



U.S. PRESIDENT'S MALARIA INITIATIVE



# ETHIOPIA INDOOR RESIDUAL SPRAYING SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT 2015 – 2020

## AMENDMENT #2

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The views expressed in this document do not necessarily reflect the views of the United States Agency for International Development or the United States Government.



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## AMENDMENT #2

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# ACRONYMS

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|               |  |
|---------------|--|
| <b>BMPs</b>   | <b>Best Management Practices</b>                             |
| <b>DC</b>     | <b>District Coordinator</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>SEA</b>    | <b>Supplemental Environmental Assessment</b>                 |
| <b>SUAP</b>   | <b>Safer Use Action Plan</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 Team</b>       |
| <b>WHOPES</b> | <b>World Health Organization Pesticide Evaluation Scheme</b> |

# EXECUTIVE SUMMARY

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This document has been prepared to serve as an amendment to the 2015-2020 Supplemental Environmental Assessment (SEA) for indoor residual spraying (IRS) in Ethiopia. That SEA authorized the use of the pyrethroid, carbamate, and organophosphate classes of insecticides for IRS nationwide in Ethiopia, as well as chlorfenapyr – when approved by the World Health Organization Pesticide Evaluation Scheme (WHOPES) or the Prequalification Team (WHO/PQ). This amendment to the SEA authorizes the use of clothianidin, a new IRS insecticide that was WHO/PQ-listed in 2017, in addition to a combination clothianidin/deltamethrin product (when approved by WHO/PQ).

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 Ethiopia, new viable insecticides must be introduced for use. In order for clothianidin and clothianidin combination products to be added as IRS alternatives, 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 clothianidin/deltamethrin combination, as well as the legal and regulatory status of this active ingredient in Ethiopia and in the United States.

Ethiopia has been implementing IRS for malaria control as part of an integrated vector management (IVM) strategy for about five decades. The country has been targeted for PMI-support since 2008. Starting in 2017, the number of PMI-supported districts was set at 44. A long-lasting insecticide in the organophosphate class, Actellic 300CS will be used in all districts in 2018. However, this SEA is seeking authorization for the future use of clothianidin and clothianidin/deltamethrin combination nationwide in Ethiopia.

Therefore the proposed actions analyzed in this document are:

- The continuation of IRS programming for 2018-2020, implementing a rotational or mosaic technique, using pyrethroids, carbamates, organophosphates, or clothianidin, as well as chlorfenapyr and clothianidin/deltamethrin combination (when recommended by WHO/PQ) where appropriate, based on pesticide resistance patterns throughout the country, and other critical factors.
- The authorization of closely supervised hut trials using clothianidin and/or clothianidin/deltamethrin combination product, as described further herein.

All conditions of the existing 2015 SEA, including the Safer Use Action Plan (SUAP) will remain valid, and all PMI IRS operations in Ethiopia 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 #2 OF THE 2015 – 2020 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR THE U.S. PRESIDENT’S MALARIA INITIATIVE INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL IN ETHIOPIA**

The United States Agency for International Development (USAID) Global Health Bureau has determined that the proposed indoor residual spraying effort, as described here in Amendment #2 to the 2015 - 2020 SEA, responds to the needs of the community and country as it relates to managing malaria in Ethiopia, and also conforms to the requirements established in Title 22 Code of Federal Regulations 216.

The action recommended for approval in this 2018 SEA amendment is to continue IRS programming for 2018–2020 using a rotational or mosaic technique, involving pyrethroids, carbamates, organophosphates, clothianidin, or chlorfenapyr or clothianidin/deltamethrin combination (when recommended by the WHO Prequalification Team), where appropriate, based on pesticide resistance patterns throughout the country and other critical factors. This amendment also seeks the authorization of closely supervised hut trials using clothianidin and/or clothianidin/deltamethrin combination.

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, eliminate, 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 Ethiopia’s and USAID’s goal of reducing malaria incidence in Ethiopia while minimizing negative impact to the environment and to human health.

The Safer Use Action Plan in Chapter 8 of the SEA and the PMI best management practice (BMP) manual provide detailed guidance on the performance of all activities associated with IRS.

**CLEARANCE:**

Mission Director: \_\_\_\_\_ Date: \_\_\_\_\_  
USAID/Ethiopia Leslie Reed

**CONCURRENCE:**

Acting Bureau Environmental \_\_\_\_\_ Date: \_\_\_\_\_  
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# I. BACKGROUND AND PURPOSE

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## I.1 OBJECTIVES

PMI's IRS activities in Ethiopia operate under an SEA that was approved in July 2015. 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-recommended pesticides: pyrethroid, carbamate, and organophosphate, and chlorfenapyr when recommended by WHO Pre-qualification Team (PQ). This document has been prepared to serve as an amendment to that SEA, and proposes to authorize the use of clothianidin and a combination clothianidin/deltamethrin product (when recommended by WHO/PQ) for IRS in all areas of Ethiopia, including hut trials to be performed in 2018.

In order to expand the insecticide options for IRS to manage vector insecticide resistance in Ethiopia, new viable insecticides must be introduced for use. Changing insecticide 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 Ethiopia and the National Malaria Control Program are seeking authorization to spray clothianidin and a combination clothianidin/deltamethrin product (when recommended by WHO/PQ) insecticides nationwide, as needed, for the duration of the 2015 SEA Amendment #1 (2018-2020).

Sumishield 50WG is a new insecticide formulation from Sumitomo Chemical, Japan that is listed by WHO PQ. The active ingredient in Sumishield 50WG is the neonicotinoid clothianidin. Fludora Fusion is currently being reviewed by WHO for pre-qualification listing. The active ingredients are clothianidin and deltamethrin, a pyrethroid. Clothianidin has not yet been fully authorized by the National Environmental Management Council (NEMC), the competent authority responsible for the approval of insecticide in Ethiopia, but the manufacturer is in the process of registering this insecticide with the NEMC. Registration by the NEMC and amending the current 2015 – 2020 SEA are required for USAID/PMI to use clothianidin and the clothianidin/deltamethrin combination in Ethiopia.

## I.2 AREA AND SCOPE OF CLOTHIANIDIN AND CLOTHIANIDIN/DELTAMETHRIN USE FOR IRS IN ETHIOPIA IN 2018

Experimental hut trials with clothianidin and/or clothianidin/deltamethrin combination product in Ethiopia seek to: (1) determine the residual efficacy of SumiShield® 50WG and Fludora Fusion in Ethiopia, and, (2) evaluate the effect of

different wall surfaces commonly found in Ethiopia on the persistence of SumiShield® 50WG and Fludora Fusion. The residual activity and persistence tests of Sumishield and Fludora Fusion will be conducted in Gerbi-Widena-Boremo kebele, which is close to Ziway town in Adami Tullu and Jido Kombolcha District in East Oromia. Similar data will be collected by the Tropical and Infectious Diseases Research Center (TIDRC), Jimma University, in Sekoru District located at a distance of 102 km from Jimma town in southwestern Ethiopia.

The proposed SumiShield and Fludora Fusion experimental hut trials will be carried out in circular huts constructed from mud or bricks made of mud walls. The roof is made of a frame of eucalyptus wood beams covered with grass. The interior diameter of a hut is approximately 2.5-3.5m and the height of the wall is 2 m. Each hut has all of four surfaces types namely: rough (one layer of mud), smooth (two layers of mud), dung plastered, and painted, which are demarcated and clearly labeled to avoid confusion.

Throughout the bioassay trial period, the huts won't be occupied by humans or animals; they will remain locked and only be opened during the spraying and testing times. An experienced sprayer will be selected from one of the districts and further trained until the operator is able to consistently apply the target dose (volume of water). The same person will be responsible for spraying the insecticides in both districts – Adami Tullu and Jido Kombolcha; and Sekoru – to avoid sprayer bias. Representatives from PMI, Federal Ministry of Health of Ethiopia, Adamitulu District, and Jimma University will supervise the spraying.

For the trial, three huts from each district are proposed to be sprayed with SumiShield at the dose of 300 mg active ingredient/m<sup>2</sup> using the standard Hudson Expert sprayer, three huts will be sprayed with Fludora Fusion at the dose of 200 mg clothianidin/ m<sup>2</sup> and 25 mg deltamethrin/ m<sup>2</sup> using the standard Hudson Expert sprayer, and a positive control hut will be sprayed with Actellic 300 CS at the target dose of 1000 mg active ingredient/m<sup>2</sup>, and the negative control hut will be sprayed with water only.

The bio-efficacy and residual activity of SumiShield and Fludora Fusion will be assessed using a susceptible insectary colony of *Anopheles arabiensis* which has been maintained at the Aklilu Lemma Institute of Pathobiology at Addis Ababa University. Cone bioassays will be used to monitor the residual action of the insecticides as described in the WHO guideline (WHO 2006). The residual activity of the insecticides will be assessed monthly until mortality of test mosquitoes falls below 80% for two consecutive months.

## **I.3 ENTOMOLOGICAL MONITORING**

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

When used in order to determine the quality of spraying and the residual performance of clothianidin or the clothianidin/deltamethrin combination 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 mud brick 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 measure 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 mosquitoes falls below 80%.

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

To monitor changes in mosquito populations, the following activities will be performed: catches at two sites sprayed with clothianidin or the clothianidin/deltamethrin combination product, two sites sprayed with Actellic 300 CS, two control sites and two former IRS sites.

## 2. PROPOSED ACTION AND ALTERNATIVES

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This section describes the alternatives to clothianidin and clothianidin/deltamethrin combination 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 and clothianidin/deltamethrin combination nationwide in Ethiopia for IRS. Clothianidin is listed by WHO/PQ and the combination clothianidin/ deltamethrin product is currently under WHO review for PQ listing, with a listing expected in 2018. If authorized for PMI use in Ethiopia, they will provide additional options 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 2015 SEA under Pesticide Procedures part b. (Section 6.2).

### 2.2 NO-PROJECT ALTERNATIVE

Insecticide resistance is one of the most serious threats to malaria 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” will maintain the limited number of available alternative IRS insecticides, and possibly result in increasing resistance to them. 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 Ethiopia NMCP.

### 2.3 ALTERNATIVE IRS GEOGRAPHICAL SITES CONSIDERED

All regions and districts in Ethiopia are eligible for PMI support for IRS according to the current SEA. This amendment seeks to maintain nationwide coverage and add clothianidin and the combination clothianidin/deltamethrin product as IRS options. 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 Ethiopia and the Ethiopia NMCP regularly conduct entomological testing to help determine the best choice of insecticide. This amendment proposes to add clothianidin and clothianidin/deltamethrin combination as alternative insecticides. Clothianidin has now been listed by WHO/PQ and the combination clothianidin/deltamethrin product is currently

under WHO review for IRS, and it is anticipated that they will be registered for public health use in Ethiopia. Thereafter, and on approval of this SEA amendment, clothianidin and the combination clothianidin/deltamethrin product will be an available alternative insecticides.

# 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 Ethiopia; this section of the amendment addresses any clothianidin- and clothianidin/deltamethrin combination-specific aspects of those factors.

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

Clothianidin and deltamethrin are currently registered with United States Environmental Protection Agency (USEPA).

## 3.2 THE BASIS FOR SELECTION OF THE REQUESTED PESTICIDES

**Recommended by WHO:** Clothianidin was included on the WHO PQ list in 2017 and the clothianidin/deltamethrin combination is currently under WHO PQ review.

**Registration for use in Ethiopia:** Clothianidin and the clothianidin/deltamethrin combination are currently not registered for IRS in Ethiopia, but the needed registration process is ongoing for clothianidin. PMI will spray with clothianidin or the clothianidin/deltamethrin combination only when Sumishield or Fludora Fusion have been registered for use in Ethiopia, and not before.

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 and the clothianidin/deltamethrin combination formulations to be used (Sumishield and Fludora Fusion) on the primary wall surface types is reported to be greater than the duration of the transmission season, 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 impacts of clothianidin and deltamethrin 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 and clothianidin/deltamethrin combination 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.

### **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 indoor residual spraying. 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 and the clothianidin/deltamethrin combination 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 8 of the 2015 SEA 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 and clothianidin/deltamethrin combination 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 clothianidin and clothianidin/deltamethrin combination when used as directed for IRS.<sup>1,2</sup> Refer to the environmental and health impact section of this amendment (Section 4.2) and the PEA for greater detail about its 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

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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> <http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/deltamethrin-ext.html> Accessed 5/11/18

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>3</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>4</sup>

Deltamethrin: The risk results for the clothianidin/deltamethrin combination are based on the same study on clothianidin and, for deltamethrin, an acute study on neurological effects in rats (used for oral and inhalation), and an acute dermal contact study on rats that observed local effects on the skin. The USEPA determined that there was no apparent increase in hazard with repeated or chronic exposures, so the benchmarks derived from the acute studies were used directly as benchmarks for intermediate and chronic exposures (USEPA 2004). All derived RfDs were based on a UF of 100 that represented differences in intra-species sensitivity (10), and the lack of human exposure studies (10). Based on the risk screening results, adverse health effects for workers or residents are not expected.

### **3.6 THE EFFECTIVENESS OF CLOTHIANIDIN AND CLOTHIANIDIN/DELTAMETHRIN COMBINATION FOR THE PROPOSED USE**

Evidence on the effectiveness clothianidin and clothianidin/deltamethrin combination in Ethiopia is not available. Before either of these insecticides are used for IRS in Ethiopia, tests will be conducted to provide evidence on their effectiveness. The bio-efficacy and residual activity of SumiShield and Fludora Fusion will be assessed using a susceptible insectary colony of *Anopheles arabiensis* which has been maintained at the Aklilu Lemma Institute of Pathobiology at Addis Ababa University. Cone bioassays will be used to monitor the residual action of the insecticide as described in the WHO guideline (5). Cone bioassays will be performed according to WHO standard protocols, with one cone each at 0.5, 1.0, and 1.5m height. The residual activity of the insecticide will be assessed monthly until mortality of test mosquitoes falls below 80% for two consecutive months, based on the five-day holding period.

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

Clothianidin and clothianidin/deltamethrin combination are compatible with indoor use, which is the target ecosystem (walls, ceilings, eaves of homes). When applied properly, clothianidin and clothianidin/deltamethrin combination dry on

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<sup>3</sup> IVM PEA, 2017. Integrated vector management programs for malaria vector control (2017 update). USAID

<sup>4</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281>, accessed 7/14/17

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 and clothianidin/deltamethrin combination are incompatible with non-target ecosystems (humans, animals, and the environment). If misapplied and released to the environment in large quantities, clothianidin and clothianidin/deltamethrin combination 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, and do not come in contact with humans, animals, or the environment. IRS implementation is also designed to minimize and responsibly manage insecticide-contaminated liquids through the reuse of leftover pesticides and contaminated water; the triple rinsing of equipment; the daily washing of personal protective equipment (PPE); and, at a minimum, washing the 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 5 of the 2015 SEA provides a detailed account of the environmental conditions in Ethiopia under which clothianidin or the clothianidin/deltamethrin combination are to 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 and clothianidin/deltamethrin combination will not be stored near water habitats or 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 2015 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 2015 SEA need to be available for use in Ethiopia. This amendment to the 2015 SEA is seeking authorization to include clothianidin and the clothianidin/deltamethrin combination (when recommended by WHO/PQ) as alternative insecticide options.

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

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

The Ministry of Agriculture of Ethiopia is mandated to regulate the use of pesticides for agriculture, horticulture, forestry, gardening and public health and other uses, monitor the use of pesticides and take enforcement action against illegal use. It also provides permitting of insecticide imports and exports as well as pesticides registration & licensing. All the pesticides proposed for use must be registered for use under the Act, and importation licenses obtained.

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

Training of spray operators will be provided in the same fashion as training for other classes of pesticides, using training procedures and materials as indicated in the SUAP (chapter 8, section 8.1.3.13, pages 77-79) of the 2015 SEA.

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

Entomological monitoring is firmly established in the PMI Ethiopia project, and is used for IVM decision-making. The standard practices for entomological monitoring in the PMI Ethiopia project are presented in the approved 2015 SEA (chapter 6, section 6.12, pages 58-59).

# 4. ENVIRONMENTAL AND HEALTH IMPACTS

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## 4.1 POTENTIAL POSITIVE EFFECTS OF CLOTHIANIDIN AND CLOTHIANIDIN/DELTAMETHRIN COMBINATION

### 4.1.1 DIRECT POSITIVE EFFECTS

The overall benefits of clothianidin and clothianidin/deltamethrin combination use in IRS is improved human health and the reduced incidence of mosquito-borne illness. The direct positive impacts of the use of clothianidin and clothianidin/deltamethrin combination in IRS will include improved capacity for insecticide resistance management, as they will serve as additional options for rotation of insecticides to prevent resistance. Other positive direct impacts of clothianidin and clothianidin/deltamethrin combination in IRS derive from the expected health, economic, and environmental benefits provided by IRS itself. (Refer to Section 7.1 in the 2015 SEA.)

### 4.1.2 INDIRECT POSITIVE EFFECTS

The indirect positive impacts of using clothianidin and clothianidin/deltamethrin combination in IRS are the same as the positive impacts of using the other four WHO-recommended classes of pesticides. (Refer to section 7.1, page 60 of the 2015 SEA for more details.)

## 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 3900 mg/kg body weight (bw) for male rats and 4700 mg/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>5</sup>

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<sup>5</sup> United States EPA assessment report (2003)

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. Reports from attempts at 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.

For deltamethrin, the corresponding characteristics are:

- Acute oral LD50: LD50 in rats is 9.36 mg/kg
- Inhalation LC50 (2h): for rats is 785 mg/L
- Dermal LD50: LD50 in rabbits is 2,000 mg/kg

Deltamethrin is of moderate toxicity to mammals as it is rapidly metabolized and does not accumulate. Deltamethrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the sodium channels of nerve cells. Typical symptoms of acute exposure are irritation of skin and eyes and neurological effects such as severe headaches, dizziness, nausea, anorexia, vomiting, diarrhea, excessive salivation, and fatigue. Tremors and convulsions have been reported in severe poisonings. Dermal exposure to deltamethrin has been shown to cause reversible cutaneous paresthesia (a burning, tingling, or stinging of the skin). Limited data exist for humans following chronic exposures. Chronic occupational exposure to deltamethrin has resulted in skin and eye irritation. Long-term animal studies have not shown reproductive or mutagenic effects. IARC has classified deltamethrin as “not classifiable as to its carcinogenicity in humans.” Aquatic Life

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.

In one study, the aquatic half-life of deltamethrin ranged from 8-48 hours. Variations of the half-life were due to the method of application. Other reported aquatic half-lives range from one to four hours. Deltamethrin was stable to hydrolysis in solutions of pH 5 and 7. In a pH 9 solution, the average half-life was 2.5 days. Deltamethrin was stable to direct aqueous photolysis in a 30 day study. Due to its Henry's law constant ( $1.2 \times 10^{-4} \text{ atm}\cdot\text{m}^3/\text{mol}$  at 25 °C), deltamethrin has a higher potential to volatilize from water compared with other pyrethroids

Clothianidin and the clothianidin/deltamethrin combination will not be stored within 30 meters of water bodies, and any transport over water will be according to PMI BMPs.

#### **4.2.2 BIRDS**

According to the United States EPA, clothianidin and clothianidin/deltamethrin combination are practically non-toxic to bird species that were fed relatively large doses of the chemical on an acute basis.

#### **4.2.3 BEES**

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 Sumishield and Fludora Fusion 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.

#### **4.2.4 CUMULATIVE IMPACT**

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

# 5. SAFER USE ACTION PLAN

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The procedures and protocols of the SUAP of the 2015 SEA (chapter 8, pages 67-92) remain in effect, and will be used for clothianidin and the clothianidin/deltamethrin combination. Clothianidin- and deltamethrin-specific considerations are discussed below. See Annex A of this amendment for health and safety impacts of clothianidin and treatment recommendations. The development of the SUAP and completion of the EMMP (Annex B) are requirements of PMI and mandatory conditions for the use of clothianidin and the clothianidin/deltamethrin combination in Ethiopia.

## 5.1 PESTICIDE EXPOSURE AND TREATMENT

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 Ethiopia 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 and deltamethrin.

# 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>1</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>2</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>3</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>4</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>5</sup></p> |

<sup>1</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.  
<sup>2</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281> Accessed 7/14/17.  
<sup>3</sup> Ibid.  
<sup>4</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.  
<sup>5</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281> Accessed 7/14/17.

| <b>Clothianidin</b>  |  |
|--|--|
| <b>Human side effects</b>  | <b>Treatment</b>   |
| <p>Deltamethrin is a powerful broad-spectrum synthetic pyrethroid. It is of moderate toxicity to mammals as it is rapidly metabolized and does not accumulate. It poses low risk to humans when used at levels recommended for its designed purpose. Deltamethrin exhibits its toxic effects by affecting the way the nerves and brain normally function by interfering with the sodium channels of nerve cells. Typical symptoms of acute exposure are irritation of skin and eyes and neurological effects such as severe headaches, dizziness, nausea, anorexia, vomiting, diarrhea, excessive salivation, fatigue, irritability, abnormal sensations of the face and skin, and numbness. Tremors and convulsions have been reported in severe poisonings. Inhaled deltamethrin has been shown to cause reversible cutaneous paresthesia (a burning, tingling, or stinging of the skin). Limited data exist for humans following chronic exposures. However, the following effects are suspected to be a result of chronic exposures in humans: choreoathetosis, hypotension, prenatal damage, and shock. Chronic occupational exposure to deltamethrin causes skin and eye irritation. IARC has classified deltamethrin as “not classifiable as to its carcinogenicity in humans.”</p> | <p>If exposed immediately remove any contaminated clothing. Soak any liquid contaminant on the skin clean affected area with soap and warm water.</p> <p>Rinse copiously with water when eye exposures occur or 4 percent sodium bicarbonate.</p> <p>Vomiting should not be induced following ingestion exposures, but the mouth should be rinsed.</p> |
| <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

## A. Environmental Mitigation and Monitoring Plan PMI VectorLink Project (AID-OAA-TO-17-00027)

| 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   | N/A – Categorical Exclusion   | N/A                                | N/A                  | N/A               | N/A                     |

| 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  |
|---|--|--|--|--|--|--|
|   | directly affect the environment (such as construction of facilities), are recommended for categorical exclusion.   |  |  |  |  |  |
| 2. Research and Development   | Entomological 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 | Implement laboratory 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.<br><br>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, | Laboratory personnel within the respective country, with oversight provided by Abt Associates technical experts. | EHS manual/Standard operating procedures (SOPs) implemented per PMI and country-specific requirements<br><br>Training of staff in activities related to the laboratory EHS manual/SOPs | Review of EHS 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. | Routine site visits, as needed, to ensure accordance with operating plan |

| <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>properly managed. These materials require special care and management to minimize their expiration and/or damage.</p>   | <p>FAO) and host country requirements.</p> <p>Provide training to workers on the approved SOPs or Waste Management Plan (WMP) developed for properly handling and disposing of wastes.</p> |   |                             | <p>Review training materials and logs to verify trainings were conducted</p> <p>Confirm during routine visits that SOPs are being effectively implemented and that workers are reporting EHS incidents</p> <p>Include date of visits, findings and any non-compliance issues in the annual EMMR</p> <p>Include photographs from site visits</p> |                                |

| 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  |
|---|---|--|---|--|--|--|
| 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. Rehabilitation or cosmetic improvements may lead to adverse environmental and health impacts if hazardous materials are present, or if rehabilitation activities are not | Implement rehabilitation activities in conformance with USAID best practices and host country laws and regulations. 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> ).<br><br>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 | Abt Associates technical overseers, and sub-contractors, with assistance from IP home office and USAID Missions personnel | Best practices implemented<br><br>Records of staff briefings on activities requiring best practices. | Review rehabilitation plans prior to renovations.<br><br>Reports from sub-contractors during rehabilitation activities | As required prior to rehabilitation.<br><br>Weekly during rehabilitation.<br><br>Prior to disposal of wastes.<br><br>Final report upon completion of rehabilitation. |

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|--|--|---|---|--|--|---|
|  | <p>properly managed. Exposure to certain building materials during rehabilitation activities can result in health impacts to workers.</p>  | <p>country.</p> <p>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.</p> <p>Implementing partners and/or sub-contractors will provide training to workers on applicable best practices.</p> |   |  |  |   |
|  | <p>Rehabilitation of facilities may generate debris and wastes that contain both non-hazardous and hazardous materials and require proper</p>  | <p>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</p>  | <p>Abt Associates EHS managers and sub-contracting supervisors.</p> | <p>Best practices implemented</p> <p>Correspondence with contractors on renovation waste disposal.</p> | <p>Review of intended best practices to ensure it is adequate</p> <p>Review records to verify trainings/</p> | <p>At least once, and as required prior to rehabilitation</p> <p>Once post-rehabilitation but prior to final disposal</p> |

| <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>disposal.. Workers and others disposing of debris and wastes may experience negative health effects if the appropriate PPE is not used.</p>   | <p>waste.</p> <p>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 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.</p> <p>All results of the testing for asbestos shall be communicated to the COR.</p> |   |                             | <p>briefings were conducted</p> <p>Receive and review certificates of waste disposal.</p> | <p>of wastes.</p>              |
| <p>5. Small-Scale Water and</p>  | <p>N/A</p>   | <p>N/A</p>   | <p>N/A</p>                                | <p>N/A</p>                  | <p>N/A</p>  | <p>N/A</p>                     |

| 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  |
|---|--|---|---|---|---|--|
| Sanitation  |  |   |   |   |   |  |
| 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-approved insecticides, improper storage, or poor inventory management). | <p>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.</p> <p>Procurement and inventory logs must be maintained.</p> <p>Ensure storage facility and personal protective equipment (PPE) are appropriate for the active ingredient used and in accordance with approved SOPs.</p> <p>Distribute insecticides to facilities that can manage such</p> | District Coordinator (DC), Operations Manager (OM), Abt Environmental Compliance Officer (ECO), Abt Vector Control Manager (VCM), Storekeepers (These positions are | <p>PMI BMPs reviewed and implemented</p> <p>Procurement and inventory logs maintained</p> <p>Proper PPE used by workers, if needed.</p> <p>Operations facilities are sited appropriately</p> <p>All insecticide management records are reviewed and</p> | <p>Inspection of facilities, conditions, PPE use, and logs</p> <p>Review of waste management records and storekeeper performance checklists.</p> <p>Verify that inspection reports and storage records are properly maintained and document</p> | <p>Daily monitoring by storekeeper or site supervisor</p> <p>Weekly monitoring by DC</p> <p>Monthly review of procurement logs and inventories by OM</p> |

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|---|---|---|---|--|---|--|
|   |   | commodities safely in storage, use, and disposal (i.e. in a manner generally equivalent to Implementing Partner's own SOPs/WMP)   | representative of the responsibilities required, but may not reflect the exact job title.)      | maintained   | verification in the annual EMMR.<br>ECO performs mid-application inspections. Verify that inspection reports are properly maintained and document verification in the annual EMMR |  |
|   | 2. Occupational risks for workers involved in IRS campaigns.  | Inspect and certify vehicles used for insecticide or team transport prior to contract.<br>Train drivers<br>Ensure availability of cell phone, personal protective equipment (PPE) and spill kits during insecticide | DC, OM, ECO, Chief of Party, and Abt Associates technical experts within the respective country | a. Transport vehicles have a valid inspection certificate on-board.<br>b. Drivers have a certificate of training | a-c. ECO inspection of vehicles in the field.<br>d-e. ECO inspection of health records at operations sites.   | a-c. 2 inspections per week.<br>d-e. One inspection per campaign, additional |

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|--|--|--|---|--|---|---|
|  |  | <p>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 insecticides and the proper use and maintenance of application equipment.</p> <p>Provide adequate facilities and supplies for end-of-day cleanup.</p> <p>Enforce application and clean-up procedures.</p> |   | <p>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 medical exam results for all team members.</p> <p>f. Operators wear complete PPE during application and clean-up, according to SOP requirements.</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>i. Monitoring of on-line database for submission of inspection reports.</p> | <p>inspection if new hires or more than 30 application days.</p> <p>f-h. ECO pre-application inspections 2 per campaign, ECO mid-application inspections 5 times per week.</p> <p>i. Weekly</p> |

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|---|---|---|--|---|--|---|
|   |   |   |  | <p>g. Operators mix insecticide properly, and equipment does not leak.</p> <p>h. All facilities are compliant, and materials required for clean-up are present.</p> <p>i. Inspections are performed as scheduled, corrective action is taken as needed.</p> |  |   |
|   | 3. Health and safety risks for residents of treated houses (e.g., risks from skin contact   | a. Implement Information, Education and Communication (IEC) campaigns to inform homeowners of responsibilities and precautions, including washing itchy skin and going to | IEC officers, OM, ECO, host country Ministry of Health/Environment | a. Review IEC materials and records and execute pre-application IEC   | a. Review IEC materials and records to verify IEC pre-application campaigns were | a. Review IEC materials once per campaign |

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|---|---|---|--|---|--|--|
|   | and/or ingestion of insecticides)   | health clinic if symptoms develop and do not subside<br><br>b. Ensure health facility staff are aware of insecticide poisoning management   | officials.   | campaigns   | conducted and homeowners were informed of responsibilities and precautions   |  |
|   | 4. Nearby residents may be exposed to insecticides if insecticides are not securely stored to prevent theft and misuse incidents, including the illegal resale of insecticides.           | Storage facilities and transportation vehicles must be physically secured to prevent theft.<br><br>Maintain records of all insecticide receipts, issuance, and return of empty containers.<br><br>Conduct analysis comparing number of houses treated vs. number of containers used.<br><br>Examine houses treated to confirm application<br><br>Perform physical inventory counts during the application | Storekeepers, District coordinators, sector managers, logistics coordinator, OM, ECO | Storage facilities and transportation vehicles are secured.<br><br>All insecticide management records are reconciled. | Inspection of storage facilities and transportation vehicles.<br><br>Inspection of insecticide management records.<br>Storekeeper performance checklists.<br><br>ECO mid-campaign inspections. | Daily monitoring by storekeeper or site supervisor. Weekly monitoring by District Coordinator<br><br>Examine houses during campaign according to schedule in SOPs.<br><br>Physical |

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|---|---|---|------------------------------------|--|--|--|
|   |   | season.   |                                    |  |  | inventory counts twice per campaign per store room.  |
|   | 5. Ecological risk to non-target species and water bodies from use of insecticides  | <p>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 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</p> | DC, OM, ECO                        | <p>Training materials and records</p> <p>Equipment is maintained and operated to eliminate leaks.</p> <p>Applicators only mix and apply insecticides according to SOPs</p> | <p>Review training materials and records to verify trainings were conducted</p> <p>Conduct inspections during operations.</p> <p>Verify that inspection and incident reports are properly maintained and document verification in the annual EMMR. Include any</p> | <p>Inspect work records once per campaign</p> <p>Inspections during operations 3 times per week</p> <p>Review training materials once per campaign</p> |

| <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>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> |   |   | <p>issues identified during inspections in the annual EMMR</p>   |   |
|  | <p>6. Environmental risk from disposal of liquid and solid wastes</p>  | <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</p>  | <p>DC, OM, ECO</p>                        | <p>WMP implemented and disposal sites inspected and certified before campaigns.</p> <p>Disposal sites</p> | <p>Review WMP/SOPs to ensure it conforms to PMI BMPs and WMP is available on site</p> <p>Pre-application</p> | <p>Pre-application inspections: once per campaign</p> <p>Mid- and post-application inspections:</p> |

| <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>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> <p>Monitor waste storage and management during campaign</p> <p>Monitor disposal procedures post-campaign</p> |   | <p>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 according to PMI BMPs</p> <p>Waste disposal is conducted in accordance with the WMP/SOPs</p> | <p>inspections. Verify that inspection reports are properly maintained and document verification in the annual EMMR. Include any issues identified during inspections in the annual EMMR</p> <p>Mid- and post-application inspections and monitoring. Verify disposal practices in inspection reports and document in the</p> | <p>twice per campaign</p> <p>Review of WMP/SOPs during campaign</p> |

| 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  |
|---|---|---|-------------------------------------|---|--|--|
|   |   |   |                                     | and records maintained  | annual EMMR. Include any issues identified during inspections in the annual EMMR.<br><br>Review WMP/SOPs to for effectiveness and maintain on site |  |
|   | 7. Improper incineration of wastes and disposal of residual ash can pose a threat to air quality, soil, and the water supply and result in environmental and public health                | Wastes will only be disposed in incinerators that comply with PMI BMPs Collect and maintain treatment and disposal documents and records on file<br><br>Country-level USAID EC documentation must contain guidance on proper disposal of wastes | COR, Abt ECO, Abt Technical Experts | Incinerator specifications<br><br>Maintenance of treatment and disposal records<br><br>Reg 216 documentation for incinerator procurement and management | Review incineration records and document in the annual EMMR  | Review incinerator specifications prior to disposal arrangement<br><br>Annual review of disposal records |

| <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> |
|--|--|--|---|--------------------------------------|--------------------------|--------------------------------|
|  | hazards.   |  |   | services reviewed by COR and GH BEO. |                          |                                |

| 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       |
|---|--|---|---|--|--|-------------------------------|
| 8. Testing of Insecticide-Treated Nets  | <ul 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> </ul> | <ul 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> </ul> | 1-4 Environmental Compliance Officer, USAID Mission | <ul 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> </ul> | <ul style="list-style-type: none"> <li>1. Inspection of storeroom using checklists.</li> <li>2. Inspection of disposal/destruction records.</li> </ul> | 1-4. Once per fiscal quarter. |
| 8. Emergency  | N/A  | N/A   | N/A   | N/A  | N/A  | N/A                           |

| <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> |
|--|--|--|---|-----------------------------|--------------------------|--------------------------------|
| Response   |  |  |   |                             |                          |                                |

# ANNEX C: ENVIRONMENTAL MITIGATION AND MONITORING REPORT

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Implementing organization:

Geographic location of USAID-funded activities:

Period covered by this Reporting Form and Certification:

## Environmental Mitigation and Monitoring Report PMI VectorLink Project (AID-OAA-TO-17-00027)

Add Introduction and additional narrative here, as needed.

| List each Mitigation Measure from column 3 in the EMMP<br>(EMMT Part 2 of 3) | Status of Mitigation Measures | List any outstanding issues relating to required conditions | Remarks |
|--|-------------------------------|---|---------|
| 1. Education, Technical Assistance, Training                                 |                               |   |         |
| 2. Research and Development  |                               |   |         |
| 3. Public Health Commodities   |                               |   |         |

|                                     |  |  |  |
|-------------------------------------|--|--|--|
|                                     |  |  |  |
| 4. Small-Scale Construction         |  |  |  |
| 5. Small-Scale Water and Sanitation |  |  |  |
| 6. Nutrition                        |  |  |  |
| 7. Vector Control                   |  |  |  |
| 8. Emergency Response               |  |  |  |

Prepared by:

Signature

Date: \_\_\_\_\_

Name and Title

# ANNEX D: BIBLIOGRAPHY

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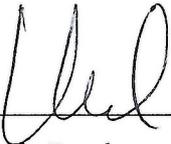
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Leslie Reed

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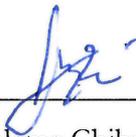
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Brian Hirsch

Date: \_\_\_\_\_

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