydrolysis in pH 5 and pH 7 buffered solutions is demethylated fenitrothion. The major degradate in pH 9 buffered solution is 3-methyl-4-nitrophenol. Seven degradates were identified from photodegradation in soil. In loam soil, the major nonvolatile degradates from aerobic soil metabolism was 3-methyl-4-nitrophenol. Additional degradates included fenitrooxon, desmethylfenitrooxon, and 3-methyl-4-nitroanisole. The major volatile degradate was carbon monoxide (U.S. EPA, 1995).

Environmental Behavior

Fate and Transport in Terrestrial Systems

In most soil types, fenitrothion degrades rapidly with a half-life ranging from 3 to 25 days (U.S. EPA, 1995). Fenitrothion is mostly found in the top six inches of soil and is not very mobile and only slightly persistent in soil (U.S. EPA, 1995). In nonsterile muck and sandy loam soils, a half-life of less than one week is reported. Fenitrothion is intermediately mobile in soils ranging from sandy loam to clay (EXTOXNET, 1995). However, when applied to silty clay loam, silty clay, and sandy loam under laboratory conditions, fenitrothion appears to be immobile (U.S. EPA, 1995). Fenitrothion leaches very slowly into groundwater from most soils; however, some runoff can occur (WHO, 2004).

Fate and Transport in Aquatic Systems

On lakes, surface foam can trap fenitrothion from aerial spraying (EXTOXNET, 1995). In water, fenitrothion is unstable in the presence of sunlight or microbial contamination (WHO, 2003). Laboratory studies at 23°C and pH 7.5 in the dark resulted in a half-life of 21.6 days for buffered lake water and 49.5 days for natural lake water. However, in field experiments, the half-life was 1.5-2 days at pH 7.0-7.5 and 19-23°C (EXTOXNET, 1995). Phenyl labeled [¹⁴C]-fenitrothion had a half-life of 4-7 days, while the anaerobic aquatic half-life is reported at 0.82 days. In fish, fenitrothion accumulates rapidly but at low concentrations (U.S. EPA, 1995).

Human Health Effects

Acute Exposure

Effects / Symptoms

Acute oral and dermal experimental data are available for human exposures to fenitrothion. No effect on acetylcholinesterase activity was observed in volunteers following a single oral dose of up to 0.33 mg/kg body weight or repeated doses of up to 0.36 mg/kg body weight/day for 4 days. Volunteers ingested technical-grade fenitrothion via capsule at doses of 0.18 mg/kg/day followed 2 weeks to 5 months later by 0.36 mg/kg/day, with each daily dose continued for 4 consecutive treatments. No significant effect of treatment was seen on blood pressure or pulse, and observed clinical signs were not considered to be treatment related. Transient decreases in erythrocyte cholinesterase activity were observed in two volunteers, but no treatment-related changes in hematological or clinical chemistry parameters were observed. No dermal irritation and no effects on cholinesterase activity were observed in volunteers exposed to up to 0.5 mg/kg/day fenitrothion orally followed by 0.1 mg/kg/day dermally to the arms and face for 9 days (IPCS, 2000).

Case reports of humans accidentally or intentionally ingesting fenitrothion indicate that fenitrothion is lethal at oral doses of 3 g. Additionally, death from respiratory insufficiency was observed 6 days after a man ingested 60 mL of a 50 percent emulsion in a suicide attempt. Other acute oral effects included paralysis at 1.5 to 6 g. In patients exhibiting paralysis, plasma cholinesterase was inhibited by 40 percent to more than 80 percent. In patients who consumed 50 to 100 mL of a 50 percent fenitrothion solution either accidentally or in suicide attempts, 6 of 16 died within 5 to 22 days, despite receiving medical attention. Intermediate syndrome, characterized by muscular weakness affecting the neck, proximal limb, and respiratory muscles, was observed in 7 of 10 survivors. Of those with intermediate syndrome, plasma cholinesterase activity was not observed at time of hospitalization. Recovery ranged from 5 weeks to more than 10 weeks in patients with intermediate syndrome, versus 2 to 4 weeks in those without (IPCS, 2000).

No clinical signs were observed in spray operators or villagers one week after exposure to a 5 percent fenitrothion spray. However, a 40–60 percent decrease in cholinesterase activity was observed in spray operators using fenitrothion indoors for 4 weeks in the absence of clinical symptoms of organophosphate toxicity. Orchard spray operators who inhaled a mean concentration of 0.011 µg/L fenitrothion for 3 consecutive days also showed no clinical signs but had lower maximum plasma concentration of fenitrothion than unexposed operators, with relatively rapid clearance from plasma (IPCS, 2000).

In animals, the acute toxicity of fenitrothion is low. The oral LD₅₀ ranges from 240 to 1,700 mg/kg in rats, 715 to 1,400 mg/kg in mice, and 500 mg/kg in guinea pigs (EXTOXNET, 1995; IPCS, 2000). The acute dermal LD₅₀ is reported to be 890–5,000 mg/kg in rats and greater than 3,000 mg/kg in mice (EXTOXNET, 1995; IPCS 2000). The acute inhalation LC₅₀ ranges from 2.2 to 5.0 mg/L in rats (EXTOXNET, 1995; IPCS 2000). In cats, acute oral toxicity was 142 mg/kg (IPCS, 2000). Toxicity is dependent on sex and vehicle used; males are sensitive than females (IPCS, 2000). This is illustrated by the reported acute toxicity of the fenitrothion preparation Sumithion Technical (97.2 percent); the oral LD₅₀ is 330 mg/kg in males and 800 mg/kg in females, and the dermal LD₅₀ is 890 mg/kg in males and 1,200 mg/kg in females (U.S. EPA, 1995).

The signs of acute fenitrothion toxicity in animals are consistent with cholinesterase inhibition (IPCS, 2000). In hens, no evidence of delayed neurotoxicity or increased neurological lesions was seen following a single dose (WHO, 2004) or acute administration of Sumithion Technical (97.2 percent) (U.S. EPA, 1995). However, the fenitrothion product Sumithion 50EC has been shown to cause delayed neurotoxicity in adult rats as well as humans (EXTOXNET, 1995). In rats, cholinergic signs and erythrocyte and brain cholinesterase inhibition were seen at a number of doses, but cholinergic signs were seen only when brain cholinesterase was inhibited by more than

58 percent of erythrocyte acetyl cholinesterase was inhibited by more than 38 percent (WHO, 2004).

Technical grade fenitrothion (95 percent) does not cause dermal or ocular irritation in rabbits or dermal sensitization in guinea pigs (IPCS, 2000; U.S. EPA, 1995). However, mild dermal irritation was seen following exposure to Sumithion 8-E (77 percent ai) (U.S. EPA, 1995). Other acute effects in animals include those caused by O,O,S-trimethyl phosphorothioate, one of the contaminants of fenitrothion, including cytotoxic effects in rat lungs and modulated immune response in mice (EXTOXNET, 1995).

Treatment

Dermal exposure to fenitrothion should be treated by removing contaminated clothing, rinsing the skin with water, washing the exposed areas with soap and water, then seeking medical attention. If fenitrothion gets into the eyes, they should be rinsed with water for several minutes. Contact lenses should be removed if possible and medical attention should be sought. Ingestion of fenitrothion should be treated by rinsing the mouth and inducing vomiting if the person is conscious. Inhalation exposures require removal to fresh air and rest in a half-upright position. Artificial respiration should be administered if indicated and medical attention should be sought (PAN, 2005).

Chronic Exposure

Noncancer Endpoints

Limited data are available on the chronic toxicity of fenitrothion in humans. Chronic symptoms of toxicity in humans include general malaise, fatigue, headache, loss of memory and ability to concentrate, anorexia, nausea, thirst, loss of weight, cramps, muscular weakness, and tremors. At sufficient exposure levels, typical symptoms of cholinergic poisoning may be seen (EXTOXNET, 1995). Mild clinical signs such as nausea and dizziness and whole-blood cholinesterase inhibition were observed in spray operators following occupational exposure to fenitrothion used during a 30-day malaria control operation. However, no treatment-related effects were seen in operators spraying fenitrothion for 5 hours/day, 5 days a week, intermittently for 2 years (IPCS, 2000).

The main toxicological finding from long-term animal studies was cholinesterase activity inhibition (red blood cell, plasma, and brain) in all species studied (IPCS, 2000; U.S. EPA, 1995; EXTOXNET, 1995). Signs of poisoning and cholinergic stimulation were also reported at higher levels.

In animals, reproductive and developmental toxicity are of concern. Developmental effects were seen at doses that were maternally toxic in rats. Reduced body weight, viability, and lactation indices were seen in offspring. In rats and rabbits, no fetal toxicity or treatment-induced malformations were seen at the highest dose tested in the presence of maternal cholinergic signs and decreased body weight gain (WHO, 2004). Others have reported an increase in fetal and skeletal variations at doses causing maternal toxicity (U.S. EPA, 1998). Behavioral effects were observed in rat pups following maternal exposure to Sumithion 50EC on gestation days 7 to 15 and included differences in simple behavioral measures and complex measures, which persisted up to 104 days after birth. No effects were seen at lower levels (EXTOXNET, 1995).

Fenitrothion is not teratogenic, mutagenic, or genotoxic in chronically exposed animals and is not expected to cause those effects in humans (EXTOXNET, 1995). Additionally, fenitrothion did not induce immunotoxicity (WHO, 2004).

Cancer Endpoints

Data on the carcinogenic potential of fenitrothion indicate that it is unlikely to pose a carcinogenic risk to humans. EPA has classified fenitrothion as a Group E chemical, “evidence of noncarcinogenicity for humans” (U.S. EPA, 1995, 1999a). Evidence from animal studies suggests that fenitrothion is not carcinogenic in animals.

Toxicokinetics

Fenitrothion is readily absorbed from the intestinal tract of most mammalian species, with about 90 to 100 percent of the dose absorbed (IPCS, 2000; EXTOKNET, 1995). In rats, oral absorption is approximately 90 to 100 percent within 72 hours, while in humans, it is about 70 percent in 96 hours (IPCS, 2000). Within 24 hours of dermal application, about 45 percent of the applied dose is absorbed (WHO, 2004; IPCS, 2000). In rats, a dermal absorption rate of slightly over 1 percent is suggested as fenitrothion disappeared rapidly during the first hour (EXTOKNET, 1995). Fenitrothion is widely distributed in the body. In rats, the highest concentrations after 48 hours are found in the liver, kidneys, and fat. It is rapidly activated and deactivated (IPCS, 2000). In the liver, fenitrothion is activated by oxidative desulfuration to the activated metabolite fenitrooxon (WHO, 2004; IPCS, 2000). It is then rapidly degraded by demethylation and hydrolysis into the inactive metabolites 3-methyl-4-nitrophenol and dimethylphosphate. Further oxidation to 3-carboxyl-4-nitrophenol is involved in a minor metabolic pathway. In dermally exposed rats, the area of highest concentration (other than skin) of fenitrothion after 31 hours was the cartilaginous part of the bones (EXTOKNET, 1995). Within 24 hours of oral exposures, up to 93 percent of the dose is excreted via the urine, and 5 to 15 percent is excreted in the feces (WHO, 2004; IPCS, 2000; U.S. EPA, 1995). In rats, rabbits, and dogs, seventeen metabolites have been isolated in the urine, and the parent compound was not detected (U.S. EPA, 1995).

Toxicokinetic studies in humans have shown the time to maximal plasma concentration was 1 hour in volunteers who ingested two capsules 12 hours apart that contained 0.09 or 0.18 mg fenitrothion/kg body weight for 4 days. The elimination half-time ranged from 2 to 3 hours for both doses. The maximal plasma concentration following a single oral dose was 0.09 mg/kg body weight 1 day after exposure and 0.84 ng/mL 4 days after exposure. Higher doses resulted in higher maximal concentrations on days 1 and 4 after exposure (1.8 ng/mL and 7.7 ng/mL, respectively). In addition, the elimination half-time of fenitrothion was 2 to 4.5 hours (WHO, 2004; IPCS, 2000). Human studies also indicate that fenitrothion does not accumulate. In humans, doses of 2.5 and 5 mg/man/day administered for 5 days were all excreted within 12 hours without accumulation. Urinary excretion of the metabolite 3-methyl-4-nitrophenol was almost complete within 24 hours in subjects given single oral doses of approximately 0.042 to 0.33 mg/kg body weight fenitrothion. Peak excretion occurred after 12 hours and plasma cholinesterase inhibition was seen in only one subject at the highest dose (EXTOKNET, 1995).

Ecological Effects

Acute Exposure

Fenitrothion has been shown to be moderately to highly toxic to birds (WHO, 2004; U.S. EPA, 1995) and highly toxic to honeybees (U.S. EPA, 1995). It is also toxic to spider mites and has a long residual action (EXTOKNET, 1995). The toxicity of fenitrothion in birds ranges from highly toxic in game birds to slightly toxic in waterfowl. The oral LC₅₀ in pheasants was reported as 450–500 ppm for 2-week-old pheasants fed fenitrothion in the diet for 5 days (EXTOKNET, 1995). In bobwhite quail, an LC₅₀ of 157 ppm and an LD₅₀ of 23.6 mg/kg have been reported (U.S. EPA,

1995; EXTTOXNET, 1995). An LD50 of 1,190 mg/kg is reported in mallard ducks (EXTTOXNET, 1995). The oral LD50 for chickens is reported as 28 mg/kg and fenitrothion was negative for delayed neurotoxicity in hens (EXTTOXNET, 1995). In honeybees, the oral LD50 is reported between 0.02 and 0.38 µg/bee. In mammals, the acute oral toxicity data indicate that fenitrothion is moderately toxic to small mammals. Fenitrothion was acutely toxic to rats at 330 to 355 mg/kg (U.S. EPA, 1995). Additionally, fenitrothion was acutely toxic to mule deer at 727 mg/kg (EXTTOXNET, 1995).

Fenitrothion has been shown to be moderately toxic to both warm and coldwater fish (WHO, 2004; U.S. EPA, 1995). Acute 96-hour LC50 values range from 1.7 ppm for brook trout to 3.8 ppm for bluegill sunfish, while the 48-hour LC50 ranges from 2.0 to 4.1 mg/L in carp. In various North American freshwater fish, the 96-hour LC50 values range from 2 to 12 µg/L (EXTTOXNET, 1995). Studies have shown that the toxicity of fenitrothion in rainbow trout was dependent on the developmental stage of the fish during exposure and the water temperature. Fingerlings and adult fish were the most sensitive, the sac fry stage was intermediate, and embryos were least sensitive to the toxic effects of fenitrothion. Additionally, the toxicity increased as water temperatures increased. In fish, sublethal effects of fenitrothion exposure include morphological and anatomical changes, behavioral changes, biochemical changes, respiratory effects, and effects on growth (EXTTOXNET, 1995). Because fenitrothion breaks down rapidly, it does not accumulate in fish (WHO, 2004).

Fenitrothion is highly toxic in freshwater invertebrates. Acute exposure to 95 percent fenitrothion resulted in EC50/ LC50 values ranging from 4.3 ppb in Gammarus to 11 ppb in Daphnia magna (U.S. EPA, 1995). It is also moderately to very highly toxic to estuarine organisms. Acute exposure to 75 percent fenitrothion resulted in EC50/ LC50 values ranging from 1.5 ppb in pink shrimp to > 1,000 ppb in Sheepshead minnow (U.S. EPA, 1995).

Chronic Exposure

Chronic toxicity data for non-target terrestrial organisms are limited. Fenitrothion has been shown to cause reproductive impairment in birds. Chronic exposure to 17 ppm fenitrothion reduced egg production in bobwhite quail, with a NOEL of 13 ppm (U.S. EPA, 1995).

Limited data for chronic duration exposures of aquatic organisms were located. In fish, the chronic toxicity of fenitrothion is generally considered to be low (EXTTOXNET, 1995). In freshwater fish, studies have reported effects in rainbow trout chronically exposed to 94.5 percent fenitrothion. A LOEL of 88 ppb was determined for weight and length effects, with a NOEL of 46 ppm. In freshwater aquatic invertebrates, chronic exposure to 94.5 percent fenitrothion resulted in a 21 day LOEL of 0.23 ppb for adult daphnid survival in Daphnia magna with a NOEL of 0.087 ppb (U.S. EPA, 1995).

Profile for Propoxur:

CAS Registry Number 114-26-1

Summary of Insecticide

Chemical History

Propoxur is a broad spectrum, nonsystemic carbamate insecticide that was first introduced in 1959. It is used by homeowners and pest control operators in both agricultural and nonagricultural applications to kill a variety of chewing and sucking pests, mosquitoes, ants, flies, cockroaches, hornets, crickets, and lawn and turf insects (U.S. EPA, 1997a, 2000; EXTOWNET, 1996). Propoxur (Baygon) was first registered in the United States for pesticide use in 1963 and currently there are two registered technical products, several manufacturing use only products, and 173 registered products containing propoxur (U.S. EPA, 1997b).

Propoxur exhibits its toxic effects through reversible cholinesterase inhibition (U.S. EPA, 2000). It has moderate toxicity in mammals (WHO/FAO, 1976), high toxicity in birds, and moderate toxicity in fish (EXTOWNET, 1996; U.S. EPA, 1997b). Short-term exposures may cause effects on the nervous system, liver, and kidneys (IPCS, 1994). 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 inhalation exposures in humans results in cholinesterase inhibition, headaches, nausea, and vomiting (U.S. EPA, 2000). Propoxur pesticides are available as emulsifiable concentrates, wettable powders, dusts and powders, baits, aerosols, fumigants, granular baits, containerized baits, pest strips, shelf paper, pet flea collars, and oil sprays (EXTOWNET, 1996; U.S. EPA, 1997a). Applications methods include aerosol can and injection tube; concentrated liquid using a compressed air sprayer or hand or power sprayer; wettable powder using a ready-to-use sprayer liquid, a power or had pressurized sprayer, or a low pressure sprayer for oil soluble liquid (U.S. EPA, 1997b).

Description of Data Quality and Quantity

Extensive review data for propoxur are limited. Relevant resources include
Propoxur: Registration Eligibility Decision (RED) Document (U.S. EPA, 1997b)

IRIS summary review (U.S. EPA, 2006)

Pesticide Information Profile for Propoxur (EXTOWNET, 1996)

Data Sheet on Pesticides. No. 25: Propoxur (WHO/FAO, 1976)

International Safety Cards: Propoxur (IPCS, 1994).

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

Summary Table

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute, Intermediate, Chronic	Inhalation	0.004	mg/kg/day	Inhalation NOEL (2.2 mg/m ³) for neurological effects in rats, adjusted for	U.S. EPA (1997b)

				intermittent exposure and UF of 100 applied	
Acute, Intermediate, Chronic	Oral	0.005	mg/kg/day	Chronic RfD based on LOEL in humans with UF of 30 applied	U.S. EPA (1997b)
Acute, Intermediate, Chronic	Dermal	10	mg/kg/day	Dermal NOAEL for toxicity in rabbits with UF of 100 applied	U.S. EPA (1997b)
Cancer	Inhalation, Oral, Dermal	0.0037	per mg/kg/day	Cancer slope factor based on male rat bladder tumors	U.S. EPA (1997b)

For inhalation exposure, a NOEL of 2.2 mg/m³ (2.4 mg/kg/day)⁶ was identified in rats exposed to propoxur (Pauluhn, 1992, 1994) via inhalation for 6.3 hours per day, 5 days per week for 2 years. Significant plasma, red blood cell, and brain cholinesterase inhibition were observed at higher concentrations (U.S. EPA, 1997b). The concentration was adjusted for intermittent exposure⁷ (0.4 mg/kg/day) and an uncertainty factor of 100 was applied to account for interspecies and intrahuman variation, for an inhalation benchmark of 0.004 mg/kg/day. This value is appropriate for all exposure durations. However, the vapor pressure of propoxur is extremely low and significant human exposure via inhalation is not expected (U.S. EPA, 1997b).

For oral exposure, the chronic oral RfD of 0.005 mg/kg/day was calculated based on a LOEL of 0.15 mg/kg for a 40 percent red blood cell cholinesterase inhibition reported in a human exposure study (Vandekar et al., 1971) with an uncertainty factor of 30 applied to account for intrahuman variability (10) and the use of a LOEL (3) (U.S. EPA, 1997b). This value is appropriate for all exposure durations.

For dermal exposure, a NOEL of 1,000 mg/kg/day for lack of toxic effects in a subchronic rabbit study (Diesing and Flucke, 1989) is appropriate for all exposure durations (U.S. EPA, 1997b); an uncertainty factor of 100 was applied to account for interspecies and intrahuman variability. This value is appropriate for all exposure durations. However, studies indicate a very low absorption potential (<20 percent in humans) and/or hazard by the dermal exposure route (U.S. EPA, 1997b). EPA classified propoxur as a Group B2 chemical, probable human carcinogen. EPA calculated a unit risk of 3.7 x 10⁻³ per mg/kg/day based on bladder tumors in male rats (U.S. EPA, 1997b).

Insecticide Background

CAS #: 114-26-1

Synonyms: o-isopropoxyphenyl methylcarbamate (IUPAC); 2-(1-methylethoxy) phenyl methylcarbamate (CA) (WHO, 2005; U.S. EPA 1997b) 2-Isopropoxyphenyl

⁶ Conversion between mg/m³ and mg/kg/day assumes, for Wistar rats, an average body weight of 0.187 kg and inhalation rate of 0.2 m³/day (U.S. EPA, 1988).

⁷ Adjustment for intermittent exposure is the product of air concentration and exposure of 6.3/24 hours/day and 5/7 days/week.

methylcarbamate

Phenol, 2-(1-methylethoxy)-,methylcarbamate, Phenol, o-isopropoxy-, methylcarbamate, Propoxur [Phenol, 2-(1-methylethoxy) -, methylcarbamate 2-(1-Methylethoxy)phenyl methylcarbamate
PHC (PAN, 2005; IPCS, 1994)

Chemical Group: carbamate (EXTOXNET, 1996; U.S. EPA 1997b)

Registered Trade Names: Trade and other names for propoxur include: Arprocarb, Bay, Bay 9010, Bay 5122, Bay 9010, Baygon, Bayer 39007, Bifex, Blattanex, Blattosep, Brifur, Bolfo, BO Q 5812315, Chemagro 9010, Compound 39007, Dalf dust, DMS 33, ENT 25671, Invisi-Gard, OMS 33, PHC (JMAF), Pillargon, Prentox Carbamate, Propogon, Propotox, Propyon, Rhoden, Sendra, Sendran, Suncide, Tendex, Tugon, Fliegenkugel, UN Carbamate, Unden, and Undene (WHO, 2005; PAN, 2005; EXTOXNET, 1996; IPCS, 1994; WHO/FAO, 1976; IPCS, 1973)

Usage

Propoxur is a residual carbamate insecticide that has a variety of indoor uses, including the control of mosquitoes, ants, cockroaches, crickets, flies, bees, hornets, wasps, ticks, yellow jackets, bedbugs, fleas, woodlice, and spiders (U.S. EPA, 1997b; WHO, 2005; WHO/FAO, 1976). Indoor food applications include only crack and crevice treatment in food areas (U.S. EPA, 1997b). There are limited outdoor applications consisting mostly of perimeter and spot treatments of nests and lawn and turf insects (U.S. EPA, 1997b, 2000). Crop applications include sugar cane, cocoa, grapes, other fruit, maize, rice vegetables, cotton, lucerne, forestry, and ornamentals (WHO, 2005). Propoxur is used in the control of malaria and in pet flea collars (U.S. EPA, 2000). In public health and agricultural applications, propoxur is applied as a dust or by spraying (WHO, 2005). It is available in commercial products as a single active ingredient or combined with other pesticides (U.S. EPA, 1997b).

Formulations and Concentrations

Common formulations of pesticides containing propoxur include technical grade propoxur, emulsifiable concentrates, wettable powders, baits, aerosols, fumigants, granules, and oil sprays (EXTOXNET, 1996). Typical formulations and percent propoxur content include ready-to-use liquid (0.5–1 percent), pressurized aerosol liquid (0.25–2 percent), oil-soluble liquid/liquid concentrate (8–19.6 percent propoxur), pastes (2 percent), wettable powders (70 percent), solid baits (0.25–2 percent), pet flea collars (impregnated plastic) (0.4–10 percent), impregnated shelf papers (1 percent), and insecticidal tapes (10 percent) (U.S. EPA, 1997b). Common formulations used for agricultural, horticultural, and forestry applications include wettable powders (50 percent), dusts (1–2 percent), granules, oils, emulsifiable concentrates (200 g/L; 20 percent w/w), pressurized sprays, smokes, baits (various concentrations) (WHO/FAO, 1976; IPCS, 1973).

WHO (2005) indicated that the propoxur content in various preparations should be declared and contain the following:

Technical grade propoxur: not less than 980 g/kg

Wettable Powder: 500 g/kg \pm 5% of the declared content.

Shelf Life

Propoxur is reported to be stable under normal storage and use conditions (IPCS, 1973) but unstable in highly alkaline media. The half-life propoxur is reported as 40 minutes at pH 10 at 20°C (WHO/FAO, 1976). WHO (2005) reported that following storage at 54 \pm 2°C for 14 days, 97 percent or greater of the active ingredient must be present in wettable powder formulations.

Degradation Products

In vivo, propoxur is biotransformed by depropylation to 2-hydroxyphenol-N-methylcarbamate and by hydrolysis to the phenol. The glucuronides detected in urine are accounted for by ring hydroxylation and isopropoxy hydroxylation followed by conjugation. Major metabolites in rats include 5-hydroxy-2-isopropoxyphenyl n-methylcarbamate, 2-hydroxyphenyl n-methylcarbamate, o-isopropoxyphenol, o-isopropoxyphenyl, and n-hydroxymethylcarbamate. In mice, the major metabolites include o-isopropoxyphenyl n-hydroxymethylcarbamate. In bean plants, the major metabolites include 4-hydroxy-2-isopropoxyphenyl n-methylcarbamate, 2-hydroxyphenyl n-methylcarbamate, and o-isopropoxyphenyl n-hydroxymethylcarbamate (HSDB, 2005). Limited human data are available. Many propoxur metabolites were found in the urine of a person attempting suicide by ingestion of a large quantity of the emulsifiable concentrate formulation. These were present both as free compound or conjugated with glucuronide or sulfate. As in other species, biotransformation was from depropoxylation, hydrolysis of the ester bond and ring hydroxylation (IPCS, 1989).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Propoxur is expected to be moderately to very highly mobile and moderately persistent in soil (HSDB, 2005; U.S. EPA, 1997a, 1997b; EXTOXNET, 1996). With a K_{oc} ranging from <1 to 103, high to very high mobility is expected if propoxur is released in soil (HSDB, 2005); however, the mobility depends on the soil type and previous exposures to propoxur. Biodegradation in soil is more rapid in previously exposed soils. In many soil types, propoxur is highly mobile due to its low affinity for soil binding (EXTOXNET, 1996; U.S. EPA, 1997a, 1997b). It evaporates from soil, with the amount increasing with the moisture content of the soil, and the half-life is 6–8 weeks, depending on the soil type (IPCS, 1973). Data from studies of the persistence of propoxur in several soil types suggest that it moves rapidly through all soil profiles below the 12 inch sampling depth. Its fate and transport characteristics are similar to those chemicals that are known to leach into groundwater (U.S. EPA, 1997b).

Hydrolysis appears to be the primary mode of degradation (U.S. EPA, 1997b). At neutral pH, propoxur is hydrolytically stable but degrades rapidly at alkaline pH values (U.S. EPA, 1997b). Half-life values of a propoxur in aqueous solutions at 20°C are reported to range from 1 minute at pH 12.8 to 40 minutes at pH 10.8 (IPCS, 1973). Half-life values of 16 days at pH 8, 1.6 days at pH 9, and 0.17 days at pH 10 are reported (U.S. EPA, 1997b). Volatilization is not expected to be a major fate process from moist soil surfaces (HSDB, 2005). The major fate process in moist soils is biodegradation. Under aerobic conditions, biodegradation half-lives of 80 days in silt loam soil and 120 days in sandy loam soil are reported (HSDB, 2005). On inert surfaces, however, volatilization is the main fate process. On a glass surface, 50 percent of a propoxur residue was still present 1.8 hours after application (IPCS, 1973). Propoxur in soil shows no or little susceptibility to photolysis

(U.S. EPA, 1997b; IPCS, 1973). Half-lives of several months were reported for the degradation of propoxur under aerobic and anaerobic conditions (U.S. EPA, 1997b).

Fate and Transport in Aquatic Systems

Propoxur is highly soluble in water and there is a high likelihood of groundwater penetration because it does not adsorb strongly to soil particles (HSDB, 2005; EXTOXNET, 1996; U.S. EPA, 1997a). It is relatively stable in water at pH 7 or less but hydrolyzes rapidly at pHs greater than 7 (IPCS, 1973). In a 1 percent aqueous solution at pH 7, propoxur hydrolyzes at a rate of 1.5 percent per day (EXTOXNET, 1996). Reported field half-lives for propoxur are 14–50 days (EXTOXNET, 1996). The hydrolysis half-life of propoxur is reported to be 1 year at pH 4, 93 days at pH 7, and 30 hours at pH 9 (HSDB, 2005). Volatilization from water is not expected to be a major fate process. However, propoxur is susceptible to photolysis in water (U.S. EPA, 1997b). The half-life of propoxur irradiated with light more than 290 nm is reported as 88 hours (HSDB, 2005). Because propoxur degrades rapidly in water, bioconcentration in fish is unlikely (HSDB, 2005).

Human Health Effects

Acute Exposure

Effects/Symptoms

Propoxur causes its toxic effects by reversible inhibition of cholinesterase. Short-term exposures may cause effects on the nervous system, liver, and kidneys (IPCS, 1994). 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 (U.S. EPA, 2000). Limited data exist on the human health effects of acute exposure to propoxur. In volunteers, a single oral dose was reported to cause stomach discomfort, sweating, and redness of the face. However transient erythrocyte cholinesterase activity inhibition (up to 27 percent) was observed at a higher level and was associated with vomiting, sweating, and blurred vision (WHO/FAO, 1976). When used to control for malaria, spray operators experienced occasional short-lasting symptoms including nausea, headache, sweating, and weakness from which they quickly recovered (WHO/FAO, 1976; EXTOXNET, 1996). Additionally, some mild reactions were reported by residents where it was applied (WHO/FAO, 1976).

In animals, propoxur is acutely toxic via the oral, inhalation, and dermal routes (U.S. EPA 1997b, 2000; EXTOXNET 1996). Acute inhalation and dermal exposures are moderate to highly toxic while oral exposures are highly to be extremely toxic (U.S. EPA, 1997a, 2000). Propoxur is highly toxic to animals via ingestion. In rats, the oral LD50 for propoxur ranges from 68 mg/kg in females to 116 mg/kg in males (EXTOXNET, 1996; WHO/FAO, 1976; U.S. EPA, 1997b). In other species, reported oral LD50 values include approximately 100 mg/kg in mice and 40 mg/kg in guinea pigs (EXTOXNET, 1996). Reported dietary levels causing no toxic effects in animals include 300mg/kg/day for mice, 10 mg/kg/day for rats, and 5 mg/kg/day for dogs (IPCS, 1989). Via the dermal route, the reported LD50 values in various species include greater than 2,400 mg/kg in rats (EXTOXNET, 1996; WHO/FAO, 1976) and 500 mg/kg to > 2000 mg/kg in rabbits (EXTOXNET, 1996; U.S. EPA, 1997b). Via inhalation, the reported LC50 values include a 4-hour LC50 of >0.5 mg/L in rats (U.S. EPA, 1997b) and a 1-hour LC50 of > 1.44 mg/L (EXTOXNET, 1996).

Similar to its effects in humans, acute exposure to propoxur in animals causes symptoms typical of cholinesterase inhibition (EXTOXNET, 1996; U.S. EPA, 1997b). Cholinesterase depression, muscle spasms, and salivation have been reported within 10 minutes of oral administration in rats (U.S. EPA, 1997b). In rats fed propoxur in their diet for 16 weeks, whole blood cholinesterase was

inhibited at dietary levels over 500 ppm while plasma, whole blood, and brain cholinesterase were inhibited at dietary levels greater than 1,000 ppm at study termination. Signs of cholinesterase inhibition were also observed in both rats and mice within 15 minutes of exposure to different concentrations of propoxur aerosol (WHO/FAO, 1976). Brain pattern and learning ability changes can occur at lower concentrations than those that cause cholinesterase inhibition and/or organ weight changes (EXTOXNET, 1996).

Although propoxur is a mild eye irritant in rabbits, it is not a skin irritant in rabbits or a dermal sensitizer in guinea pigs (U.S. EPA, 1997b). Acute exposure to propoxur is not considered to be teratogenic in rats (WHO/FAO, 1976).

Treatment

Exposure to propoxur may be determined through laboratory tests that determine cholinesterase levels in blood with erythrocyte cholinesterase being a more informative indicator than either plasma or whole blood. However, the enzyme will only be inhibited for a few hours following exposure. Additionally, phenol metabolites may be determined in urine (WHO/FAO, 1976; U.S. EPA, 2000). However, neither of these tests are reliable indicators of total exposure because they are not specific for propoxur (U.S. EPA, 2000).

Propoxur poisoning should be treated by first removing any contaminated clothing, and washing affected skin with soap and water and flushing the area with large amounts of water (WHO/FAO, 1976; IPCS, 1994). If propoxur gets in the eyes, they should be rinsed immediately with isotonic saline or water. Contact lenses should be removed, if possible. Oral exposure to propoxur should be treated by administration of activated charcoal (HSDB, 2005; IPCS, 1994). Rapid gastric lavage with 5 percent sodium bicarbonate is indicated if the patient is not already vomiting. Medical attention should be sought (WHO/FAO, 1976; HSDB, 2005). Inhalation exposures should be treated by removal to fresh air, placing in a half-upright position, monitoring for respiratory distress, and seeking medical attention (HSDB, 2005; IPCS, 1994). Because propoxur is quickly metabolized and symptoms are of a short duration, atropine treatment is not usually necessary by the time the patient reaches medical help (WHO/FAO, 1976). However, adults showing signs of propoxur toxicity should be treated with 1–2 mg atropine sulfate given intramuscularly or intravenously as needed. Oxygen may be necessary for unconscious patients or those in respiratory distress. Pralidoxime is usually not necessary unless the poisoning is severe. Barbiturate and central stimulants are contraindicated (HSDB, 2005; WHO/FAO, 1976).

Chronic Exposure

Noncancer Endpoints

Limited data are available on the effects of chronic exposure to propoxur in humans. Chronic effects are expected to be similar to acute effects (EXTOXNET, 1996). Cholinesterase inhibition, headaches, vomiting, and nausea were reported in humans following chronic inhalation exposure (U.S. EPA, 2000). When used to control for malaria, spray operators experienced occasional short lasting symptoms including nausea, headache, seating, and weakness from which they quickly recovered (WHO/FAO, 1976). No data are available on human reproductive or developmental effects (U.S. EPA, 2000).

In animals, propoxur is quickly detoxified and does not accumulate in body tissues over time. Daily doses approximating the LD50 have been tolerated by rats for long periods of time when the dose was given over the course of the day (EXTOXNET, 1996; WHO/FAO, 1976). Chronic oral exposure to propoxur in animals has been reported to cause cholinesterase inhibition, decreased body

weight, liver and bladder effects, and a small increase in neuropathy (U.S. EPA, 1997b, 2000; WHO/FAO, 1976). Significant plasma, red blood cell, and brain cholinesterase inhibition was observed in male and female rats exposed to propoxur in air over a 2-year period (U.S. EPA, 1997b).

The nervous system and liver are the main organs affected by propoxur in both humans and animals (EXTOXNET, 1996). Increased liver weights were observed in rats fed propoxur in feed for 2 years (WHO/FAO, 1976). Reproductive and developmental effects have not been reported in rabbits orally exposed to propoxur. However, some fetotoxicity, decreased litter size, central nervous system impairment in offspring, and decreased fetal weights have been reported in rats orally exposed to propoxur (U.S. EPA, 1997b, 2000; WHO/FAO 1976). The data indicate that reproductive effects in humans are not expected at typical exposure levels and teratogenic effects will occur only at high levels (EXTOXNET, 1996). The available data indicate that propoxur is not mutagenic (EXTOXNET, 1996; U.S. EPA, 1997a).

Cancer Endpoints

EPA's OPP has classified propoxur as Group B2, probable human carcinogen, with a unit risk of 3.7×10^{-3} per mg/kg/day (U.S. EPA, 1997a, 1997b). No information is available on the carcinogenicity of propoxur in humans (U.S. EPA, 2000). A significant increase in bladder papillomas and/or carcinomas was reported in male rats while a significant increase in hepatocellular adenomas and combined adenoma/carcinoma was reported in male mice (U.S. EPA, 1997b, 2000). High dose exposure to propoxur is also associated with an increase in tumors of the uterus (U.S. EPA, 2000).

Toxicokinetics

Like most carbamates, propoxur can be absorbed through the oral, inhalation, and dermal pathways (HSDB, 2005; IPCS, 1994; WHO/FAO, 1976). It is readily absorbed by the lungs (HSDB, 2005) and gastrointestinal tract (IPCS, 1994) but to a lesser extent through the skin (WHO/FAO, 1976). Dermal rat studies indicate that absorption decreases with dose in a nonlinear way. Absorption of a dermal dose of $6.91 \mu\text{g}/\text{cm}^2$ was 7.88, 10.2, 17.9, 23.2 and 32.5 percent for durations of 0.5, 1, 2, 4, 8, and 32 hours, respectively, which was a higher rate of absorption than in human studies of 8 and 24 hour exposures. Human studies indicate that the rate of 19.6 percent absorption most closely approximates the rate expected in the field (U.S. EPA, 1997b). Approximately 16 percent of the dose of radiolabeled propoxur applied to the forearms of volunteers was available for percutaneous absorption (HSDB, 2005). Additionally, the rate of dermal absorption is affected by the solvent used (U.S. EPA, 1997b).

Propoxur and its metabolites are distributed by the lymph system. Metabolism studies in rats exposed to radiolabeled propoxur have shown radioactivity in all organs (especially the intestines) except bones at 1 hour. High concentrations of radioactivity were still present in the gastrointestinal tract, bladder, and mucous membranes of the pharyngeal system after 24 hours. Some radioactivity was still present in the liver, kidneys, and mucous membranes of the pharyngeal region at 48 and 72 hours (U.S. EPA, 1997b). Peak concentrations were seen in the blood (at 15 minutes), brain (1 hour), liver (4 hours), and kidneys (6 hours) after oral exposure to 50 mg/kg propoxur, with the highest concentrations seen in the kidneys and the lowest concentration in the brain (HSDB, 2005). Ingested propoxur is rapidly absorbed, broken down, and excreted in the urine (EXTOXNET, 1996; U.S. EPA 1997b). The major routes of metabolism in rats are depropylation to

2-hydroxyphenyl-N-Methylcarbamate and hydrolysis to isopropoxyl phenyl. Peak circulating and tissue concentrations of isopropoxyl phenol were achieved 30–60 minutes after a single oral dose in rats (HSDB, 2005). Because of its rapid metabolism and excretion, propoxur does not accumulate in mammalian tissues (EXTOXNET, 1996). The main route of excretion for propoxur is probably the urine (WHO/FAO, 1976) accounting for 60–95 percent of the dose (HSDB, 2005). In humans, 38 percent of a single oral dose of Baygon was excreted in the urine within the first 24 hours. Of that, most was excreted by the first 8–10 hours (EXTOXNET, 1996). In dermal studies in humans, total excretion was 19.6 percent of the total dermal dose (U.S. EPA, 1997b). Lesser amounts of propoxur are excreted as carbon dioxide (20–26 percent) and in feces (4 percent) (HSDB, 2005).

Ecological Effects

Acute Exposure

Acute exposure to technical grade propoxur is very highly toxic to many bird species (EXTOXNET, 1996; U.S. EPA, 1997b). Remarkable variation in the results of dietary studies of the toxicity of propoxur has been reported. Oral LD50 values for 97 percent ai in a 2 percent bait product range from 4.2 mg ai/kg body weight in mourning doves to 120 mg ai/kg body weight in sharp-tailed grouse (U.S. EPA, 1997b; EXTOXNET, 1996). An unexplained phenomenon where, in some instances, birds of a given species are able to metabolize propoxur has been reported. U.S. EPA (1997b) indicated more confidences in the LD50 values for Mallard ducks (9.44 mg ai/kg) and Bobwhite quail (1,005 mg ai/kg formulated product). In the diet, subacute 5-day LC50 values range from 206 ppm in Northern bobwhite quail exposed to an unknown concentration to greater than 5,000 ppm in Mallard ducks exposed to 98.8 percent ai and Japanese quail exposed to an unknown concentration (U.S. EPA, 1997b). The reported oral LD50 in mule deer is 100–350 mg/kg (EXTOXNET, 1996). Additionally, propoxur has been found to be highly toxic to honeybees (EXTOXNET, 1996).

Propoxur is expected to pose a minimal risk to aquatic organisms because of its limited outdoor bait use (U.S. EPA, 1997b). However, when exposures occur, they pose a slight to moderate acute risks to fish and other aquatic species (EXTOXNET, 1996). In freshwater fish, propoxur is moderately toxic with LC50 values ranging from >1–10 ppm (U.S. EPA, 1997b). The reported 96-hour LC50 values range from 3.7 ppm in rainbow trout exposed to 98.8 percent ai to 25 ppm in fathead minnow exposed to 88 percent ai (U.S. EPA, 1997b; EXTOXNET, 1996). The 96-hour LC50 for bluegill sunfish was reported as of 6.6 mg/L (EXTOXNET, 1996).

Propoxur is more toxic in freshwater and estuarine invertebrates. Acute exposure to technical grade propoxur is very highly toxic to freshwater and estuarine invertebrates with EC/LC50 values of 0.011 ppm in daphnids, 0.034 ppm in amphipods, 0.18 ppm in stonefly, and 0.041 ppm in pink shrimp (U.S. EPA, 1997b). An oral LD50 of 595 mg/kg was reported for propoxur in bullfrogs (EXTOXNET, 1996).

Chronic Exposure

Very little data exist for chronic exposure to propoxur in non-target terrestrial organisms. In birds, no reproductive effects were seen in Northern bobwhite quail fed diets containing greater than 320 ppm (98 percent ai) of propoxur for a number of weeks. No effects on brain cholinesterase were seen at concentrations up to 80 ppm. In Mallard ducks, no reproductive or brain cholinesterase effects were seen in birds fed diets containing 80 ppm (98 percent ai) for 23 weeks. However, reduced egg production and embryo survival were noted at 320 ppm (U.S. EPA, 1997b). Little or

no data exist for chronic exposure to propoxur in marine/estuarine organisms. However, no significant accumulation of propoxur is expected in aquatic organisms (EXTOXNET, 1996).

Profile for Pirimiphos-Methyl:

CAS Registry Number 29232-93-7

Summary of Insecticide

Chemical History

Pirimiphos-methyl is a fast-acting, broad spectrum, noncumulating organophosphate insecticide and acaricide used in agricultural, horticultural, and public health applications (WHO/FAO, 1983, 1974). In public health applications, it is used to control disease vector insects, including mosquitoes, ants, beetles, bed-bugs, cockroaches, fleas, flies, lice, and mites (WHO/FAO, 1983, 1974). Pirimiphos-methyl has both contact and fumigant action (WHO/FAO, 1974). It is applied as a liquid concentrate, ready to use formula, and as treated articles (ear tags) (U.S. EPA, 1999b). It can be applied by closed system containers, low- and high-pressure hand wands, backpack sprayers, tagging equipment, and foggers (U.S. EPA, 2001). Pirimiphos-methyl acts like other organophosphates by inhibiting cholinesterase activity (U.S. EPA, 1999d). It is of low mammalian toxicity (WHO/FAO, 1983). WHO/FAO (1992) has classified it as slightly hazardous. Early symptoms of pirimiphos-methyl exposure include excessive sweating, headache, weakness, giddiness, nausea, vomiting, stomach pains, blurred vision, slurred speech, and muscle twitching. Symptoms of more severe poisoning may advance to convulsions, coma, loss of reflexes, and loss of sphincter control (WHO/FAO, 1983).

Description of Data Quality and Quantity

Comprehensive reviews on the toxicity of pirimiphos-methyl have been prepared:
Interim Reregistration Eligibility Decision for Pirimiphos-methyl Case No. (2535) (U.S. EPA, 2001)
IRIS summary review (U.S. EPA, 2006)

Data Sheet on Pesticide No. 49 – Pirimiphos-methyl (WHO/FAO, 1983).

EPA has developed quantitative human health benchmarks that include an oral acute and chronic RfD and short- and intermediate-term inhalation and dermal benchmarks.

Summary Table

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute	Inhalation	0.015	mg/kg/day	Oral LOAEL for neurological effects in rats with UF of 1000 applied; assume no portal of entry effects	U.S. EPA (2001)
Intermediate	Inhalation	0.0007	mg/kg/day	Oral LOAEL for neurological effects in rats with UF of 300 applied; assume no portal of entry effects	U.S. EPA (2001)
Chronic	Inhalation	0.0007	mg/kg/day	Adopt intermediate for chronic duration	U.S. EPA (2001)
Acute	Oral	0.015	mg/kg/day	Acute oral RfD based on a LOAEL of 15 mg/kg/day for neurological effects in rats and UF of 1,000 applied	U.S. EPA (2001)
Intermediate	Oral	0.0002	mg/kg/day	Adopt chronic RfD for intermediate duration	U.S. EPA (2001)
Chronic	Oral	0.0002	mg/kg/day	Chronic oral RfD based on a LOAEL of 0.2 mg/kg/day for neurological effects in rats and UF of 1,000 applied	U.S. EPA (2001)
Acute	Dermal	0.015	mg/kg/day	Oral LOAEL for neurological effects in rats with UF of 1,000 applied; assume no first pass effects and 100% oral absorption	U.S. EPA (2001)
Intermediate	Dermal	0.0007	mg/kg/day	Oral LOAEL for neurological effects in rats with UF of 300 applied; assume no first pass effects and 100% oral absorption	U.S. EPA (2001)
Chronic	Dermal	0.0007	mg/kg/day	Adopt intermediate for chronic duration	

For oral exposure, an acute RfD of 0.015 mg/kg/day was derived based on a LOAEL of 15 mg/kg/day for brain, red blood cell, and plasma cholinesterase inhibition in rats (EPA MRID# 43594101, citation not provided). An uncertainty factor of 1,000 was applied for the use of a LOAEL and the degree of cholinesterase inhibition (10), and intra- and inter-species variability (100) (U.S. EPA, 2001).

A chronic oral RfD of 0.0002 mg/kg/day was derived based on an LOAEL of 0.2 mg/kg/day for plasma cholinesterase inhibition in a subchronic rat study (EPA MRID# 43608201, citation not provided). An uncertainty factor of 1,000 was applied for the use of a LOAEL and data gaps for long-term studies (10), and intra- and inter-species variability (100) (U.S. EPA, 2001). The chronic RfD was used to represent intermediate exposures.

For inhalation and dermal exposure, the oral toxicity endpoints (i.e., LOAELs) were selected for use, and both assume 100 percent absorption and no first pass or portal-of-entry effects (U.S. EPA, 2001). For acute inhalation and dermal benchmarks, an uncertainty factor of 1,000 was applied for the use of a LOAEL and the degree of cholinesterase inhibition (10), and intra- and inter-species variability (100). For intermediate inhalation and dermal benchmarks, an uncertainty factor of 300 was applied for the use of a LOAEL (3) and intra- and inter-species variability (100). The intermediate benchmark was used to represent chronic exposures.

Insecticide Background

CASRN:	29232-93-7
Synonyms:	O-(2-Diethylamino)-6-methyl-4-pyrimidinyl O,O-dimethyl phosphorothioate, 2-diethylamino-6-methylpyrimidin-4-yl dimethyl phosphorothionate, pirimifosmethyl, methylpirimiphos, pyridimine phosphate, ENT 27699GC, PP511, CMS 1424 (U.S. EPA, 2001, 2006; WHO/FAO, 1983)
Chemical Group:	organophosphate (U.S. EPA, 2001; WHO/FAO, 1983)
Registered Trade Names:	Actellic 5E, Atellic, Atellic, Atellifog, Blex, Nu-Gro Insecticide, Nu-Gro 5E, Tomahawk Insecticide Ear Tags, LPM Insecticide Ear Tags, Silosan, Sybol (U.S. EPA, 2001, 2006; WHO/FAO, 1983)

Usage

Pirimiphos-methyl is a fast-acting, broad spectrum organophosphate insecticide and acaricide used to control a wide variety of sucking and chewing pests in agricultural and horticultural applications. It is used in horticultural applications; to clean fruits and vegetables before harvest; to control pests on stored products; and to eradicate nuisance and disease vector insects, including mosquitoes, ants, beetles, bed-bugs, cockroaches, fleas, flies, lice, and mites (WHO/FAO, 1983, 1974). The intended uses of existing products include greenhouse applications, treatment of stored grain and seeds (corn and sorghum) intended for both human and animal consumption, and direct animal applications including incorporation into cattle eartags and sprays (U.S. EPA, 1999c, n.d.).

Pirimiphos-methyl is used to control a large number of different insects including, but not limited to, cigarette beetles; confused flour beetles; corn sap beetles; flat grain beetles; hairy fungus beetles; red flour beetles; sawtoothed beetles; granary weevils; maize weevils; merchant grain beetles; rice weevils; lesser grain borers; and angoumois grain moths, Indian meal moths, and almond moths on corn (seed and whole-grain), rice (whole-grain), wheat (whole-grain), and grain sorghum (seed and whole-grain); mealy bugs; mites (iris bulbs) horn flies and face flies (U.S. EPA, 2001). For malaria control, typical use includes the application of 1 or 2 g pirimiphos-methyl/m³ of a 2–5 percent suspension to indoor walls and ceilings every 3 months. Ultra-low-volume (ULV) sprays

and thermal fogs are additional application methods. To control DDT resistant fleas, a 2 percent dust is applied in rodent burrows. Pirimiphos-methyl is not recommended for use directly on humans or on processed foods (WHO/FAO, 1983; U.S. EPA, 1999c). Current registered uses in the United States include food and non-food uses. Food uses include use on sorghum, corn (grain and seed), nonlactating dairy cattle, beef/range/feeder cattle, and calves. Non-food uses include use on iris bulbs. No residential or public health uses are currently registered in the United States (U.S. EPA, 2001)

Formulations and Concentrations

There are several typical formulations for pirimiphos-methyl, each formulation varying in the amount of active ingredient (ai) it contains. The typical formulations for pirimiphos-methyl include (U.S. EPA, 1999c, 2001; WHO/FAO, 1983) the following:

- U.S. registered formulations: emulsifiable liquid concentrate (57 percent ai), treated ear tags (14 percent and 20 percent ai)
- For agricultural and horticultural uses: emulsifiable concentrate (250–500 g ai/L), ULV concentrate (500 g ai/L), encapsulated formulas (250–400 g ai/kg), dusts (10 and 20 g ai/kg), wettable powders (250 and 400 g ai/kg), fog (100 g ai/L), aerosol (20 g ai/L with pyrethroids), solvent free formulation (900 g ai/kg), smoke generator formulation
- For public health uses: emulsifiable concentrate (250 and 500 g ai/L), ULV concentrate (500 g ai/L), encapsulated formulation (200 g ai/L), dusts (10 and 20 g ai/kg), wettable powder (250 and 400 g ai/kg), fog (100 g ai/L), aerosol (20 g ai/L with pyrethroids), solvent-free formulation (900 g ai/kg), smoke generator formulation
- For household uses: emulsifiable concentrate (80 g ai/L), dusts and aerosols (with pyrethroids) for use in the home and garden.

Degradation Products

Stored pirimiphos-methyl products are broken down by hydrolysis of the phosphorus-ester side chain, which results primarily in the parent hydroxyl-pyrimidine (WHO/FAO, 1974). The main hydrolysis degradates at pH 5, 7, and 9 were 2-(diethylamino)-4-hydroxy-6-methyl pyrimidine and O-2-diethylamino-6-methylpyrimidin-4-yl o-methyl-phosphorothioate (U.S. EPA, 2001). In soil, the major metabolite is the parent hydroxypyrimidine (IV) together with smaller amounts of the related compounds (V) and (VI). Compound (IV) is the major degradation product in water with only trace quantities of the P=O analogue (III) detected (WHO/FAO, 1974).

In humans, pirimiphos-methyl is broken down into the degradation products desethyl pirimiphos-methyl and pirimiphos-methyloxon, which are also active and have transient stability (WHO/FAO, 1983). When pirimiphos-methyl is broken down in rats and dogs, the major urinary metabolite (30 percent of administered dose) was 2-ethylamino-4-hydroxy-6-methylpyrimidine. Other metabolites included 4-O-(2-diethylamino-6-methylpyrimidinyl)- β -D-glucosiduronic acid (11 percent of dose in dogs), an unidentified phosphorus-containing product likely to be a dealkylated derivative of either pirimiphos-methyl or its oxygen analogue (12 percent of dose in rats), and 2-amino-4-hydroxy-6-methyl pyrimidine (8 percent of dose in rats and 5 percent of dose in dogs) (WHO/FAO, 1992).

Shelf Life

Under normal storage conditions at room temperature, pirimiphos-methyl is stable for up to 6 months. However, it decomposes in sunlight (WHO/FAO, 1983).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Pirimiphos-methyl has limited mobility and persistence in soil (WHO/FAO, 1974). For a variety of soil types, pirimiphos-methyl has a half-life of less than one month (WHO/FAO, 1974). It hydrolyzes rapidly in acidic soils and is stable in neutral and alkaline environments with a half-life of 7.3 days at pH 5, 79 days at pH 7, and 54–62 days at pH 9 (U.S. EPA, 2001). Pirimiphos-methyl decomposes in sunlight (WHO/FAO, 1983).

Fate and Transport in Aquatic Systems

Pirimiphos-methyl is not expected to have a significant impact on water resources due to the lack of significant outdoor uses (U.S. EPA, 2001). It degrades in water mainly by hydrolysis, which is attenuated by sunlight. In sunlight, 50 percent degradation occurs within one day. Volatilization also occurs from still water; however, it is not as significant as hydrolysis (WHO/FAO, 1974).

Human Health Effects

Acute Exposure

Effects/Symptoms

Similar to other organophosphates, pirimiphos-methyl is a cholinesterase inhibitor and interferes with the normal functioning of the nervous system. It causes dose-related reversible decreases in plasma, red blood cell, and brain cholinesterase at very low doses by ingestion, dermal, and inhalation exposures. It is of relatively low acute oral, dermal, and inhalation toxicity (U.S. EPA, 1999b). In two human studies, volunteers were fed a dose of 0.25 mg/kg/day for up to 56 days. Marginal plasma cholinesterase depression was observed after both dosing periods (U.S. EPA, 1998b, 2006). However, these studies have many deficiencies and should be used as supplemental data. When compared to animal data, they provide some evidence that humans may be more sensitive than animals as is indicated by the lower effect level for cholinesterase inhibition in humans (U.S. EPA, 1999b). No human poisonings from mishaps with pirimiphos-methyl have been reported (WHO/FAO, 1983).

Animal studies have shown that pirimiphos-methyl is only slightly toxic following acute oral and dermal exposures, with reported LD50 values in rats of >2,400 mg/kg (U.S. EPA, 1999a). Other reported oral LD50s are as follows: rabbit (male) 1,154–2,300 mg/kg, mouse (male) 1,020–1,360 mg/kg, guinea pig (female) 1,000–2,000 mg/kg, dog (male) > 1,500 mg/kg, and cat (female) 575–1,150 mg/kg. The reported dermal LD50 is > 4,500 mg/kg in female rats (WHO/FAO, 1983), >4,050 mg/kg in female rabbits, and 2,200–4,050 mg/kg in male rabbits (U.S. EPA, 2001, 1999a, 1998a). The reported acute inhalation LC50 is > 4.7 mg/L for rats (U.S. EPA, 2001, 1999a, 1998a). Among mammals, no one species appears to be more susceptible. However, the hen is appears to be highly susceptible with a reported LD50 of 79–80 mg/kg (WHO/FAO, 1983). Clinical signs of exposure include neurotoxicity, excessive salivation, abnormal gait, ataxia, and leg paralysis. Dermal exposure also decreased plasma cholinesterase levels (WHO/FAO, 1983). Eye and skin irritation have been observed in rabbits (U.S. EPA 1999d, 1998b); however, pirimiphos-methyl has not been shown to be a dermal sensitizer in guinea pigs or rats (U.S. EPA, 1998b; WHO/FAO, 1983).

Treatment

Exposure to pirimiphos-methyl may be determined through laboratory tests of urine and blood that measure breakdown products of pirimiphos-methyl in urine or cholinesterase levels in blood. Blood levels of cholinesterase, especially in plasma, are the most useful in diagnosis of poisoning. However, neither urinary or blood tests are specific for pirimiphos-methyl exposure. Early symptoms of pirimiphos-methyl exposure include excessive sweating, headache, weakness, giddiness, nausea, vomiting, stomach pains, blurred vision, slurred speech, and muscle twitching. Symptoms of more severe poisoning may advance to convulsions, coma, loss of reflexes, and loss of sphincter control. Following dermal exposures, the person should stop working and any contaminated clothing should be removed. Exposed areas of skin should be washed with soap and water and flushed with large quantities of water. For oral exposures, vomiting should not be induced unless a potential lethal dose has been ingested and the person is conscious. Care should be taken as the vomitus may contain toxic amounts of the chemical. Once under medical care, potential lethal doses should be treated by rapid gastric lavage unless the patient is already vomiting. Any ocular exposure should be treated by washing with isotonic saline. If no respiratory insufficiency is noted, peripheral symptoms should be treated with 2–4 mg of atropine sulfate and 1,000–2,000 mg pralidoxime chloride or 250 mg toxogonin (adult dose) by slow intravenous injection. If severe respiratory difficulties, convulsions, and unconsciousness are present, atropine and a reactivator should be given immediately. The airway should be maintained. Morphine, barbiturates, phenothiazine, tranquilizers, and central nervous system stimulants are all contraindicated (WHO/FAO, 1983).

Chronic Exposure

Noncancer Endpoints

Workers in two WHO-supervised health spray program did not show any signs of pesticide poisoning; however, at the end of one of the programs, plasma cholinesterase activity was 70–75 percent of the mean of pre-exposure values. The people living in the spray areas exhibited no signs of poisoning and no effect on cholinesterase activity. Volunteers exposed to 0.25 mg/kg/day for up to 56 days exhibited no toxic effects on liver function or blood tests and an acceptable daily intake (ADI) of 0.01 mg/kg was established (WHO/FAO, 1983).

Chronic exposure data in animals indicates that a main target of pirimiphos-methyl toxicity is the nervous system. Rats repeatedly exposed to high doses of pirimiphos-methyl showed a cumulative inhibitory effect on cholinesterase (WHO/FAO, 1983). In 90-day and 2-year dietary studies in rats, plasma cholinesterase and some erythrocyte and brain cholinesterase inhibition was reported. In a 2-year dog study and an 80-week mouse study, similar effects were observed (WHO/FAO, 1983). In developmental and reproductive toxicity studies in rats and rabbits, maternal/parental NOELs were less than or the same as offspring NOELs. No increased sensitivity was noted in fetuses or pups. There is no evidence that pirimiphos-methyl is teratogenic in rat or rabbit feeding studies (U.S. EPA, 1998b, 2006; WHO/FAO, 1983). In several mammalian studies, no mutagenic potential was observed (U.S. EPA, 1998b; WHO/FAO, 1983).

Cancer Endpoints

EPA determined that the carcinogenic potential of pirimiphos-methyl could not be determined because a reliable rat carcinogenicity study is lacking (U.S. EPA, 1998b). In an 80-week mouse feeding study, a 78-week mouse feeding study, a 80-week mouse oral study, a 2-year rat feeding study, a 78-week rat feeding study, and a 2-year oral dog study, no evidence of carcinogenic potential was identified (WHO/FAO, 1983; U.S. EPA, 1998b, 2006). Additionally, mammalian

mutagenicity studies do not provide any evidence that supports a carcinogenic potential for pirimiphos-methyl (WHO/FAO, 1983).

Toxicokinetics

Pirimiphos-methyl can be absorbed via the gastrointestinal tract, the skin, or, less commonly, by inhalation of fogs, smokes, or spray mists. It is rapidly metabolized and excreted. Pirimiphos-methyl is broken down into desethyl pirimiphos-methyl and pirimiphos-methyloxon, which are also active and have transient stability. In rats dosed with radiolabeled pirimiphos-methyl, 70 percent was excreted within 24 hours and 100 percent was excreted within 5–6 days. Excretion was mainly in the urine (85 percent) and to a lesser extent, feces (15 percent). Pirimiphos methyl and its metabolites do not accumulate in the liver, kidneys, or fatty tissues of rats and domestic animals following oral exposure (WHO/FAO, 1983).

Ecological Effects

Acute Exposure

Pirimiphos-methyl is not expected to pose a hazard to birds and mammals from acute exposure, because of lack of exposure. In the laboratory, pirimiphos-methyl exhibits relatively high toxicity to birds (WHO/FAO, 1983). Acute oral LD50 values in various bird species include chickens (79–80 mg/kg), Japanese quail (140 mg/kg), and green finches (200–400 mg/kg). Dietary LD50s of 630 mg/kg for mallard ducks and 206 mg/kg for bobwhite quail chicks were identified. No lasting adverse effect on hens; chicks; or egg production, quality, or hatchability was seen in studies of chickens fed 4–40 ppm in their diet (WHO/FAO, 1983).

When used for its registered purposes, pirimiphos-methyl is not expected to result in significant exposures of aquatic organisms (U.S. EPA, 2001). Additionally, any risk would be mitigated by its strong tendency to decompose in water and to undergo photo-oxidation (WHO/FAO, 1983). In static tests, the reported 48-hour LC50 was 1.4 mg/L in carp and 0.25 mg/L in rainbow trout. The 24-hour LC50 for carp was 1.6 mg/L. In flow-through tests, the reported 48-hour LC50 was 4.1 mg/L in fathead minnow and 0.53 mg/L in rainbow trout, while the 24-hour LC50 was 5.6 mg/L in fathead minnow and 0.78 mg/L in rainbow trout (WHO/FAO, 1983).

Chronic Exposure

Due to low risk of both terrestrial and aquatic acute ecological effects of pirimiphos-methyl, serious adverse effects are not anticipated from chronic exposures. Subchronic 90-day exposure of birds to oral doses of up to 10 mg/kg did not result in clinical or histopathological findings (WHO/FAO, 1983).

Profile for Malathion:

CAS Registry Number 121-75-5

Summary

Chemical History

Malathion is an organophosphate pesticide used in a wide variety of applications, including agricultural, veterinary, and public health uses. In pest eradication programs, malathion is used to eradicate mosquitoes, Mediterranean fruit flies, and boll weevil (ATSDR, 2003b). The primary target of malathion is the nervous system; it causes neurological effects by inhibiting cholinesterase in the blood and brain. Exposure to high levels can result in difficulty breathing,

vomiting, blurred vision, increased salivation and perspiration, headaches, and dizziness (U.S. EPA, 2005c). Loss of consciousness and death may follow very high exposures to malathion (ATSDR, 2003b).

- Description of Data Quality and Quantity
- Several comprehensive reviews on the toxicity of malathion have been prepared or updated in recent years:
- EPA risk assessment for the Reregistration Eligibility Decision (RED) document (U.S. EPA, 2005c)
- IRIS summary review (U.S. EPA, 2005d)
- Toxicological Profile for Malathion (ATSDR, 2003b)
- Specifications and Evaluations for Public Health Pesticides for Malathion (WHO, 2003).

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

Summary Table

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute, Intermediate, Chronic	Inhalation	0.026	mg/kg/day	Inhalation LOAEL for respiratory effects in rats of 25.8 mg/kg/day (0.1 mg/L) with UF of 100 and SF of 10 applied	U.S. EPA (2005c)
Acute	Oral	0.14	mg/kg/day	Acute RfD based on neurological effects in rats	U.S. EPA (2005c)
Intermediate	Oral	0.03	mg/kg/day	Adopt chronic oral RfD for intermediate duration	
Chronic	Oral	0.03	mg/kg/day	Oral RfD based on neurological effects in rats	U.S. EPA (2005c)
Acute, Intermediate, Chronic	Dermal	0.05 (child) 0.5 (adult)	mg/kg/day	Dermal NOAEL for neurological effects in rabbits with UF of 100 applied (for children, an additional SF of 10 was also applied)	U.S. EPA, 2005c

For inhalation exposure, a LOAEL of 0.1 mg/L (25.8 mg/kg/day, assuming absorption via inhalation route is equivalent to oral absorption) for histopathological lesions in the nasal cavity and larynx of rats was identified for malathion. Uncertainty factors of 10 each were applied to account for interspecies and intrahuman variability and a safety factor of 10 to account for the extrapolation from LOAEL to NOAEL and the severity of effect (U.S. EPA, 2005c). This value is appropriate for short- (1–30 days) and intermediate-term (1–6 months) inhalation exposures; this value was also adopted for chronic (long-term, >6 months) exposures.

For oral exposure, an acute oral RfD of 0.14 mg/kg/day was derived based on the inhibition of red blood cell (RBC) cholinesterase in rats and uncertainty factors of 10 each to account for interspecies and intrahuman variability (U.S. EPA, 2005d). A chronic oral RfD of 0.03 mg/kg/day was derived based on the RBC cholinesterase inhibition in rats and uncertainty factors of 10 each to account for interspecies and intrahuman variability (U.S. EPA, 2005c).

For dermal exposures, a NOAEL of 50 mg/kg/day for plasma, RBC, and brain cholinesterase inhibition in rabbits exposed dermally was identified for malathion. Uncertainty factors of 10 each to account for interspecies and intrahuman variability were applied; a safety factor of 10 to account for susceptibility of young was applied to be protective of children (U.S. EPA, 2005d). This value is appropriate for short- (1–30 days), intermediate- (1–6 months), and long-term (>6 months) dermal exposures.

Background

CASRN:	121-75-7
Synonyms:	1, 2-Di (ethoxycarbonyl) ethyl, O, O-dimethyl, phosphorodithioate (ATSDR, 2003b), maldison, malathon, mercaptotion, mercaptotion, carbofos (WHO, 2003)
Chemical Group:	organophosphate
Registered Trade Names:	Cekumal, Fyfanon®, Malixol®, Maltox® (ATSDR, 2003b); Celthion, Cythion, Dielathion, EI 4049, Emmaton, Exathios, Fyfanon and Hilthion, and Karbofos (EXTOXNET, 1996)

Usage

Malathion is a nonsystemic, broad-spectrum organophosphate insecticide used to control sucking and chewing pests in agricultural and horticultural applications (WHO, 2003). It is also used to control household insects, fleas, ectoparasites in animals, and head and body lice in humans (EXTOXNET, 1996). A major public health use of malathion is to eradicate mosquitoes and Mediterranean fruit flies, with ground application and aerial spraying being the most common methods of application (ATSDR, 2003b).

Formulations and Concentrations

There are several typical formulations for malathion, each formulation varying in the amount of active ingredient (ai) it contains. The typical formulations for malathion are (U.S. EPA, 2005c; ATSDR, 2003b)

- Technical grade (91–95 percent ai)
- Dust (1–10 percent ai)
- Emulsifiable concentrate (3–82 percent ai)
- Ready-to-use liquid (1.5–95 percent ai)
- Pressurized liquid (0.5–3 percent ai)
- Wettable powder (6–50 percent ai).

- Malathion may also be used to formulate other pesticides (ATSDR, 2003b).

Degradation Products

In the United States, technical grade malathion is >90 percent pure and contains less than 5 percent impurities (reaction byproducts and degradation products). As many as 14 different impurities have been identified in technical grade malathion (ATSDR, 2003b), some of which are toxic themselves and potentiate the toxicity of malathion. Because of their toxicological properties, relevant impurities include malaoxon (CASRN 1634-78-2), isomalathion (CASRN 3344-12-5), MeOOSPS-triester (CASRN 2953-29-9), MeOOOPS-triester (CASRN 152-18-1), MeOSSPO-triester (CASRN 22608-53-3), and MeOOSPO-triester (CASRN 152-20-5). Both isomalathion and malaoxon are more toxic than malathion, and isomalathion is a potentiator of malathion (WHO, 2003). Degradation products of malathion include dimethyl phosphate, dimethyldithiophosphate, dimethylthiophosphate, isomalathion (a metabolite of malathion), malaoxon, and malathion dicarboxylic acid and are generally the result of impurities or exposure to extreme storage conditions (PAN, 2005).

In dustable powder form, malathion levels decrease when it is stored and it is converted into the more toxic metabolite isomalathion (WHO/FAO, nd). In the environment, malathion is usually broken down into other chemical compounds within a few weeks by water, sunlight and bacteria found in the soil and water (ATSDR, 2003b). At pH 5.0, malathion is reasonably stable to hydrolysis. It hydrolyzes rapidly at pH 7.0 and above or below pH 5.0 (WHO, 2003; ATSDR, 2003b). It is stable in an aqueous solution that is buffered at a pH of 5.26 (WHO/FAO, nd). In air, malathion is broken down by reacting with sunlight as well as other chemicals found naturally in the air (ATSDR, 2003b). Malathion is generally stable to photolysis (WHO, 2003).

Shelf Life

Malathion levels decline over time during storage. The extent of the decline depends on the type of formulation, as does the increase in isomalathion levels. Technical grade malathion stored at 20°C for 25–30 months lost 3–8 g/kg, while isomalathion levels increased 2.2–2.4 mg/kg. Levels of other impurities did not increase significantly. Malathion stored for 14 days at 54°C declined 2.6 percent as an emulsifiable concentrate, 2.8 percent as an emulsion (oil in water), and 5 percent as a dustable powder, while isomalathion levels increased 0.11 percent, 0.095 percent, and 1.35 percent, respectively (WHO, 2003).

Environmental Behavior

Fate and Transport in Terrestrial Systems

Malathion is released directly into the air during aerial application to target areas such as crops or residential areas. It may also be released via volatilization from crop and ground surfaces. Aerial applications may also release malathion into the soil by way of spray droplets that reach the surface of the soil. This may include spraying and fogging applications. Malathion may also be released into the soil as a consequence of wet deposition applications or when improperly disposed of (ATSDR, 2003b).

In air, malathion may be transported from the site of application to other areas by wind and precipitation. In soils, malathion is moderately to highly mobile, indicating a potential to readily move from soil into groundwater. However, because malathion degrades rapidly in the environment, movement from soil to groundwater is not a significant concern (ATSDR, 2003b).

Malathion degrades through atmospheric photo-oxidation, hydrolysis, and biodegradation. (ATSDR, 2003b). In the atmosphere, malathion breaks down rapidly in sunlight, with a half-life of 1.5 days. In soil, malathion is of low persistence with an average half-life of 6 days. It degrades rapidly depending on the degree of soil binding, which is generally moderate (EXTOXNET, 1996). Malathion degrades more quickly in moist soil (ATSDR, 2003b). The persistence of malathion in vegetation depends largely on the lipid content of the plant. The degradation process is increased with moisture content (EXTOXNET, 1996).

Fate and Transport in Aquatic Systems

Malathion may be released into surface waters through direct applications, spills, runoff from sprayed areas, wet deposition from rain, manufacturing or processing facilities, and wastewater releases (ATSDR, 2003b). The water solubility of malathion is 148 mg/l at 25°C. At pH 5, it is reasonably stable to hydrolysis; however, as pH increases, malathion hydrolyzes more readily (WHO, 2003). Because it is highly soluble and binds moderately to soil, malathion may also pose a risk to groundwater or surface waters (EXTOXNET, 1996).

In water, malathion degrades relatively quickly due to the action of the water as well as bacteria in the water (ATSDR, 2003b). In water, malathion breaks down into mono- and dicarboxylic acids. However, degradation also depends on the temperature and pH of the water. In river water, malathion breaks down in 1 week, while it is stable in distilled water for 3 weeks. Degradation increases with water temperature, alkalinity, and salinity of the water. Because of its short half-life in water, malathion is not expected to bioaccumulate in aquatic organisms (EXTOXNET, 1996).

Human Health Effects

Acute Exposure

Effects/Symptoms

Similar to other organophosphates, malathion is a cholinesterase inhibitor and interferes with the normal functioning of the nervous system. Malathion exhibits low acute toxicity via ingestion, dermal, and inhalation exposures (ATSDR, 2003b). Human volunteers fed very low doses of malathion for 6 weeks showed no significant effects on blood cholinesterase activity (ATSDR, 2003b). However, acute exposure to high concentrations can cause numbness, headaches, sweating, abdominal cramps, blurred vision, difficulty breathing, respiratory distress, loss of consciousness, and occasionally death. Acute exposure data for humans are limited and come from case reports of accidental poisonings (ATSDR, 2003b).

Several factors affect the toxicity of malathion, including the product purity, route of exposure, gender, and the amount of protein in the diet. Animal studies have shown that malathion is only slightly toxic following acute oral and dermal exposures, with reported LD50 values in rats of 1,000–10,000 mg/kg and 400–4,000 mg/kg, respectively. Additionally, as protein levels in the diet decrease, malathion toxicity increases. Females have been shown to be more susceptible to malathion toxicity than males due to differences in metabolism, storage, and excretion (EXTOXNET, 1996). It is uncertain whether children are more susceptible to the toxic effects of malathion; however, animal studies have shown that very young animals are more susceptible to the effects of malathion than older ones when exposed to high levels (ATSDR, 2003b). Weanling male rats acutely exposed to malathion were twice as susceptible to malathion as adults (EXTOXNET, 1996).

Treatment

Exposure to malathion may be determined through laboratory tests of urine and blood that measure breakdown products of malathion in urine or cholinesterase levels in blood (ATSDR, 2003b).

Long-term deleterious effects may be avoided if people exposed to high amounts of malathion are given the appropriate treatment quickly after exposure (ATSDR, 2003b). Oral exposure to malathion should be treated with rapid gastric lavage unless the patient is vomiting. Dermal exposures should be treated by washing the affected area with soap and water. If the eyes have been exposed to malathion, flush them with saline or water. People exposed to malathion who exhibit respiratory inefficiency with peripheral symptoms should be treated via slow intravenous injection with 2–4 mg atropine sulfate and 1,000–2,000 mg pralidoxime chloride or 250 mg toxogonin (adult dose). Exposure to high levels of malathion that result in respiratory distress, convulsions, and unconsciousness should be treated with atropine and a reactivator. Morphine, barbiturates, phenothiazine, tranquilizers, and central stimulants are all contraindicated (WHO/FAO, nd).

Chronic Exposure

Noncancer Endpoints

Most chronic human data come from studies of workers who are exposed to malathion via inhalation or dermally. Chronic exposure data in both humans and animals indicate that the main target of malathion toxicity is the nervous system (ATSDR, 2003b). A two-year rat study showed no adverse effects other than cholinesterase enzyme depression (EXTOXNET, 1996). Chronic animal studies have shown no reproductive or developmental toxicity at doses of malathion that are not maternally toxic. Malathion has been shown to be a contact sensitizer. Recent animal studies indicate that malathion can affect immunological parameters at doses that are lower than those that cause neurotoxicity (ATSDR, 2003b).

Cancer Endpoints

EPA has classified malathion as “suggestive evidence of carcinogenicity” (U.S. EPA, 2005c). While some studies indicate an increased incidence of some forms of cancer in people who are regularly exposed to malathion, such as those exposed occupationally, there is no conclusive evidence that malathion causes cancer in humans. In one study, rodents fed very high doses of malathion in their diet had increased incidences of liver tumors (ATSDR, 2003b; U.S. EPA, 2005c).

Toxicokinetics

Malathion is absorbed via inhalation, the gastrointestinal tract, and dermally (WHO/FAO, 1997). Dermal absorption is dependent on the site and dose applied (ATSDR, 2003b). Malathion is broken down in the liver into metabolites. One of its metabolites is malaoxon, from which malathion exhibits its toxic effects via cholinesterase inhibition (ATSDR, 2003b; U.S. EPA, 2005c; WHO/FAO, 1997). Neither malathion nor its metabolites tend to accumulate in the body and are mostly excreted within a few days (ATSDR, 2003b). Malathion is excreted mostly in the urine with a small amount being excreted in the feces. A very small amount may also be excreted in breastmilk. Metabolites excreted include the monoacid and diacid of malathion, demethyl malathion, dimethyl phosphate, and O,O-dimethylphosphorothioate. In feces, the majority of material excreted is malathion with a smaller amount being malaoxon (WHO/FAO, 1997).

Ecological Effects

Acute Exposure

Malathion is not expected to pose a hazard to birds and mammals from acute dietary exposure. Malathion exhibits low to moderate toxicity to birds (U.S. EPA, 2005e). Acute oral LD50 values in various bird species include blackbirds and starlings (over 100 mg/kg), pheasants (167 mg/kg), chickens (525 mg/kg), and mallards (1,485 mg/kg). Malathion is rapidly metabolized by birds, with 90 percent being excreted in the urine within 24 hours. The toxicity of malathion to reptiles has not been evaluated, but the avian toxicity thresholds have been used to estimate the hazard. Acute effects were reported in one study of the Carolina anole and another on developing snapping turtle embryos (U.S. EPA, 2005e). Malathion is extremely toxic to beneficial insects, including honeybees (U.S. EPA, 2005e; EXTTOXNET, 1996).

Malathion also has a wide range of toxicity to species in the aquatic environment, from being quite toxic to walleye with a 96 hr LC50 of 0.06 mg/L to being slightly toxic in goldfish with a 96 hr LC50 of 10.7 mg/L (EXTTOXNET, 1996). In invertebrates and amphibians in their aquatic stages, malathion is also found to be highly toxic. In aquatic invertebrates, EC50 values range from 1 µg/L to 1 mg/L. However, since malathion has a very short half-life, there is little potential for bioconcentration in aquatic organisms (EXTTOXNET, 1996). Malathion is also highly toxic to the larvae of terrestrial, non-target insects that have aquatic early life stages (U.S. EPA, 2005e).

Chronic Exposure

Although not persistent in the environment, birds may be chronically exposed because current labels do not restrict consecutive applications, intervals, or avoidance of nesting birds. Sublethal effects to birds may include reduced nesting behavior, disorientation, and loss of motor coordination. Studies have shown that chronic malathion exposure in the diet of terrestrial avian species causes moderate toxicity. Bobwhite quail exposed to 350 ppm for 10 weeks exhibited regressed ovaries, enlarged or flaccid gizzards, and a reduction in number of eggs that hatched. At higher exposures, a reduction in the number of eggs produced, viability of embryo, and an increase in cracked eggs was observed, while studies in waterfowl showed low toxicity (U.S. EPA, 2005e).

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