



U.S. PRESIDENT'S MALARIA INITIATIVE



# AMENDMENT #1 TO THE MADAGASCAR SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL 2013 - 2018

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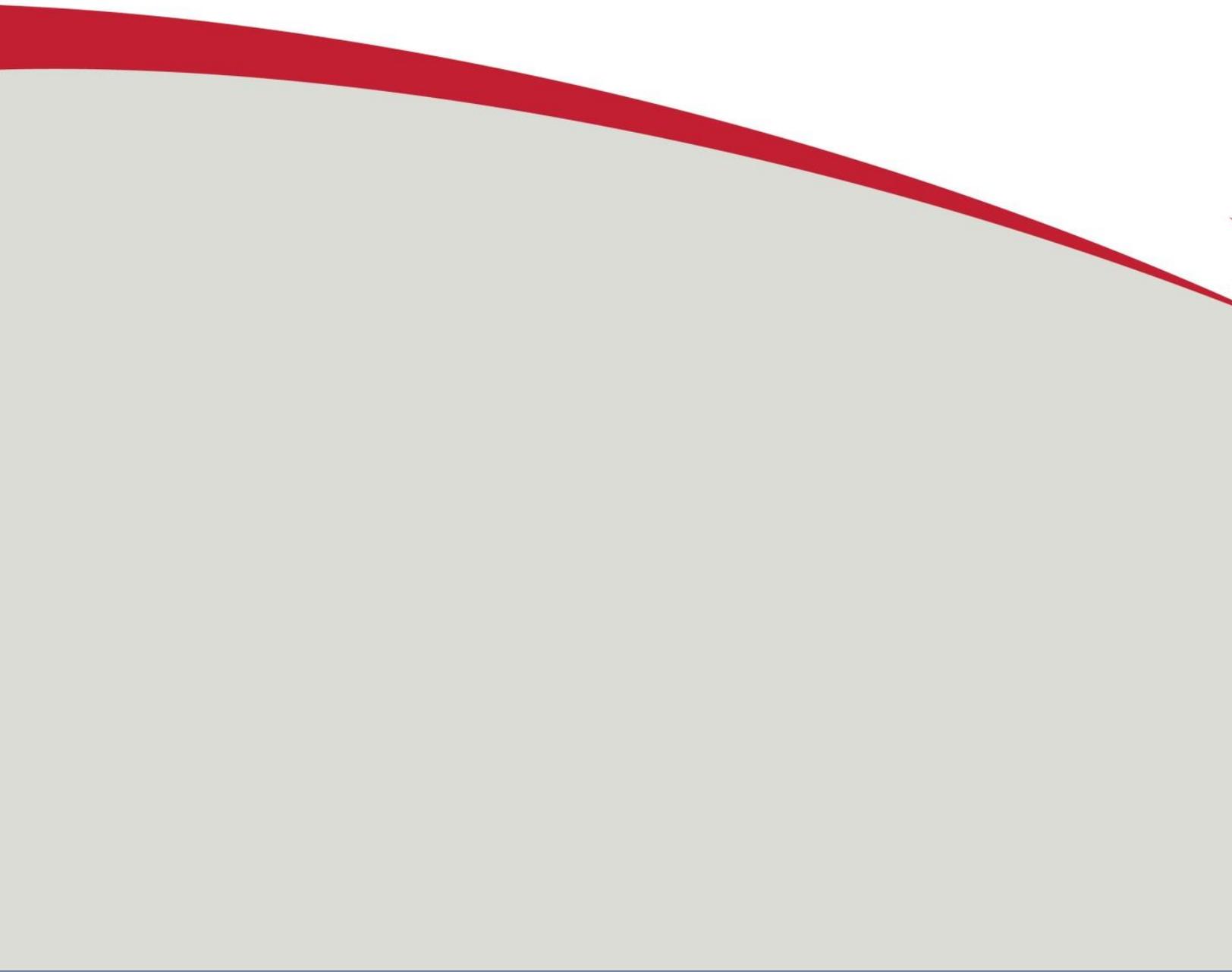
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**AMENDMENT #1 TO THE  
MADAGASCAR SUPPLEMENTAL  
ENVIRONMENTAL ASSESSMENT  
FOR INDOOR RESIDUAL  
SPRAYING FOR MALARIA  
CONTROL 2013 - 2018**



# CONTENTS

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<b>Acronyms</b>	<b>v</b>
<b>Executive Summary</b> .....	<b>vii</b>
<b>Approval</b>	<b>9</b>
<b>1. Background and Purpose</b> .....	<b>11</b>
<b>2. Proposed Action and Alternatives</b> .....	<b>13</b>
<b>3. Pesticide Procedures</b> .....	<b>14</b>
<b>4. Environmental and Health Impacts</b> .....	<b>10</b>
<b>5. Safer Use Action Plan</b> .....	<b>12</b>
<b>ANNEX A: Summary Of Acute Exposure Symptoms and Treatment Of Clothianidin</b> .....	<b>20</b>
<b>ANNEX B: Environmental Mitigation and Monitoring Plan</b> .....	<b>22</b>
<b>ANNEX C: Bibliography</b> .....	<b>Error! Bookmark not defined.7</b>

# ACRONYMS

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<b>BMPs</b>	<b>Best Management Practices</b>
<b>CFR</b>	<b>Code of Federal Regulations</b>
<b>COP</b>	<b>Chief of Party</b>
<b>DC</b>	<b>District Coordinator</b>
<b>DPV</b>	<b>Direction de la Protection des Vegetaux</b>
<b>EC</b>	<b>Environmental Compliance</b>
<b>ECO</b>	<b>Environmental Compliance Officer</b>
<b>EMMP</b>	<b>Environmental Mitigation and Management Plan</b>
<b>IEC</b>	<b>Information, Education, and Communication</b>
<b>IRS</b>	<b>Indoor Residual Spraying</b>
<b>IVM</b>	<b>Integrated Vector Management</b>
<b>NMCP</b>	<b>National Malaria Control Program</b>
<b>OM</b>	<b>Operations Manager</b>
<b>PEA</b>	<b>Programmatic Environmental Assessment</b>
<b>PMI</b>	<b>President’s Malaria Initiative</b>
<b>PPE</b>	<b>Personal Protective Equipment</b>
<b>PSC</b>	<b>Pyrethrum Spray Catches</b>
<b>SEA</b>	<b>Supplemental Environmental Assessment</b>
<b>SO</b>	<b>Spray Operator</b>
<b>SUAP</b>	<b>Safer Use Action Plan</b>
<b>TPM</b>	<b>Technical Program Manager</b>
<b>USAID</b>	<b>United States Agency for International Development</b>
<b>USEPA</b>	<b>United States Environmental Protection Agency</b>
<b>WHO</b>	<b>World Health Organization</b>
<b>WHO PQ</b>	<b>World Health Organization Prequalification</b>

## EXECUTIVE SUMMARY

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This document has been prepared to serve as an amendment to the 2013 - 2018 Supplemental Environmental Assessment (SEA) for indoor residual spraying (IRS) in Madagascar. That SEA authorized the use in Madagascar of the pyrethroid, carbamate, and organophosphate classes of insecticides recommended by the World Health Organization for IRS. This amendment to the SEA authorizes the use of clothianidin, a new IRS insecticide that was listed by World Health Organization (WHO) Pre-Qualification (PQ) in 2017, and clothianidin/deltamethrin formulations, once the combination is listed by the WHO PQ. This document also serves to extend the period of the SEA through December 31, 2018, to cover the entire IRS campaign in Madagascar.

Changing or rotating insecticides of different classes over time and space is a leading way to manage vector resistance. In order to expand the insecticide options for IRS to manage vector insecticide resistance in Madagascar, new viable insecticides must be introduced for use. For clothianidin and clothianidin/deltamethrin formulations to be added as options for IRS, the United States Agency for International Development (USAID) and the President's Malaria Initiative (PMI) must approve this amendment to the existing SEA.

This SEA amendment outlines the characteristics, benefits, and potential hazards of clothianidin and its mixtures with deltamethrin, as well as the legal and regulatory status of these active ingredient in Madagascar and in the United States. PMI has consistently supported implementation of IRS for malaria control in Madagascar as part of an integrated vector management (IVM) strategy since 2008. In 2018, PMI proposes to spray eight high burden malaria districts: Fenerive Est, Brickaville, Tamatave II, Farafangana, Vohipeno, Manakara, Manajary, Tuléar II, and Sakaraha. A long-lasting insecticide in the organophosphate class, Actellic 300 CS, will be the predominant insecticide used. Clothianidin is proposed to be used in the Farafangana and Vohipeno districts that was previously sprayed using Actellic 300 CS. This SEA amendment is seeking authorization for the use of clothianidin in any area of the country, while also extending the existing validity of the SEA until December 31, 2018, to cover the entire spray season.

Therefore, the proposed action analyzed in this document is:

- **Continue IRS programming for 2013 - 2018, implementing a rotational or mosaic technique, using pyrethroids, carbamates, organophosphates, or clothianidin, based on pesticide resistance patterns throughout the country and other critical factors.**

All conditions of the existing 2013 SEA, including the Safer Use Action Plan (SUAP), will remain valid, and all PMI IRS operations in Madagascar will be performed according to the protocols and procedures found therein. This amendment contains a revised Environmental Mitigation and Monitoring Plan (EMMP), Annex B, which reflects the increased potential scope of PMI VectorLink activities as compared to the PMI AIRS project it replaces.

# APPROVAL

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## **APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED**

### **AMENDMENT OF THE 2013 – 2018 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR THE U.S. PRESIDENT’S MALARIA INITIATIVE INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL IN MADAGASCAR**

The USAID Global Health Bureau has determined that the proposed indoor residual spraying effort, as described here in Amendment #1 to the 2013 - 2018 SEA, responds to the needs of the community and country as it relates to managing malaria in Madagascar, and also conforms to the requirements established in Title 22 Code of Federal Regulations 216.

This document does not mandate the execution of the proposed IRS. Rather, it documents the environmental planning and impact analysis executed by the IRS team in preparation for the proposed action. The IRS program’s design and standards of operation are intended to reduce, and if possible, avoid, any potential adverse impact on individuals or the environment. USAID has concluded that the proposed action, when executed as described in the SEA and in the Programmatic Environmental Assessment for PMI IVM (2012 and 2017), is consistent with the Government of Madagascar’s and USAID’s goal of reducing malaria incidence in Madagascar while minimizing negative impact to the environment and to human health.

The action recommended for approval in this 2018 SEA amendment is to continue IRS programming through December 31, 2018 using a rotational or mosaic technique, involving pyrethroids, carbamates, organophosphates, and clothianidin formulations, based on pesticide resistance patterns throughout the country and other critical factors.

The Safer Use Action Plan in Chapter 7 of the 2013-2018 SEA and the PMI best management practice (BMP) manual provide detailed guidance on the performance of all activities associated with IRS.

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T. Christopher Milligan

Date: 7/9/2018

**CONCURRENCE:**

GH/Bureau Environmental Officer:

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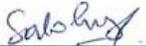
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# I. BACKGROUND AND PURPOSE

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## I.1 OBJECTIVES

PMI's IRS activities in Madagascar operate under an SEA that was approved in September 2013. The SEA was prepared in accordance with the provisions of Title 22 Code of Federal Regulations (216) regarding the use and application of pesticides. It is nationwide in scope, and authorizes the use of three classes of WHO PQ-recommended pesticides: pyrethroid, carbamate, and organophosphate. This document has been prepared to serve as an amendment to that SEA, and proposes to also authorize the use of clothianidin for IRS in all areas of Madagascar, and extend the validity of the SEA through December 31, 2018.

In order to expand the insecticide options for IRS to manage vector insecticide resistance in Madagascar, new viable insecticides must be introduced for use. Changing insecticides classes over time and space is a leading way to manage resistance, and having more alternatives available increases the chances of mitigating resistance. For these reasons, PMI Madagascar and the National Malaria Control Program are seeking authorization to spray clothianidin insecticide in the Farafangana and Vohipeno Districts, two of the eight target districts during the 2018 IRS season. The rest of the target districts will continue using Actellic 300 CS.

Sumishield 50WG is a new insecticide formulation from Sumitomo Chemical, Japan that is approved by the World Health Organization (WHO). The active ingredient in Sumishield 50WG is the neonicotinoid clothianidin. Clothianidin has not yet been fully authorized by the Direction de la Protection des Vegetaux (DPV), Service de la Phytopharmacie, the competent authority for the approval of insecticide in Madagascar, but the manufacturer is in the process of registering this insecticide with the DPV. Registration by the DPV and amending the current 2013 – 2018 SEA are required for USAID/PMI to use clothianidin in Madagascar. As PMI must comply with host country environmental regulations unless otherwise directed in writing by USAID, PMI has received an official written approval from the General Secretary of the Ministry of Health of Madagascar, regarding the use of Clothianidin.

## I.2 AREA AND SCOPE OF IRS IN MADAGASCAR IN 2018

In 2018, if this SEA amendment is approved, IRS will be conducted using clothianidin in Farafangana and Vohipeno of the South East, and Actellic will be used in Fenerieve Est, Brickaville, Tamatave II, Mananjary, Manakara, Sakaraha and Tulear II. Based on the enumeration, Farafangana and Vohipeno Districts have a population of 587,536 persons (Farafangana: 391,225 persons, Vohipeno: 196,311 persons). Geographically, the Farafangana District is bordered by Vohipeno District on the north, Vangaindrano District on the south, Indian Ocean on the east, and Vondrozo District on the west. The Vohipeno District is bordered by Manakara District on the north, Farafangana District on the south, Indian Ocean on the east, and Vondrozo and Ikongo Districts on the west. For IRS purposes, the district of Farafangana has 86,830 spray-able structures, and the average insecticide usage rate is 7.3 structures per bottle/sachet which amounts to 11,895 sachets of clothianidin (Sumishield) required to spray all available structures, as per 2017 IRS findings. For the district of Vohipeno, 47,840 spray-able has censused, and the average insecticide usage rate is 6.9 structures per bottle/sachet which amounts to 6,933 sachets of clothianidin (Sumishield) required to spray all available structures, as per 2017 IRS findings.

The National Malaria Control Program (NMCP), in consultation with PMI, selected Farafangana and Vohipeno Districts as the IRS beneficiary districts to receive spraying with clothianidin in 2018. Factors contributing to the selection of these districts include previous good history of IRS acceptance by

households, this is the 4<sup>th</sup> spraying year for the district of Farafangana, and 3<sup>rd</sup> spraying year for the district of Vohipeno. Organophosphates were used during those years and to manage the resistance factor, the change of class has been chosen. These two factors make using Sumishield in these districts for the first time in Madagascar a priority.

## **I.3 ENTOMOLOGICAL MONITORING**

### **I.3.1 QUALITY OF SPRAYING AND RESIDUAL PERFORMANCE OF CLOTHIANIDIN**

In 2018, to determine the quality of spraying and the residual performance of clothianidin on walls, WHO bioassays will be conducted 2-3 days after IRS, and continued monthly. This will be done in randomly selected houses: four with falafa (thatch) made walls and four with walls made of wood.

WHO cone bioassays are the standard method for assessing the mortality rates of susceptible mosquitoes exposed to sprayed walls. Bioassays conducted 24-72 hours after spray are measuring the quality of the spray. If these assays, result in a mortality rate of 98-100% the quality of the spray is ideal. The monthly bioassays determine the residual performance of the insecticide. The residual performance of the insecticide is determined when the mortality rate of susceptible mosquitos falls below 80%.

### **I.3.2 VECTOR DENSITY SURVEILLANCE**

To monitor changes in mosquito populations, the following activities will be performed: entomological monitoring at two sites sprayed with clothianidin (Farafangana and Vohipeno), two sites sprayed with Actellic 300 CS (Ambohimirina II and Marofarihy), two control sites (Lopary and Tsaravary), and two former IRS sites (Ambodifaho and Vohitrambato).

## 2. PROPOSED ACTION AND ALTERNATIVES

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This section describes the alternatives to clothianidin that were considered in the preparation of this report, including those that were accepted or rejected.

### 2.1 DESCRIPTION OF PROPOSED ACTION

The preferred action is to authorize the use of clothianidin nationwide in Madagascar for IRS, which was listed by WHO PQ in October 2017. If authorized for PMI use in Madagascar, it will provide an additional option for implementing IRS in selected communities while balancing current entomological, epidemiological, logistical, environmental, and economic priorities. The pesticide to be used in an IRS season will be determined by a process fully explained in the 2013 SEA under Pesticide Procedures part b. (Section 5.2 p. 53).

### 2.2 NO-PROJECT ALTERNATIVE

Insecticide resistance is one of the most serious threats to malaria vector control, and resistance management is a key component of IVM. Changing or rotating insecticides in IRS operations is one of the critical strategies in the management of vector resistance to insecticides. A “no-project alternative” may reduce the number of available alternatives IRS insecticides, and possibly result in increasing resistance to the available insecticides. This could raise rates of infections, transmission, mortality, and morbidity, due to the increased prevalence of resistant and infected vectors. Therefore, the “no-project alternative” does not meet the overall goals of USAID/PMI, or of the Madagascar NMCP.

### 2.3 ALTERNATIVE IRS GEOGRAPHICAL SITES CONSIDERED

All regions and districts in Madagascar are eligible for PMI support for IRS according to the current SEA. This amendment seeks to maintain nationwide coverage and add clothianidin as an IRS option, plus extend the validity of the SEA through December 31, 2018. The choice of spray sites is made by the NMCP and PMI based on entomological and other data. Use of different criteria to choose spray sites could reduce the effectiveness of the intervention.

### 2.4 USE OF ALTERNATIVE INSECTICIDE(S)

Only pesticides recommended by WHO PQ may be selected for use in PMI-supported IRS. PMI Madagascar and the Madagascar NMCP regularly conduct entomological testing to help determine the best choice of insecticide. This amendment proposes to add clothianidin as an alternative insecticide, as it has now been listed by WHO/PQ for IRS, and in anticipation of it being registered for public health use in Madagascar. Thereafter, clothianidin will be an available alternative insecticide.

## 3. PESTICIDE PROCEDURES

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Title 22 of the United States Code of Federal Regulations 216 mandates the consideration of 12 factors when a project includes “assistance for the procurement or use, or both, of pesticides.” The existing SEA addresses the 12 factors for the IRS Malaria Control Program in Madagascar; this section of the amendment addresses any clothianidin-specific aspects of those factors.

### 3.1 THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY’S REGISTRATION STATUS OF THE REQUESTED PESTICIDE

Clothianidin was registered with United States Environmental Protection Agency (USEPA) in 2003.

### 3.2 THE BASIS FOR SELECTION OF THE REQUESTED PESTICIDES

**Recommended by WHO:** Clothianidin was included on the WHO Prequalification Team list in 2017. PMI plans to use clothianidin, as it is now recommended by WHO.

**Registration for use in Madagascar:** Clothianidin is currently not registered for IRS in Madagascar, but the needed registration process is ongoing for clothianidin. PMI will spray with clothianidin only when Sumishield has been registered for use in Madagascar.

Since the Farafangana and Vohipeno Districts are included in the available DPV certificate for IRS in Madagascar, VectorLink Madagascar can conduct IRS with the clothianidin upon registration of Sumishield in Madagascar.

**Residual effect for a period longer than, or at least equal to, the average duration of the malaria transmission season in the area:** The duration of effectiveness of clothianidin to be used on the primary wall surface types is reported to be greater than the duration of the transmission season (about eight months), but these properties will be investigated further in upcoming operations if this amendment is approved.

**Ecological Impact:** If PMI BMPs for IRS are strictly followed, the release to the environment, and therefore the impact to the environment, should be negligible. More information on the potential ecological impact of clothianidin and mixtures is found in the 2017 Programmatic Environmental Assessment (PEA) for IVM.

**Human Health Impact:** The 2017 IVM PEA also assessed cancer and non-cancer risks associated with clothianidin by process (e.g., mixing insecticide, spraying, residing in sprayed house) and pathway (e.g., inhalation, dermal, ingestion, etc.). Based on the risk screening results, adverse human health effects for workers or residents are not expected from the use of clothianidin or mixtures with deltamethrin.

### 3.3 THE EXTENT TO WHICH THE PROPOSED PESTICIDE USE IS PART OF AN INTEGRATED PEST MANAGEMENT/IVM PROGRAM

IVM for the control of the malaria vector population is practiced using two primary interventions, insecticide-treated nets and IRS. Environmental management for malaria control is limited to some common-sense safeguards, such as eliminating standing water, which can serve as a breeding ground for mosquitoes. PMI does not support environmental management as a vector control method, because the life-cycle requirements and the adaptability shown by IRS vectors limit the large-scale effectiveness of these measures. PMI strategy has been that IRS will be implemented as a component of IVM for malaria control.

### 3.4 THE PROPOSED METHOD OR METHODS OF APPLICATION, INCLUDING AVAILABILITY OF APPROPRIATE APPLICATION AND SAFETY EQUIPMENT

Clothianidin will be applied using the same compression spray equipment and techniques as other WHO-recommended insecticides, and the same cautions apply. The SUAP in Chapter 7 of the 2013 SEA (pp. 72-76) and the PMI IRS BMP Manual must be consulted and followed.

### 3.5 ACUTE AND LONG-TERM TOXICOLOGICAL HAZARDS ASSOCIATED WITH THE PROPOSED USE AND MEASURES AVAILABLE TO MINIMIZE SUCH HAZARDS

The 2017 IVM PEA assessed the toxicity of clothianidin to non-target organisms, including mammals, birds, fish, bees, and other aquatic organisms. Submitted data indicate that no significant adverse environmental impacts are expected to occur from the use of these active ingredients.<sup>1</sup> Refer to the environmental and health impact section of this amendment (Section 4.2) and the PEA for greater detail about their toxicity.

#### 3.5.1 HUMAN HEALTH HAZARDS

Clothianidin: The risk results for clothianidin are based on a two-generation reproduction study on rats, in which the rats were exposed through normal feeding; endpoints included weight gain, sexual maturation, and stillbirths. The health benchmark derived from this study and recommended by the USEPA is: 0.0098 mg/kg/day, this is the calculated human exposure toxicity level with the 100x risk factor included (USEPA 2012). This value was calculated using an uncertainty factor of 100 to account for differences in intra-species sensitivity (10), and the lack of human exposure studies (10). In addition, a modifying factor of 10 was also applied to capture uncertainty associated with the lack of a developmental immune-toxicity study (a requirement under USEPA pesticide registration guidelines). The application of the same health benchmark across all exposure durations and exposure routes provides a conservative representation of toxicity, as absorption is typically higher for oral administration than for dermal contact, and the physiological response to shorter exposures allows recovery (in contrast with chronic exposures). Based on the risk screening results and the inherently conservative nature of the calculation, adverse human health effects for workers or residents are not expected from the use of clothianidin.<sup>2</sup> Clothianidin does not damage genetic material, nor is there evidence that it causes cancer in rats or mice; it is unlikely to be a human carcinogen.<sup>3</sup>

### 3.6 THE EFFECTIVENESS OF CLOTHIANIDIN FOR THE PROPOSED USE

To determine the quality of spray and residual performance of clothianidin on the walls, cone bioassays will be conducted within two weeks of IRS, and this will be continued monthly. Bioassays will be conducted using the WHO cone bioassay method in four with falafa (thatch) made walls and four with walls made of wood. Cone bioassays will be performed according to WHO standard protocols, with one cone each at 0.5, 1.0, and 1.5m height. Cone bioassays will continue monthly until vector mortality is below 80% for two consecutive months, based on the five-seven day holding period.

Abbott's correction implemented if mortality is between 5% and 20% in the negative controls after five-seven days. If mortality is >20% after 5 days in untreated controls, tests will be repeated.

To monitor changes in mosquito populations, the following activities will be performed:

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<sup>1</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17

<sup>2</sup> IVM PEA, 2017. Integrated vector management programs for malaria vector control (version 2017). USAID

<sup>3</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281>, accessed 7/14/17

- Two sites sprayed with clothianidin (Farafangana and Vohipeno districts),
- Two sites sprayed with Actellic 300 CS (Ambohimiarina II (Mananjary district) and Marofarihy (Manakara district), and
- Two control sites (Lopary (Vangaindrano district) and Tsaravary (Mananjary district).

### **3.7 COMPATIBILITY OF CLOTHIANIDIN WITH TARGET AND NON-TARGET ECOSYSTEMS**

Clothianidin formulations are compatible with indoor use and applied to walls, ceilings, eaves of homes. Properly administered clothianidin dries on the indoor surfaces and are not released to receptors or the general environment to any great extent. The dried pesticide remains on the sprayed surfaces and performs as designed, killing vector mosquitoes that rest on them, and the exposure to non-target organisms and ecosystems is very limited.

Clothianidin is incompatible with human consumption and can be detrimental to the health of the natural environment. If misapplied and released to the environment in large quantities, clothianidin could have negative effects on land- and water-based flora and fauna. The IRS implementation process is designed to ensure that, to the maximum extent possible, pesticides are deliberately and carefully applied to the walls and ceilings of dwellings (target areas), and do not come in contact with humans, animals, or the natural environment. IRS implementation is also planned to minimize and responsibly manage insecticide-contaminated liquids through the reuse of leftover pesticides and contaminated water, the triple rinsing of equipment, and the daily washing of personal protective equipment (PPE) and, at a minimum, faces and hands of spray team members. Liquid and solid contaminated wastes are managed in accordance with PMI best management practices.

### **3.8 THE CONDITIONS UNDER WHICH THE PESTICIDE IS TO BE USED**

Chapter 4 of the 2013 SEA provides a detailed account of the environmental conditions in Madagascar under which clothianidin will be used. During IRS operations, particular attention is paid to any sensitive areas identified in the environmental assessment, including water bodies, schools, hospitals, and any area where organic farming is practiced or where beekeeping or natural bee habitats are established. Bird-nesting and bee habitat will be protected, and clothianidin will not be stored near water habitats and resources. IRS will be prohibited within 30 meters of all sensitive ecosystems.

### **3.9 THE AVAILABILITY AND EFFECTIVENESS OF OTHER PESTICIDES OR NON-CHEMICAL CONTROL METHODS**

Only WHO-recommended pesticides may be used for PMI-supported IRS. Other non-chemical control methods are covered under the 2013 SEA recommendations for IVM.

Insecticide resistance in mosquitoes in a targeted IRS area tends to develop after a number of years of continued use of a single insecticide. In order to prevent or overcome this problem, other insecticides beside those that are currently approved by the 2013 SEA need to be available for use in Madagascar. This amendment to the 2013 SEA is seeking authorization to include clothianidin as alternative insecticide option.

### **3.10 THE REQUESTING COUNTRY’S ABILITY TO REGULATE OR CONTROL THE DISTRIBUTION, STORAGE, USE, AND DISPOSAL OF THE REQUESTED PESTICIDE**

#### **3.10.1 PESTICIDE AND TOXIC SUBSTANCE REGULATION**

Malagasy pesticide regulations (Arrêté n° 7452-92 règlementant le stockage et le reconditionnement des produits agropharmaceutiques) provide the guidelines and measures for management of pesticides including storage, transport, and usage. These regulations will be complied with in the implementation of the IRS program. DPV is mandated to regulate the use of pesticides for agriculture, horticulture, forestry, gardening and other uses, as well as monitoring the use of pesticides and taking enforcement action against illegal use. DPV also provides permitting of insecticide imports and exports as well as pesticides registration and licensing. All the pesticides proposed for use must be registered and importation licenses obtained.

#### **3.11 THE PROVISIONS MADE FOR TRAINING OF SPRAY OPERATORS**

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. PMI has developed guidelines for IRS operations (Best Management Practices (BMP) for Indoor Residual Spraying in Vector Control Interventions, updated 2015), and provides a training manual (Spray Operator Pocket Guide, updated 2014). A summary of the training provided to spray operators and other actors is provided in Chapter 5 of this SEA.

PMI will support the training of spray operators and supervisors, and provide overall guidance and logistical support to the IRS operations in Madagascar. The implementing partner 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 supervisors, storekeepers and team leaders are trained on all aspects of IRS operation. 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.
- The training of temporary workers recruited from local areas and trained as spray team members (operators, team leaders, and wash persons). New operators will receive five to seven days of training prior to the spray operations.

#### **3.12 THE PROVISIONS MADE FOR MONITORING THE USE AND EFFECTIVENESS OF THE PESTICIDE**

Entomological monitoring is firmly established in the PMI Madagascar project, and is used for IVM decision-making. The standard practices for entomological monitoring in the PMI Madagascar project are presented in the approved 2013 SEA.

## 4. ENVIRONMENTAL AND HEALTH IMPACTS

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### 4.1 POTENTIAL POSITIVE EFFECTS OF CLOTHIANIDIN

#### 4.1.1 DIRECT POSITIVE EFFECTS

The overall benefits of clothianidin use in IRS is improved human health and the reduced incidence of mosquito-borne illness. Other direct positive impacts of approving the use of clothianidin in IRS will include improved capacity for insecticide resistance management, as clothianidin will serve as an additional option for rotation of insecticides to prevent resistance. Additional positive direct impacts of clothianidin in IRS derive from the expected economic and environmental benefits provided by IRS. (Refer to Section 6.1 p. 66 in the 2013 SEA.)

#### 4.1.2 INDIRECT POSITIVE EFFECTS

The indirect positive impacts of using clothianidin in IRS are the same as the positive impacts of using the four WHO PQ-recommended classes of pesticides. (Refer to section 6.1.2 p. 66 of the 2013 SEA for more detail.)

### 4.2 NEGATIVE EFFECTS – TOXICITY OF CLOTHIANIDIN TO AVIFAUNA, AQUATIC LIFE, MAMMALS, AND INSECTS BY CLASS

#### 4.2.1 MAMMALIAN TOXICITY AND HUMAN EXPOSURE/RISK IMPACTS

Important clothianidin characteristics are listed below.

- Acute oral LD50: LD50 is 3900mg/kg body weight (bw) for male rats and 4700mg/kg bw for female rats.
- Skin and eye: for rabbits, slight (barely perceptible) transient skin irritation; and it is an eye irritant.
- Inhalation LC50 (4h): for male and female rats >2.3mg/L.
- Other: Not mutagenic. Not oncogenic in rats and mice. Not teratogenic in rats and rabbits.<sup>4</sup>

The acute health risks to humans from exposure to clothianidin are minimal due to its low mammalian toxicity in the context of IRS. Extrapolation to humans from test results on animals suggests that clothianidin is moderately toxic through oral exposure, but that toxicity is low through skin contact or inhalation. Potential beneficiary exposure will principally be via skin contact with treated walls, so the product should not pose any significant risk to residents. While clothianidin may cause moderate eye irritation, it is not a skin sensitizer. Clothianidin does not damage genetic material, nor is there evidence that it causes cancer in rats or mice; it is unlikely to be a human carcinogen. Mild to moderate poisoning can cause nausea, vomiting, diarrhea, abdominal pain, dizziness, headache, and mild sedation. Due to reports of unfortunate attempts of human suicides, accounts have indicated that large deliberate ingestions have caused agitation, seizures, metabolic acidosis, coma, hypothermia, pneumonitis, respiratory failure, hypotension, ventricular dysrhythmias, and death. Rare caustic injury to the esophagus has been reported. This is likely due to the solvent component (N-methyl-2-pyrrolidone) of the insecticide as opposed to the neonicotinoid. Overall, when used properly, the product does not pose significant risks to residents.

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<sup>4</sup> United States EPA assessment report (2003)

United States EPA fact sheet for clothianidin (2003) states that the chemical should not present a direct acute or chronic risk to freshwater and estuarine/marine fish, or a risk to terrestrial or aquatic vascular and nonvascular plants. Clothianidin may be toxic to aquatic invertebrates if disposal of wastes is not in accordance with BMPs and runoff into waterbodies results.

#### **4.2.2 AQUATIC LIFE**

United States EPA factsheet for clothianidin (2003) states that the chemical should not present a direct acute or chronic risk to freshwater and estuarine/marine fish, or a risk to terrestrial or aquatic vascular and nonvascular plants. Clothianidin may be toxic to aquatic invertebrates if disposal of wastes is not in accordance with BMPs. Clothianidin will not be stored within 30 meters of water bodies, and any transport over water will be according to PMI BMPs.

#### **4.2.3 BIRDS**

According to the United States EPA, clothianidin is practically non-toxic to selected test bird species that were fed relatively large doses of the chemical on an acute basis.

#### **4.2.4 BEES**

Bee keeping is still practiced in Madagascar through the traditional methods; however there are efforts by several non-governmental organizations to promote the modern techniques of bee keeping. Some NGOs for example are supporting a bee-keeping project in Vohilengo (Farafangana district) which aims to increase villagers' incomes whilst also promoting forest conservation. Spraying in areas near beehives can lead to the death of the bees, which are vulnerable to clothianidin and the clothianidin/deltamethrin combination. In addition, spraying near hives can lead to contamination of edible honey. These risks must be mitigated at all times. The implementing partner will identify locations where beehives are kept, and observe a 30 meter no-spray buffer zone around them. Messages on the potential toxicity of these active ingredients to bees will be included in Information, Education and Communication (IEC) material, advising homeowners with beehives to temporarily move them away from structures to be sprayed, before spray teams arrive in their community.

#### **4.2.5 CUMULATIVE IMPACT**

No cumulative impacts are expected as a result of using clothianidin in IRS if PMI BMPs are followed. IVM, including the use clothianidin and combinations, should reduce the spread of mosquito-borne disease.

## 5. SAFER USE ACTION PLAN

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This Safer Use Action Plan replaces Chapter 7 of the 2013 SEA, and outlines the safer use action plan proposed to mitigate the potential adverse impacts of all pesticides included in the SEA, as outlined in Chapter **Error! Reference source not found.** of this amendment. The primary mitigation measures include delivery of a mix of IEC approaches targeting the residents and spray operators and all IRS personnel, training of spray operators and strengthening supervision and monitoring, and provision of appropriate PPE and facilities for the storage and disposal of pesticides and contaminated waste. The mitigation measures, along with monitoring and reporting information, are compiled in the EMMP found in Annex B.

### 5.1 IMPLEMENTATION CONDITIONS

During implementation, PMI/Madagascar and its PMI IRS IPs will adhere to the conditions detailed in this Safer Use Action Plan, and in the Environmental Monitoring and Mitigation Plan (EMMP), Annex B of this amendment.

#### 5.1.1 QUANTIFICATION OF PESTICIDE REQUIREMENTS

The PMI IRS IP will conduct an annual logistics assessment for all targeted sub-counties for planning and procurement of the correct quantity of materials, including insecticides. Purchase of insufficient pesticide will lead to shortages, delays, and possibly the inability to spray all targeted areas. Purchase of too much pesticide may lead to expiration of the pesticide before it can be used up, which creates serious storage and disposal problems.

#### 5.1.2 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.

The PMI program will procure the insecticide from a reputable supplier. Pesticide batches will be analyzed for the concentration of the active ingredient prior to shipment to Madagascar. Additional sampling and testing may be performed upon arrival. Delivery of all insecticide to the central warehouse will be supervised by PMI and NMCP before being dispatched to the districts where spray operations will be concentrated.

#### 5.1.3 PESTICIDE TRANSPORT

After the receipt of insecticide at the central warehouse, insecticides are transported to the district warehouses (during the campaign) by road. During transportation, there is a risk of vehicle accidents and consequent insecticide spillage. It is essential that the vehicle type and speed of transport be matched to the conditions. Drivers must take no chances.

A lockable box truck is the expected vehicle to transport insecticides from central to sub-county stores. If box trucks are not available, the IP will notify the COR to receive instructions for an alternative security mechanism. All vehicles must be in good condition and pass the Pre-Contract Vehicle Inspection performed by the Environmental Compliance Officer or their qualified designate, using a smart phone. If during transport the pesticides are to be left unattended for any period of time, including lunch breaks or overnight stops, a lockable box truck is required.

Prior to long-distance transport of the insecticide from the customs warehouse or central storage facility, drivers will be trained about general issues surrounding the insecticide and how to handle emergency situations such as accidents or spillage. Training for long-distance transport will include the following information:

- Purpose of the insecticide (indoor usage for malaria protection, not for agricultural or any other outdoor use)
- Toxicity of the insecticide
- Security issues, including implications of the insecticide getting into public access.
- Hazardous places along the routes to be taken, and mitigation measures.
- Steps to take in case of an accident or emergency (according to BMP standards)
- Combustibility and toxicity of the combustion byproducts of insecticide

Drivers hired for transport of insecticide within a county and spray team members during the spray campaign will receive training in:

- Operator transportation best practices and vehicle requirements from PMI IRS BMP #2, Worker and Resident Health and Safety.
- Health and safety as provided to spray operators, with the exception of sprayer operation and spray practice.
- Handling an accident or emergency according to BMP standards.
- Handling vehicle contamination.
- Vehicle decontamination procedures.

Figure 5-1 below provides a list of key responses to mitigate the impact of the insecticide spills.

## FIGURE 5-1: EMERGENCY RESPONSE TO A SPILL

### IN CASE OF INSECTICIDE SPILLS

1. Control, contain and clean up the spill
2. Don protective clothing 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 must be shut off and smoking in the area strictly prohibited.
4. Onlookers and bystanders must be kept away from the accident site.
5. If the crew has come in contact with the pesticides, they must remove contaminated clothing immediately and wash the pesticide off their skin.
6. For major spills send for help immediately; drivers must have cell phones and an emergency number for use in such cases.
7. People must 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 are required to 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, it is important to ensure that vehicles are decontaminated after use. 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, overalls, 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 and water. If pesticide is transported over water, BMP #10, Water Transport (PMI IRS BMP Manual, 2015) must be followed in every detail.

### 5.1.4 QUALIFICATION OF WAREHOUSES (STORAGE FACILITIES)

IRS pesticides can cause adverse impacts to human health, animals, and the natural environment if not properly stored according to PMI BMPs. Before insecticides are procured or transported to the spray areas, suitable warehouse(s) must be assessed to ensure that they can meet BMP standards. During the geographical reconnaissance and logistics assessments, the need for new or rehabilitation of previously used program warehouses to meet PMI IRS BMP standards for pesticide storage will be assessed. The standards include:

Located at least 30 meters from flood plains, wetlands and water bodies, markets, schools, dwellings, beehives, and protected areas. Warehouses may not be located in the buffer zones of protected areas, or in schools.

- Spacious enough to store insecticides in bulk and to store other IRS commodities separately
- A separate space for the storekeeper's office.

- Well ventilated and allowing for air circulation
- Built of concrete or other solid material
- Impervious flooring, or floor must be completely covered by a leak-free tarpaulin
- Watertight roofing
- Barred and screened windows
- Preferably two exits from the pesticide storage area for emergency purposes
- Fire extinguisher

In addition to the above, all facilities used for storage, distribution, and transportation of insecticide products should comply with relevant requirements of Madagascar in pesticide regulations. During the logistical needs assessment, the PMI IRS IP will identify warehouses at the county level that can meet these requirements. PMI cannot provide funds for the construction of new buildings, but can assist in the modification or renovation of existing facilities

### **5.1.5 QUALIFICATION OF LIQUID WASTE DISPOSAL FACILITIES (WASH AREAS, SOAK PITS)**

Pyrethroids, organophosphates, carbamates and clothianidin degrade quickly when exposed to environmental action such as photolysis, hydrolysis, and bacterial action. If wash areas and soak pits are properly constructed in appropriate locations and used according to BMPs, liquid pesticide waste will be captured in the charcoal layer of the soak pit and held until it breaks down by these natural processes.

Site considerations for locating IRS cleaning and waste management facilities (progressive rinse, wash areas, soak pits) include soil type, topography, vertical distance to ground water, and proximity to schools, lakes, streams, and other sensitive areas. Ideally, disposal facilities should be located adjacent to the storage facilities, where they can be more easily protected and monitored. However, the setting or the function of buildings provided for storage are not always appropriate for setting a wash area, so it may need to be placed some distance away. Due to access limitations and distance to some spray sites; it may be more feasible to locate a small wash facility in an appropriate area near the spray site.

Soak pits must be located at least 30 meters from any sensitive areas such as water bodies, flood plains, habitat, schools and other public buildings, areas protected by regulations, and areas of high groundwater. They should be located on relatively high ground to increase the vertical distance to groundwater. The general area should be level, but the wash area must be constructed to slope gently toward the soak pit or toward the collection point that is piped to the soak pit.

Although the soak pit captures the majority of pesticide from wash waters, small amounts may pass through and enter the soil below. Soil characteristics affect how pesticides move through the soil, and how they break down by environmental or microbiological degradation. Clay soils have a high capacity to absorb many pesticides, but if hard-packed, may have limited percolation abilities. Sandy soils have a much lower capacity to absorb pesticides, but liquids percolate rapidly. Where possible, locate facilities on fine textured soils with organic content and good absorptive properties to capture and degrade trace amounts of pesticide. Hard packed clay or rocky soils are not appropriate.

Pesticides may move in water runoff as compounds dissolve in water or attach to soil particles. Facilities should be located on high, level ground to minimize exposure to runoff. Avoid steep slopes or natural runoff flow lines. Where necessary, curbs or berms will be constructed around wash areas to divert storm water runoff away from the soak pit, and to contain any spills or overflows. In very rainy areas or seasons, it may be necessary to cover the soak pit and wash area when not in use with a tarpaulin, to prevent flooding of the soak pit and subsequent runoff of pesticide-contaminated water.

### 5.1.6 WAREHOUSE/STORAGE RISK MANAGEMENT

In order to mitigate risks associated with pesticide storage, the following will serve as warehouse/storage best management practices:

- A trained storekeeper will manage each facility and will wear gloves, mask, overalls, and boots when in the pesticide area of storage.
- No smoking or eating will be allowed within 30 meters of the pesticide storeroom.
- Pesticide storage facilities must have thermometers installed for daily temperature recording.
- Soap and clean water will be available at all times in all the facilities.
- Recommended pesticide stacking position and height in the warehouse as provided in the FAO Storage and Stock Control Manual will be followed.
- A fire extinguisher will be available in the storage facilities and all site workers will be trained on how to use this device.
- Warning notices will be placed outside of the store with skull and crossbones pictogram, and warnings in the local language
- Insecticides must be lifted off of the floor via pallets or shelves.
- First aid kits must be fully stocked and available in all the central warehouses and secondary stores. Security and inventory management of first aid supplies is mandatory.

#### *ACCIDENTAL WAREHOUSE FIRES*

Inhalation of toxic fumes in the event of a storehouse fire is a major risk of IRS. The risk can be minimized, however, by following BMPs for storage, including prohibiting lighted materials in or near the warehouse or in the vicinity of pesticides during transport to/from vehicles, providing fire extinguishers, and proper ventilation of storerooms.

### 5.1.7 FETAL EXPOSURE (PREGNANCY TESTING)

All female candidates for spray teams will be tested for pregnancy before being recruited into the spray operations and every thirty days until operations end. Provided their work history has been acceptable, females who have been hired and later found to be pregnant will be re-assigned to positions that do not have the potential for exposure to insecticides. Women who are breastfeeding cannot have any contact with pesticides, and are thus prohibited from spraying of pesticide or washing contaminated items.

### 5.1.8 SPRAY OPERATOR EXPOSURE

The individuals recruited for IRS campaigns will receive intensive training on the use, operation, calibration and repair of the spray pumps, including hands-on exercises prior to the beginning of the spraying campaign. They will also be trained 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 the IRS Training Guide for Spray Operations and the 2015 IRS BMP manual. Potential spray operators must also pass written and practical tests at the end of training.

Training for monitoring spray operators for symptoms of pesticide exposure will be mandatory for team leaders and supervisors, as well as for storekeepers and other senior personnel. Any case of an operator or beneficiary displaying symptoms of exposure will require the immediate completion of a standard Incident Report Form by the District Coordinator, who will forward the report to the COP and AIRS home office DECS and TPM, who will review the report before it is sent to the PMI Team and the PMI Resident Advisor in Madagascar.

For malathion and fenitrothion OPs, it may be necessary to monitor the level of acetyl cholinesterase in any worker who may have been exposed to contamination. Occupational exposures to OP insecticides are measurable using blood cholinesterase and urinary excretion of chemical biomarkers. WHOPES Working Group recommendations stated that, “provided that operational guidelines are followed, routine cholinesterase monitoring of spray men during IRS programs is not required” for Actellic® CS. At the present time, biomonitoring is not required for PMI IRS, but increased supervision and monitoring are.

### 5.1.9 BENEFICIARY EXPOSURE

The IP will strive to monitor any suspected cases of residential exposure that suggest adverse events with the insecticide used. 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 beneficiary exposure incidents.

NMCP, and the PMI IRS IP and other partners will work with relevant institutions at all levels to carry out an IEC campaign/BCC to sensitize residents to IRS activities, in accordance with WHO guidelines and also Madagascar Malaria Strategy 2009-2018 and PMI Malaria Operational Plans. The IEC campaign carried out by IRS project leaders 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 at least 10 meters from the home during spraying, and for two hours after spraying.
- Move and keep all animals at least 10 meters from the home during spraying, and for two hours after spraying.
- After two hours, open all windows and doors and air the house out for ½ hour.
- Sweep up any insects killed from the spraying and drop them in latrine pits before allowing re-entry by children and animals.
- Do not re-plaster or paint over the sprayed walls after spraying.
- Keep using mosquito nets for additional protection against malaria.
- If skin itches after reentrance 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 use 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 moved to the center of the room (only if necessitated by rain, etc.) More than one sheet may be required, depending on the size of structures and the amount of belongings.
- Materials can also be moved into structures that are not targeted to be sprayed, e.g., an isolated kitchen or domestic animal shelter.
- Move the household effects to one room which will 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 middle of spraying:**

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

**5.1.10 PESTICIDE EXPOSURE AND TREATMENT**

All spray operators, team leaders, and supervisors will receive detailed training on the emergency steps to take if accidental exposure of the chemical occurs including ingestion, inhalation, eye or dermal contact with the chemical. This training will be conducted by the County Coordinators and government technical services and will include drills to test knowledge of the operators. However, most interventions for acute exposure will have to be provided by medical professionals at the nearest health clinic, so transporting the exposed person to the health clinic will be the priority.

The PMI IRS IP will confirm that all the health facilities around the spray sites have in their store the recommended treatment drugs, and that all the staff responsible for administering emergency treatment to pesticide exposure receives appropriate training. Annex D provides additional information on symptoms and treatment protocols.

**5.1.11 SOLID AND LIQUID CONTAMINATED WASTE MANAGEMENT**

Non-contaminated wastes or those that can be cleaned thoroughly with soap and water will be reused or recycled whenever possible, or disposed of in a municipal landfill if there is no appropriate recycling outlet.

Liquid contaminated wastes will be disposed of on a daily basis in soak pits that are carefully sited and designed according to the criteria in the PMI BMP manual. The soak pit is designed so that pesticides are absorbed by the charcoal layer, and held until environmental processes result in the degradation of the pesticide. Thus, there should be no contaminated liquid waste to deal with at the end of the spray season.

Contaminated solid wastes are incinerated in incinerators that are capable of destroying the pesticide and preventing environmental contamination. Incinerators recommended for disposal of contaminated wastes fall into two categories, those that meet:

- Basel Convention technical standards for all insecticides that do not contain greater than 1% halogens,
- WHO/FAO standards: to be used if we are using DDT or insecticides which contain > 1% halogens.

**For wastes containing less than 1% halogens (e.g., chlorine, bromine):**

- The recommended combustion temperature is >850 °C.
- An afterburner is required, with a residence time of at least two seconds.
- The incinerator must have emission control, including particulate matter filters.
- Ash and slag produced by high-temperature incineration of pesticides are best incorporated into concrete and buried in a secure location.

**For wastes containing greater than 1% halogens:**

- The recommended combustion temperature is between 1100-1300 °C.
- An afterburner is required, with a residence time of at least two seconds.
- A quench rinse for the gas stream that causes a rapid temperature drop to below 250 °C
- The incinerator must have emission control, including particulate matter filters.
- Ash and slag produced by high-temperature incineration of pesticides are best incorporated into concrete and buried in a secure location.

Incineration is not recommended for polyvinyl chloride or other chlorinated wastes such as gloves and boots. Gloves and boots no longer usable for IRS can be easily decontaminated with soap and water and then offered to spray team members, or disposed of as normal nonhazardous waste.

Empty plastic containers should not be incinerated due to the difficulty inherent in burning them cleanly, and the nuisance and toxic emissions that may result. Once punctured to prevent reuse, plastic bottles can be triple rinsed and recycled at an appropriate facility, or land filled.

Cardboard boxes previously containing intact insecticide sachets or bottles are not considered as contaminated waste. Incineration is not recommended for cardboard boxes unless they have been contaminated by pesticide leakage, or used for the storage of other contaminated wastes. In many cases uncontaminated boxes can be recycled, or can also be disposed of as normal nonhazardous wastes. The EMMP in Annex B gives details on the steps and measures that will be taken to prevent negative impacts on the non-target ecosystems from liquid and solid IRS waste materials and disposal practices.

### **Antidotes**

No specific antidote is available for clothianidin exposure; symptomatic and supportive care is the mainstay of treatment. Most interventions will have to be provided by medical professionals at the nearest health clinic. PMI will confirm that all IRS staff and clinicians from the Madagascar Health Service in the IRS district hospital and clinics where clothianidin is used receive appropriate training on administering emergency treatment to pesticide exposure. Annex A provides additional information on symptoms and treatment protocols for exposure to clothianidin.

# ANNEX A: SUMMARY OF ACUTE EXPOSURE SYMPTOMS AND TREATMENT OF CLOTHIANIDIN

<b>Clothianidin</b>	
<b>Human side effects</b>	<b>Treatment</b>
<p>Clothianidin is a systemic insecticide belonging to the nitro-guanidine subgroup of nicotinoid insecticides. It is also referred to as a chloro-nicotinyl or neonicotinoid.<sup>5</sup> Clothianidin and other neonicotinoids act on the central nervous system of insects as an agonist of acetylcholine, the neurotransmitter that stimulates nAChR, targeting the same receptor site (AChR) and activating post-synaptic acetylcholine receptors but not inhibiting AChE. The acute health risks to humans from exposure to clothianidin are minimal due to its low mammalian toxicity. Extrapolation from test results on animals to humans suggests that clothianidin is moderately toxic through oral exposure, but toxicity is low through skin contact or inhalation. Mild to moderate poisoning can cause nausea, vomiting, diarrhea, abdominal pain, dizziness, headache, and mild sedation.<sup>6</sup> While clothianidin may cause slight eye irritation, it is not expected to be a skin sensitizer or irritant.</p> <p>Large deliberate ingestions have caused agitation, seizures, metabolic acidosis, coma, hypothermia, pneumonitis, respiratory failure, hypotension, ventricular dysrhythmias, and death. Rare caustic injury to the esophagus has been reported. This is likely due to the solvent component of the insecticide (N-methyl-2-pyrrolidone) as opposed to the neonicotinoid itself.<sup>7</sup></p> <p>Clothianidin does not damage genetic material, nor is there evidence that it causes cancer in rats or mice; it is unlikely to be a human carcinogen. Submitted data also indicate that no significant adverse environmental impacts are expected to occur from the use of clothianidin.<sup>8</sup></p>	<p>Management of mild to moderate toxicity—Treatment is symptomatic and supportive. Administer IV fluids for hypotension.</p> <p>Management of severe toxicity—Treatment is symptomatic and supportive. Treat hypotension with IV fluids; add vasopressors if hypotension persists. Treat dysrhythmias per American cardiovascular life support guidelines. Consult a gastroenterologist for patients with pain on swallowing; drooling; or other evidence of caustic injury, to evaluate for esophageal damage. Atropine should be considered if a patient is bradycardic or experiencing cholinergic symptoms, because clothianidin insecticides are frequently mixed with organophosphate and carbamate pesticides.<sup>9</sup></p>

<sup>5</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.

<sup>6</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281> Accessed 7/14/17.

<sup>7</sup> Ibid.

<sup>8</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.

<sup>9</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281> Accessed 7/14/17.

<b>Environmental Impacts</b>	
<p>In terrestrial environments, deltamethrin is not expected to be mobile, because it binds tightly to soil particles. It is insoluble in water, and recommended application rates are low. Volatilization from moist soils and biodegradation are major fate processes. However, volatilization is lessened by deltamethrin's tendency to adsorb to soil particles. As with other synthetic pyrethroids, deltamethrin degrades rapidly in soil and plants. It does not bioaccumulate in terrestrial systems. Very little leaching to groundwater is expected, because deltamethrin binds tightly to soil and is practically insoluble in water. Volatilization is a major environmental fate process in surface waters, but is lessened by soil adsorption. Deltamethrin breaks down quickly in water, with reported half-lives of 2–4 hours. It has a high potential to bioconcentrate in aquatic organisms.</p>	

## ANNEX B: ENVIRONMENTAL MITIGATION AND MONITORING PLAN

Category of Activity from the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 2.5 of the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE)	Description of Mitigation Measures for these activities as required in Section 2.6 of Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Who is responsible for monitoring?	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
1. Education, Technical Assistance, Training	Activities involving studies, education, technical assistance, training, or information transfer, except to the extent they directly affect the environment (such as construction of facilities), are recommended for categorical exclusion.	N/A – Categorical Exclusion	N/A	N/A	N/A	N/A
2. Research and	Entomological	Implement laboratory	Laboratory	EHS	Review of EHS	Routine site

Category of Activity from the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 2.5 of the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE)	Description of Mitigation Measures for these activities as required in Section 2.6 of Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Who is responsible for monitoring?	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
Development	surveillance and vector control research use laboratory equipment, chemical reagents, insecticides, and entomological surveillance supplies that have the potential to cause adverse health and environmental impacts if not properly managed. These materials require special care and management to minimize their expiration and/or	environmental, health, and safety (EHS) manuals with standard operating procedures (SOPs), or use existing SOPs, for laboratory operations in accordance with country-specific compliance mechanisms. Implement SOPs for the safe storage, transport, and use of equipment, chemical reagents, insecticides, and supplies in conformance with international best practices (e.g., WHO, FAO) and host country requirements. Provide training to workers on the approved SOPs or Waste Management Plan (WMP) developed for properly handling and disposing of wastes.	personnel within the respective country, with oversight provided by Abt Associates technical experts.	manual/Standard operating procedures (SOPs) implemented per PMI and country-specific requirements Training of staff in activities related to the laboratory EHS manual/SOPs	manual/SOPs to ensure it is appropriate, and complies with PMI, WHO and country-specific recommendations for safety, use of personal protective equipment (if needed), spill prevention, and training. Review training materials and logs to verify trainings were conducted Confirm during routine visits that SOPs are being effectively	visits, as needed, to ensure accordance with operating plan

Category of Activity from the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Describe specific environmental threats of your organization's activities (based on analysis in Section 2.5 of the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE)	Description of Mitigation Measures for these activities as required in Section 2.6 of Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE	Who is responsible for monitoring?	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
	damage.				implemented and that workers are reporting EHS incidents Include date of visits, findings and any non-compliance issues in the annual EMMR Include photographs from site visits	
3. Public Health Commodities	N/A	N/A	N/A	N/A	N/A	N/A
4. Small-Scale Construction or Rehabilitation	No construction will take place under this contract.	Implement rehabilitation activities in conformance with USAID best practices and host country laws and regulations.	Abt Associates technical overseers,	Best practices implemented Records of staff briefings on	Review rehabilitation plans prior to renovations.	As required prior to rehabilitation. Weekly during

<b>Category of Activity from the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE</b>	<b>Describe specific environmental threats of your organization's activities (based on analysis in Section 2.5 of the Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE)</b>	<b>Description of Mitigation Measures for these activities as required in Section 2.6 of Prevention of Mosquito-Borne Diseases through Vector Control IDIQ IEE</b>	<b>Who is responsible for monitoring?</b>	<b>Monitoring Indicator</b>	<b>Monitoring Method</b>	<b>Frequency of Monitoring</b>
	<p>Rehabilitation or cosmetic improvements may lead to adverse environmental and health impacts if hazardous materials are present, or if rehabilitation activities are not properly managed. Exposure to certain building materials during rehabilitation activities can result in health impacts to workers.</p>	<p>Refer to the "Small-Scale Construction" chapter of the USAID Sector Environmental Guidelines (<a href="http://www.usaidgems.org/sectorGuidelines.htm">www.usaidgems.org/sectorGuidelines.htm</a>). Only non-hazardous materials may be used for rehabilitation of facilities. In particular, asbestos and/or lead-based paint or plumbing will not be used, even if allowed by host country. If existing hazardous materials are identified during planning or rehabilitation, implementing partners will cease rehabilitation activities until all such materials have been removed by other qualified parties in compliance with host country regulations. Implementing partners and/or</p>	<p>and sub-contractors, with assistance from IP home office and USAID Missions personnel</p>	<p>activities requiring best practices.</p>	<p>Reports from sub-contractors during rehabilitation activities</p>	<p>rehabilitation. Prior to disposal of wastes. Final report upon completion of rehabilitation.</p>

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		sub-contractors will provide training to workers on applicable best practices.				
	Rehabilitation of facilities may generate debris and wastes that contain both non-hazardous and hazardous materials and require proper disposal.. Workers and others disposing of debris and wastes may experience negative health effects if the appropriate PPE is not used.	Implementing partners and sub-contractors will follow best practices, for properly disposing of waste resulting from renovation or rehabilitation activities. Contractors will train workers on the proper use of PPE, and best practices for handling and disposing of waste. If the presence of asbestos is suspected in a facility to be renovated, the facility must be tested for asbestos before rehabilitation works begins. Should asbestos be present, implementing partners and sub-contractors must cease work until removal is carried out by	Abt Associates EHS managers and sub-contracting supervisors.	Best practices implemented Correspondence with contractors on renovation waste disposal.	Review of intended best practices to ensure it is adequate Review records to verify trainings/ briefings were conducted Receive and review certificates of waste disposal.	At least once, and as required prior to rehabilitation Once post-rehabilitation but prior to final disposal of wastes.

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		others in conformity with host country requirements. Work may not re-commence until the facility is retested to demonstrate that asbestos removal has been effective. All results of the testing for asbestos shall be communicated to the COR.				
5. Small-Scale Water and Sanitation	N/A	N/A	N/A	N/A	N/A	N/A
6. Nutrition	N/A	N/A	N/A	N/A	N/A	N/A
7. Vector Control	1. Health and environmental impacts may result due to inadequate quality control of insecticides (i.e. procuring non-	Insecticide selection for any USAID-supported malaria program is subject to the criteria listed in the USAID Programmatic Environmental Assessment, country SEAs, and host country requirements.	District Coordinator (DC), Operations Manager (OM), Abt Environment	PMI BMPs reviewed and implemented Procurement and inventory logs maintained Proper PPE used	Inspection of facilities, conditions, PPE use, and logs Review of waste management records and	Daily monitoring by storekeeper or site supervisor Weekly monitoring by DC

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	<p>approved insecticides, improper storage, or poor inventory management).</p>	<p>Procurement and inventory logs must be maintained. Ensure storage facility and personal protective equipment (PPE) are appropriate for the active ingredient used and in accordance with approved SOPs. Distribute insecticides to facilities that can manage such commodities safely in storage, use, and disposal (i.e. in a manner generally equivalent to Implementing Partner's own SOPs/WMP)</p>	<p>al Compliance Officer (ECO), Abt Vector Control Manager (VCM), Storekeepers (These positions are representative of the responsibilities required, but may not reflect the exact job title.)</p>	<p>by workers, if needed. Operations facilities are sited appropriately All insecticide management records are reviewed and maintained</p>	<p>storekeeper performance checklists. Verify that inspection reports and storage records are properly maintained and document verification in the annual EMMR. ECO performs mid-application inspections. Verify that inspection reports are properly maintained and document verification in the</p>	<p>Monthly review of procurement logs and inventories by OM</p>

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					annual EMMR	
	2. Occupational risks for workers involved in IRS campaigns.	<p>Inspect and certify vehicles used for insecticide or team transport prior to contract.</p> <p>Train drivers</p> <p>Ensure availability of cell phone, personal protective equipment (PPE) and spill kits during insecticide transportation.</p> <p>Initial and 30-day pregnancy testing for female candidates for jobs with potential insecticide contact.</p> <p>Health test all spray team members for duty fitness.</p> <p>Procure, distribute, and train all workers with potential insecticide contact on the use of PPE.</p> <p>Train operators on mixing</p>	DC, OM, ECO, Chief of Party, and Abt Associates technical experts within the respective country	<p>a. Transport vehicles have a valid inspection certificate on-board.</p> <p>b. Drivers have a certificate of training completion.</p> <p>c. Transport vehicles are equipped with cell phone, spill kit, and PPE.</p> <p>d. Storekeeper has records of pregnancy testing for all female team members.</p> <p>e. Storekeeper has</p>	<p>a-c. ECO inspection of vehicles in the field.</p> <p>d-e. ECO inspection of health records at operations sites.</p> <p>f-h. ECO performs pre-application inspections of inventories and training records, and mid-application inspections of PPE use and operator performance.</p>	<p>a-c. 2 inspections per week.</p> <p>d-e. One inspection per campaign, additional inspection if new hires or more than 30 application days.</p> <p>f-h. ECO pre-application inspections 2 per campaign, ECO mid-application</p>

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		<p>insecticides and the proper use and maintenance of application equipment.            Provide adequate facilities and supplies for end-of-day cleanup.            Enforce application and clean-up procedures.</p>		<p>medical exam results for all team members.            f. Operators wear complete PPE during application and clean-up, according to SOP requirements.            g. Operators mix insecticide properly, and equipment does not leak.            h. All facilities are compliant, and materials required for clean-up are present.            i. Inspections are performed as scheduled,</p>	<p>i. Monitoring of on-line database for submission of inspection reports.</p>	<p>inspections 5 times per week.            i. Weekly</p>

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				corrective action is taken as needed.		
	3. Health and safety risks for residents of treated houses (e.g., risks from skin contact and/or ingestion of insecticides)	a. Implement Information, Education and Communication (IEC) campaigns to inform homeowners of responsibilities and precautions, including washing itchy skin and going to health clinic if symptoms develop and do not subside b. Ensure health facility staff are aware of insecticide poisoning management	IEC officers, OM, ECO, host country Ministry of Health/Environment officials.	a. Review IEC materials and records and execute pre-application IEC campaigns	a. Review IEC materials and records to verify IEC pre-application campaigns were conducted and homeowners were informed of responsibilities and precautions	a. Review IEC materials once per campaign
	4. Nearby residents may be exposed to insecticides if insecticides are not securely stored to prevent theft	Storage facilities and transportation vehicles must be physically secured to prevent theft. Maintain records of all insecticide receipts, issuance, and return of empty containers.	Storekeepers, District coordinators, sector managers, logistics coordinator,	Storage facilities and transportation vehicles are secured. All insecticide management	Inspection of storage facilities and transportation vehicles. Inspection of insecticide	Daily monitoring by storekeeper or site supervisor. Weekly monitoring by District

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	and misuse incidents, including the illegal resale of insecticides.	Conduct analysis comparing number of houses treated vs. number of containers used. Examine houses treated to confirm application. Perform physical inventory counts during the application season.	OM, ECO	records are reconciled.	management records. Storekeeper performance checklists. ECO mid-campaign inspections.	Coordinator. Examine houses during campaign according to schedule in SOPs. Physical inventory counts twice per campaign per store room.
	5. Ecological risk to non-target species and water bodies from use of insecticides	For shipments of insecticide over water, sachets/ bottles will be packed in 220 liter open top barrels with a water-tight top and a locking ring, or in a similar durable container. Waterproof labeling must be affixed to the barrel, with the identity of the pesticide, number of bottles inside, the	DC, OM, ECO	Training materials and records. Equipment is maintained and operated to eliminate leaks. Applicators only mix and apply insecticides according to	Review training materials and records to verify trainings were conducted. Conduct inspections during operations. Verify that	Inspect work records once per campaign. Inspections during operations 3 times per week. Review training materials once per campaign.

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		<p>weight, the type of hazard posed by the contents, and the personal protective equipment to be worn when handling the barrel.</p> <p>Train applicators on the SEA operational requirements, SOPs, PMI BMPs, and approved WMP, developed for the safe and effective storage, distribution, application, and disposal of insecticides</p> <p>Ensure application equipment and PPE are appropriate for the active ingredient used and in accordance with approved SOPs, and maintain equipment to avoid leaks.</p> <p>Maintain application equipment</p> <p>No application of insecticides within 30 yards of beekeeping sites</p>		SOPs	inspection and incident reports are properly maintained and document verification in the annual EMMR. Include any issues identified during inspections in the annual EMMR	

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	6. Environmental risk from disposal of liquid and solid wastes	<p>Handling, treatment, and disposal of nonhazardous (general waste) and hazardous wastes must be in accordance with the approved WMP/SOPs and the PMI BMPs. The WMP, which outlines SOPs for managing waste processes, must be in accordance with PMI best practices and host country requirements</p> <p>Choose sites for disposal of liquid wastes, including fixed and mobile soak pit sites according to PMI BMPs</p> <p>Construct fixed and mobile soak pits with charcoal according to the BMPs to adsorb insecticide from rinse water</p> <p>Maintain soak pits as necessary during season</p>	DC, OM, ECO	<p>WMP implemented and disposal sites inspected and certified before campaigns.</p> <p>Disposal sites near operations sites are appropriate according to PMI BMPs</p> <p>Soak pits are constructed according to PMI BMPs</p> <p>Soak pits perform properly throughout the application season</p> <p>Wastes are stored and managed</p>	<p>Review WMP/SOPs to ensure it conforms to PMI BMPs and WMP is available on site</p> <p>Pre-application inspections.</p> <p>Verify that inspection reports are properly maintained and document verification in the annual EMMR.</p> <p>Include any issues identified during inspections in the annual EMMR</p> <p>Mid- and post-</p>	<p>Pre-application inspections: once per campaign</p> <p>Mid- and post-application inspections: twice per campaign</p> <p>Review of WMP/SOPs during campaign</p>

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		Monitor waste storage and management during campaign Monitor disposal procedures post-campaign		according to PMI BMPs Waste disposal is conducted in accordance with the WMP/SOPs and records maintained	application inspections and monitoring. Verify disposal practices in inspection reports and document in the annual EMMR. Include any issues identified during inspections in the annual EMMR. Review WMP/SOPs to for effectiveness and maintain on site	
	7. Improper incineration of wastes and	Wastes will only be disposed in incinerators that comply with PMI BMPs Collect and	COR, Abt ECO, Abt Technical	Incinerator specifications Maintenance of	Review incineration records and	Review incinerator specifications

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	disposal of residual ash can pose a threat to air quality, soil, and the water supply and result in environmental and public health hazards.	maintain treatment and disposal documents and records on file Country-level USAID EC documentation must contain guidance on proper disposal of wastes	Experts	treatment and disposal records Reg 216 documentation for incinerator procurement and management services reviewed by COR and GH BEO.	document in the annual EMMR	prior to disposal arrangement Annual review of disposal records

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8. Testing of Insecticide-Treated Nets	<ol style="list-style-type: none"> <li>1. Risk of theft from storerooms, followed by unintended use.</li> <li>2. Pollution from improper disposal of packaging.</li> <li>3. Surface or groundwater pollution from improper disposal of wastewater from washing nets</li> <li>4. Risk of the use of nets for purposes for which they are not designed or intended.</li> </ol>	<ol style="list-style-type: none"> <li>1. Store nets only in storerooms secured with sturdy doors, double locks, and barred windows.</li> <li>2. Dispose of waste materials according to PMI BMPs.</li> </ol>	1-4 Environmental Compliance Officer, USAID Mission	<ol style="list-style-type: none"> <li>1. Storerooms are built or modified to meet PMI BMPs.</li> <li>2. Evidence of a compliant disposal program in place.</li> </ol>	<ol style="list-style-type: none"> <li>1. Inspection of storeroom using checklists.</li> <li>2. Inspection of disposal/destruction records.</li> </ol>	1-4. Once per fiscal quarter.
8. Emergency	N/A	N/A	N/A	N/A	N/A	N/A

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Response						

## ANNEX C: BIBLIOGRAPHY

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