



U.S. PRESIDENT'S MALARIA INITIATIVE



# **BENIN INDOOR RESIDUAL SPRAYING SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT 2016- 2020 AMENDMENT #1**

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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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**BENIN INDOOR RESIDUAL  
SPRAYING SUPPLEMENTAL  
ENVIRONMENTAL ASSESSMENT  
2016- 2020**

**AMENDMENT #1**

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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 Monitoring Plan</b>
<b>GoB</b>	<b>Government of Benin</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 2016-2020 Supplemental Environmental Assessment (SEA) for Indoor Residual Spraying (IRS) in Benin. That SEA authorized the use of the pyrethroid, carbamate, and organophosphate classes of insecticides for IRS nationwide in Benin, as well as chlorfenapyr – when approved by the World Health Organization (WHO) or the Prequalification Team (WHO/PQ). This amendment to the SEA authorizes the use of clothianidin, a new IRS insecticide in the neonicotinoid class, that was WHO/PQ-listed in 2017, and a combination clothianidin/deltamethrin product that was WHO/PQ-listed in 2018.

This document will also serve as the Letter Report for 2019 activities.

Changing or rotating insecticides of different classes over time and space is a leading way to manage vector resistance. In order to manage vector insecticide resistance in Benin, new viable insecticides must be introduced for use. In order for clothianidin, marketed as SumiShield, and clothianidin/deltamethrin combination, marketed as Fludora Fusion, 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 these active ingredients in Benin and in the United States. Benin has been targeted for PMI support since 2007. The country has been targeted for PMI-support since 2007. In 2019, the PMI proposes to spray six districts in the northern region of [Benin]. A long-acting organophosphate insecticide, pirimiphos-methyl marketed as Actellic 300CS, will be the main insecticide used. SumiShield is proposed to be used in the coming years. However, this amendment seeks permission to use SumiShield and Fludora Fusion in any part of the country during the period of validity of the parent SEA, in anticipation of future needs. As of 2019, the number of districts supported by the PMI has been set at six instead of eight in 2018. The long-lasting organophosphate insecticide Actellic 300CS will be used in all districts in 2019. However, a clothianidin insecticide will be used starting in 2020 and this SEA is seeking authorization for the nationwide use of clothianidin and clothianidin/deltamethrin combination in Benin.

Therefore the proposed actions analyzed in this document are:

- The continuation of IRS programming for 2019-2020, implementing a rotational or mosaic technique, using pyrethroids, carbamates, organophosphates, clothianidin, or clothianidin/deltamethrin combination as well as chlorfenapyr, a pyrrole, (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 2016 SEA, including the Safer Use Action Plan (SUAP) will remain valid, and all PMI IRS operations in Benin 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 #1 OF THE 2016- 2020 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR THE U.S. PRESIDENT’S MALARIA INITIATIVE INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL IN BENIN

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 #1 to the 2016 – 2020 SEA, responds to the needs of the community and country as it relates to managing malaria in Benin, and also conforms to the requirements established in Title 22 Code of Federal Regulations 216.

The action recommended for approval in this 2019 SEA amendment is to continue IRS programming for two years 2019 – 2020 using a rotational or mosaic technique, involving pyrethroids, carbamates, organophosphates, clothianidin, or clothianidin/deltamethrin combination or chlorfenapyr (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 Benin’s (GoB) and USAID’s goal of reducing malaria incidence in Benin while minimizing negative impact to the environment and to human health.

The Safer Use Action Plan in Chapter 7 of the SEA and the PMI Best Management Practice (BMP) Manual (USAID 2015) provide detailed guidance on the performance of all activities associated with IRS.

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Date: 3/20/2019

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# I. BACKGROUND AND PURPOSE

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## I.1 OBJECTIVES

PMI VectorLink Benin operates under an SEA that was approved in March 2016. 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 (recommended now by WHO/PQ) for IRS in all areas of Benin, including hut trials to be performed in 2019.

In order to manage vector insecticide resistance in Benin, 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 Benin and the National Malaria Control Program (NMCP) are seeking authorization to spray clothianidin, a neonicotinoid, and a combination clothianidin/deltamethrin product nationwide, as needed, for the duration of the 2016 SEA Amendment #1).

Sumishield 50WG is a new insecticide formulation from Sumitomo Chemical, Japan, which is listed by WHO PQ. The active ingredient in Sumishield 50WG is the neonicotinoid clothianidin. Fludora Fusion which is a wettable powder formulation packaged in water soluble bags (WP-SB), containing a combination of Clothianidin and Deltamethrin is recently recommended by WHO PQ. The active ingredients are clothianidin and deltamethrin, a pyrethroid. Both SumiShield 50 WG and Fludora Fusion are fully authorized by the Permanent Interstate Committee of Sahel for Drought Control in the Sahel. This international organization is the competent authority responsible for the approval of insecticide in Benin. Amendment of the current 2016 – 2020 SEA are required for USAID/PMI to use clothianidin and the clothianidin/deltamethrin combination in Benin.

## I.2 AREA AND SCOPE OF CLOTHIANIDIN USE FOR IRS IN BENIN IN 2020

In 2020, if this SEA amendment is approved, IRS will be conducted using clothianidin in Benin.

Geographically, the districts to spray using the clothianidin are not yet selected. However the decision will be made in accordance with entomological studies, and by the steering committee appointed by the NMCP.

In 2019 Benin will use the organophosphate pirimiphos-methyl (Actellic 300CS) in all districts for 21 days according to the following distribution of operational site.

Table 1: Benin 2019 Operational sites distribution

Operational Site	Confirmed or Proposed	Soak Pits Type	Year Soak Pit Constructed	Number of SOPs
<i>Anandana</i>	Confirmed	FSP	2019	43
<i>Copargo</i>	Confirmed	FSP	2017	51
<b><i>Copargo</i></b>				
<i>Barei</i>	Confirmed	FSP	2017	81
<i>Barienou</i>	Confirmed	FSP	2018	78
<i>Bougou</i>	Confirmed	FSP	2018	37
<i>Djougou I</i>	Confirmed	FSP	2018	67
<i>Djougou III</i>	Confirmed	FSP	2017	86
<i>Kolokondé</i>	Confirmed	FSP	2017	42
<i>Partago</i>	Confirmed	FSP	2017	88
<b><i>Djougou</i></b>				
<i>Ouaké</i>	Confirmed	FSP	2018	54
<i>Sèmèrè</i>	Confirmed	FSP	2018	62
<b><i>Ouaké</i></b>				
<i>Bagou</i>	Confirmed	FSP	2018	51
<i>Goumarou</i>	Confirmed	FSP	2019	69
<i>Sori</i>	Confirmed	FSP	2017	72
<b><i>Gogounou</i></b>				
<i>Angaradébou</i>	Confirmed	FSP	2017	41
<i>Kassakou</i>	Confirmed	FSP	2017	49
<i>Kandi III</i>	Confirmed	FSP	2019	65
<i>Sonsoro</i>	Confirmed	FSP	2017	74
<i>Sam</i>	Confirmed	FSP	2019	40
<b><i>Kandi</i></b>				
<i>Libantè</i>	Confirmed	FSP	2017	54
<i>Piame</i>	Confirmed	FSP	2017	74
<b><i>Ségbana</i></b>				
Monrou	Confirmed	MSP	2019	6
Mafouta	Confirmed	MSP	2019	6
Dougoulaye	Confirmed	MSP	2019	6

## **I.3 ENTOMOLOGICAL MONITORING**

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

To determine the quality of spraying and the residual performance of clothianidin on walls, WHO bioassays are conducted. The trials in controlled and natural environments were carried out by the Entomology Research Center (CREC for clothianidin approval in Benin. This study was sponsored by WHO and carried out in southern Benin in the villages of Dangbo (in the experimental station at Covè), over a period of eight months (October 2015 to May 2016). The huts were built alongside a paddy field which represents a permanent breeding site for *Anopheles* mosquitoes. Adult volunteers were recruited among the inhabitants of the site (Covè). Pregnant and breast-feeding women were not involved in the study. After canvassing the district for volunteers, selections were approved by the traditional head of the village within the study site.

Over the period of eight months evaluating the efficacy of clothianidin 50WG in comparison to that of deltamethrin 250WG, 24,135 host-seeking *An. gambiae* (s.l.) were collected from the six experimental huts used in this study. Among these mosquitoes, 35.7% (8609), 31.4% (7577) and 33.0% (7949) were collected from the untreated huts (control huts), the huts treated with clothianidin and those treated with deltamethrin, respectively. The study demonstrated good efficacy and residual effect of SumiShield 50WG against both susceptible and pyrethroid resistant *Anopheles* populations. This insecticide with a novel mode of action for vector control could be a good alternative for IRS in areas of permanent malaria transmission and where mosquitoes are resistant to other insecticides.<sup>1</sup>

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

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

Monthly cone wall bioassay, CDC Light trap, pyrethrum spray collections, and human landing catches. These tests will be performed at sites selected by the Medical Entomology Center of Cotonou in agreement with the Vector Control Technical Working Group of Benin.

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<sup>1</sup> Efficacy of a novel mode of action of an indoor residual spraying product, SumiShield® 50WG against susceptible and resistant populations of *Anopheles gambiae* (s.l.) in Benin, West

## 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 combinations nationwide in Benin for IRS. WHO/PQ has recently listed clothianidin and the combination of clothianidin and deltamethrin. If authorized for PMI use in Benin, 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 2016 SEA under Pesticide Procedures (Chapter 6, section 2.).

IRS activities are conducted to reduce malaria morbidity and mortality, but the implementation of this activity is affected by climate risks, including long-term weather pattern changes and access to water. These risks will be addressed throughout the implementation of the project, as described in the project-wide Climate Risk Management (CRM) plan. Opportunities will be sought through the project to strengthen climate resilience.

### 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 Integrated Vector Management (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 Benin NMCP.

### 2.3 ALTERNATIVE IRS GEOGRAPHICAL SITES CONSIDERED

All regions and districts in Benin are eligible for PMI support for IRS according to the current SEA. This amendment seeks to maintain nationwide coverage and add clothianidin and the clothianidin/deltamethrin combination product as IRS options. The choice of spray sites will be made by Vector Control Technical Working Group of Benin 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 Benin and the Benin NMCP regularly conduct entomological testing to help determine the best choice of insecticide. This amendment proposes to add clothianidin and clothianidin/deltamethrin combinations as alternative insecticides. Both have now been listed by WHO/PQ<sup>2,3,4</sup>, and it is anticipated that they will be registered for

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<sup>2</sup> <https://www.who.int/pq-vector-control/prequalified-lists/en/>

public health use in Benin. Thereafter, and on approval of this SEA amendment, clothianidin and the combination clothianidin/deltamethrin product will be an available alternative insecticides.

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<sup>3</sup> WHO Specifications And Evaluations For Public Health Pesticides: Clothianidin(E)-1-(2-chloro-1,3-thiazol-5-ylmethyl)-3-methyl-2-nitroguanidine

<sup>4</sup> Prequalification Team Vector Control Decision Document: Fludora Fusion; Prequalification Team–Vector Control Group (PQT-VC) Access to Medicines, Vaccines and Pharmaceuticals (MVP) World Health Organization

# 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 Benin; 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 listed by WHO PQ in 2017 and the clothianidin/deltamethrin combination on the 2018 WHO PQ list.

**Registration for use in Benin:** Clothianidin and the clothianidin/deltamethrin combination are currently registered for IRS in Benin. Upon approval of this SEA, PMI can spray with clothianidin or the clothianidin/deltamethrin combination in Benin.

**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 Integrated Vector Management Programmatic Environmental Assessment (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, the use of clothianidin, when used as directed, is not expected to result in adverse human health effects for workers or residents. .

## 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 malaria 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 Safer Use Action Plan SUAP in Chapter 7 of the 2016 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>5,6</sup> Refer to the environmental and health impact section of this amendment (Chapter 5) 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 United State Environmental Protection Agency (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>7</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>8</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 reference of Doses (RfDs) were based on a Uncertainty Factor (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.

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

<sup>6</sup> <http://pmep.cce.cornell.edu/profiles/extoxnet/carbaryl-dicrotophos/deltamethrin-ext.html> Accessed 5/11/18

<sup>7</sup> IVM PEA, 2017. Integrated vector management programs for malaria vector control (2017 update). USAID

<sup>8</sup> <https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281>, accessed 7/14/17

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

Evidence on the effectiveness of clothianidin has been conducted (see section 1.3 of this amendment). The clothianidin/deltamethrin combination will be tested before use. To determine the quality of spray and residual performance of Sumishield on the walls, cone bioassays are conducted during eight months following the spraying in Benin.

For each of the eight months, WHO cone bioassays were performed. A laboratory colony of *An. gambiae* “Kisumu” strain which were fully susceptible to all insecticides and a wild population of *An. gambiae* (s.l.) resistant to pyrethroids sampled around the study site were used. The WHO cone bioassays were carried out in week 1, and each month after spraying. During the whole study, cones were placed at fixed level (0.5, 1, 1.5 and 2 m) on the walls (treated and untreated huts). Each level was randomly selected and labelled to one wall surface of each hut. For each month, at least 10 females of the *An. gambiae* s.s. susceptible reference strain “Kisumu” and wild *An. gambiae* (s.l.) mosquitoes aged 3–5 days were introduced per cone for 30 min exposure. After this exposure period, knockdown mosquitoes were recorded and those alive were kept in observation for 24, 48, 72, 96 and 120 h to score delayed mortalities. Mosquitoes exposed to unsprayed substrates were used as controls. When the mortality in the control was between 5 and 20%, corrected mortality was determined using Abbot’s formula<sup>9</sup>.

### 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 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/or 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 inside 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 BMPs.

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<sup>9</sup> Efficacy of a novel mode of action of an indoor residual spraying product, SumiShield® 50WG against susceptible and resistant populations of *Anopheles gambiae* (s.l.) in Benin, West

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

Chapter 4 of the 2016 SEA provides a detailed account of the environmental conditions in Benin 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 2016 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 2016 SEA need to be available for use in Benin. This amendment to the 2016 SEA is seeking authorization to include clothianidin and the clothianidin/deltamethrin combination 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 Benin 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.

### 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, the Spray Operator Pocket Guide (Were, 2014). Other resources include the Manual on Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning,<sup>10</sup> USAID PMI’s IVM PEA (USAID, 2017 Update), as well as this SEA, all of which provide precautions and recommendations on many aspects of IRS operations. The IRS BMP manual and the PMI IVM PEA requirements are the primary references and have precedence, but the other documents may be used as a reference. It is not incumbent upon the IP to comply with non-PMI documentation except where required by law. However, PMI/USAID requirements are usually stricter than others, so there should not be a conflict.

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<sup>10</sup> WHO-UNEP Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning: A Resource Tool. World Health Organization, Geneva. 332 Pages. Document also accessible at: [http://www.who.int/WHOPES/PQ/recommendations/IPCSPesticide\\_ok.pdf](http://www.who.int/WHOPES/PQ/recommendations/IPCSPesticide_ok.pdf)

PMI will support the training of spray operators and supervisors, and provide overall guidance and logistical support to the IRS operations in Benin. The IP 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,<sup>11</sup> storekeepers, and team leaders are trained on all aspects of IRS operation. Areas of training will include planning of IRS, household preparations, recordkeeping, community mobilization, rational/judicious use of insecticides including sprayer and PPE cleaning, personnel management, and 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.

More information on the training that will be provided is in Section 7 (the SUAP) of the 2016 SEA.

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

Entomological monitoring is firmly established in the PMI Benin project, and is used for IVM decision-making. The procedures to be used are detailed in section 3.6 above. The standard practices for entomological monitoring in the PMI Benin project are presented in the approved 2016 SEA (chapter 6, section 6.).

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

# 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 5.1.1 in the 2016 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 5.1.2, page 29 of the 2016 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 (the dosage that is lethal to 50% of the specified population): 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) (the airborne concentration that is lethal to 50% of the specified population when exposed for four hours): for male and female rats >2.3mg/L.
- Other: Not mutagenic. Not oncogenic in rats and mice. Not teratogenic in rats and rabbits.<sup>12</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

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<sup>12</sup> United States EPA assessment report (2003)

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

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.”

## 4.2.2 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-life 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.

## 4.2.3 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.

## 4.2.4 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.

#### **4.2.5 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.

#### **4.2.6 THREATENED AND ENDANGERED SPECIES**

The activity is not likely to adversely impact threatened or endangered species or their critical habitat due to the storage safeguard requirements and the indoor spraying only of the approved pesticides.

# 5. SAFER USE ACTION PLAN

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The procedures and protocols of the SUAP of the 2016 SEA (chapter 7, pages 49 - 57) 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 Benin.

## 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 Benin 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.

**Note:** Considering the number of sprayers involved in a spray campaign, HIV and AIDS prevention will be addressed as part of health and safety training, with a view to minimizing the potential for HIV and AIDS contamination within the team of sprayers and within the targeted communities.

### 5.1.1 PREVENTION OF BENEFICIARY EXPOSURE

The PMI IRS implementing partner and other partners will work with relevant institutions at all levels to carry out an IEC campaign/BCC to sensitize residents to IRS activities, The IEC campaign (as well as IRS Project supervisors and Health Workers, who will also instruct residents on best practices prior to spraying) should focus on the following elements of residential safety during an IRS program:

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

### 5.1.2 DURING THE RAINY SEASON:

- Each spray operator must be given adequate covering material (3m by 3m minimum), which should be used to cover household effects not removed from the houses.
- Adopt a system of moving household effects to the center of the room and covering them with impermeable material, such as a tarpaulin, before spraying.
- Materials can also be moved into structures that are not targeted to be sprayed, e.g., an isolated kitchen or other 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 mid of spraying Stop the spraying activities. After the rains stop and the weather is considered good spraying can continue.
- Cover the household effects with an impermeable material. These materials should have already been procured by the program and given to each operator.

## 5.2 IRS SOLID WASTES DISPOSAL

IRS solid wastes must be classified as contaminated with insecticide, or non-contaminated, according to the guidance below. Contaminated solid wastes should be stored with pesticide stocks, separated from non-contaminated wastes and IRS commodities. At the local site level, contaminated solid wastes are separately collected, counted, and stored in labeled and sealed boxes. Unusable gloves, plastic bags, boots and plastic sheeting are washed with soap and water, air-dried and packaged by washers in closed containers.

All the decontaminated solid waste will be transferred to Natitingou's main warehouse. After decontamination the waste is sorted. Damaged gloves are treated properly as ordinary garbage and the rest are stocked for reuse. The decontaminated plastic waste is recycled in facilities approved company CISE SARL. The cardboard cartons are recycled at GHES Inter SARL (used to make art objects or decoration table etc.) and the masks are incinerated.

Contaminated wastes, including empty insecticide sachets, plastic pesticide containers, and masks, will be temporarily stored in the District warehouses. At the end of the spray campaign, the material will be relocated to the central storage facility in Natitingou (or other district capital if PMI IRS activities expand or move to other districts). All contaminated material will require disposal in an environmentally responsible manner as prescribed by the PMI IRS BMPs.

For mask and sachet disposal, as well as other contaminated wastes that cannot be cleaned with soap and water, incineration under specific conditions is highly recommended by PMI, the United Nations Environment Program (UNEP) and WHO/FAO. Incinerators recommended for disposal of (non-DDT) contaminated wastes must meet the following key requirements:

- The recommended combustion temperature is between 850°C and 1,100°C.
- An after-burner is required, with a residence time of at least two seconds.
- The incinerator should have emission control, including particulate matter filters.
- Ash and slag produced by high-temperature incineration of pesticides are best incorporated into concrete and buried in a secure location. In Benin, as solid wastes are not incinerated in a PMI-owned incinerator and the implementing partner does not have control over the ash and slag, PMI AIRS can only recommend this disposition.

Incineration is not recommended for polyvinyl chloride or other chlorinated wastes such as gloves and boots, because of the potential for dioxin generation. Gloves and boots no longer usable for IRS can be easily decontaminated with soap and water and offered to spray team members, or disposed of as normal non-hazardous 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 landfilled.

Cardboard boxes previously containing intact insecticide sachets or bottles are not considered as contaminated waste unless visibly contaminated. 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 by industries such as pulp for newspaper or card stock manufacture, or can also be disposed of as normal non-hazardous wastes.

**Table 2: Waste Management Recommendations**

<b>Waste Type</b>	<b>Disposal Recommendation</b>
Empty plastic bottles	Recycle
Hard Hats	Recycle
Face Shields	Recycle
Damaged Goizper IK Pumps	Recycle
Plastic spread Sheets	Recycle
Empty SumiShield 50WG Sachets	Incineration
Waste GAC	Incineration
Spillage/Sawdust/sand (Fixed Soak Pits)	Incineration
Exhumed charcoal (Fixed Soak Pits)	Incineration
Nose Mask/Dust mask	Incineration
Damaged Hudson Pumps	Recycle
Non-Contaminated Cardboard	Recycle
Used washers' Hand Gloves/ used Aprons	Re-use (donation)
Goizper Plastic Accessories	Recycle
Cups And Brush	Recycle
Coverall, Neck Covers, Spray Bags And Reflectors(cannot be used)	Donation /Landfill
Broken Basins And Cups	Recycle
Bad Boot(cannot be used )	Donation /Landfill

Specifically the Benin waste management plan is below listed:

**Table 3: 2019 Benin Waste Management Plan**

<b>Waste Disposal Plan</b>			
<b>Waste Type</b>	<b>Disposal Method</b>	<b>Disposal Site</b>	<b>Est. Date of Transfer to Disposal Site</b>
Empty bottles of ACTELLIC 300 and others plastics	Recycle	Cise Recycle Plant	August 15, 2019
Contaminated Cardboard, bags, nose cover and Scarves, Tyveks	Incinerated	Hospital 'de L'Ordre de Malte de Djougou' Incinerator	August 15, 2019
Non-contaminated Cardboard	Recycle	GHES Inter SARL	August 15, 2019
Non-damaged gloves	Donation or Reuse	-	July 15, 2019

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

Clothianidin	
Human side effects	Treatment
<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>13</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>14</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>15</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>16</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>17</sup></p>

<sup>13</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.

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

<sup>15</sup> Ibid.

<sup>16</sup> <http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf> Accessed 7/14/17.

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

Clothianidin/Deltamethrin combination	
Human side effects	Treatment
<p>Local:, Skin and eye paresthesia which may be severe, Usually transient with resolution within 24 hours, Skin, eye and mucous membrane irritation, Cough, Sneezing</p> <p>Systemic:, discomfort in the chest, Tachycardia, Hypotension, Nausea, Abdominal pain, Diarrhea, Vomiting, Blurred vision, Headache, anorexia, Somnolence, Coma, Convulsions, Tremors, Prostration, Airway hyper reaction, Pulmonary oedema, Palpitation, Muscular fasciculation, Apathy, Dizziness</p>	<p><b>Systemic treatment:</b> Initial treatment: symptomatic. Monitor: respiratory and cardiac functions. In case of ingestion gastric lavage should be considered in cases of significant ingestions only within the first 2 hours. However, the application of activated charcoal and sodium sulphate is always advisable. Keep respiratory tract clear. Oxygen or artificial respiration if needed. In case of convulsions, a benzodiazepine (e.g. diazepam) should be given according to standard regimens. If not effective, phenobarbital may be used.</p> <p><b>Contraindication:</b> atropine.</p> <p><b>Contraindication:</b> derivatives of adrenaline. There is no specific antidote. Recovery is spontaneous and without sequelae.</p> <p>In case of skin irritation, application of oils or lotions containing vitamin E may be considered.</p>
Environmental Impacts	
<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

## 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 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

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
<b>2. Research and Development</b>	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 properly managed. These materials require special care and management to minimize their expiration and/or damage.	<ul style="list-style-type: none"> <li>• 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.</li> <li>• 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.</li> <li>• Provide training to workers on the approved SOPs or Waste Management Plan (WMP) developed for properly handling and disposing of wastes.</li> </ul>	Laboratory personnel within the respective country, with oversight provided by Abt Associates technical experts.	<ul style="list-style-type: none"> <li>• EHS manual/Standard operating procedures (SOPs) implemented per PMI and country-specific requirements</li> <li>• Training of staff in activities related to the laboratory EHS manual/SOPs</li> </ul>	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Review training materials and logs to verify trainings were conducted</li> <li>• Confirm during routine visits that SOPs are being effectively implemented and that workers are reporting EHS incidents</li> </ul>	<ul style="list-style-type: none"> <li>• Routine site visits, as needed, to ensure accordance with operating plan</li> </ul>

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
					<ul style="list-style-type: none"> <li>• Include date of visits, findings and any non-compliance issues in the annual EMMR</li> <li>• Include photographs from site visits</li> </ul>	
<b>3. Public Health Commodities</b>	N/A	N/A	N/A	N/A	N/A	N/A
<b>4. Small-Scale Construction</b>	Minor renovations of facilities or cosmetic improvements may lead to adverse environmental and health impacts if older materials of construction are present, or if construction activities are not properly managed. Exposure to hazardous building materials during renovation activities	<ul style="list-style-type: none"> <li>• Implement, or use existing SOPs, for construction activities that are 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>).</li> <li>• Sub-contractors provide training to workers on SOPs, if applicable</li> </ul>	Abt Associates technical overseers and ECMs, with assistance from USAID Missions personnel	<ul style="list-style-type: none"> <li>• SOPs implemented</li> <li>• Staff briefings on activities related to SOPs</li> </ul>	<ul style="list-style-type: none"> <li>• Review demolition and construction plans prior to renovations.</li> </ul>	<ul style="list-style-type: none"> <li>• Pre- and post construction</li> </ul>

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
	<p>can result in health impacts to workers.</p> <p>Construction activities during renovation of facilities may generate debris and wastes that contain both non-hazardous and hazardous materials and require proper disposal. This includes chemicals, solvents, and any materials containing toxics, such as asbestos, lead-based paint, and formaldehyde. Workers and other handling construction debris and wastes may also be exposed to hazardous materials if the appropriate PPE is not used.</p>	<ul style="list-style-type: none"> <li>• Implement WMP, or equivalent SOPs, for properly disposing of construction waste. Instruct contractors on the WMP/SOPs on proper handling and disposing of construction waste.</li> <li>• If the presence of asbestos is suspected in a facility to be renovated, the facility must be tested for asbestos before rehabilitation works begins or treat as if asbestos material is present. Should asbestos be present, then the work must be carried out in conformity with host country requirements, (if any) and in conformity with guidance to be provided by the implementing partner. All results of the testing for asbestos shall be communicated to the AOR/COR. No asbestos may be used in construction or rehabilitation.</li> <li>• No lead-based paint shall be used.</li> </ul>	Abt Associates EHS managers	<ul style="list-style-type: none"> <li>• WMP /SOPs implemented</li> <li>• Correspondence with contractor on construction waste disposal.</li> </ul>	<ul style="list-style-type: none"> <li>• Review of WMP/SOPs to ensure it is adequate</li> <li>• Review records to verify trainings/ briefings were conducted</li> </ul>	<ul style="list-style-type: none"> <li>• Pre- and post-construction</li> </ul>

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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-approved insecticides, improper storage, or poor inventory management).	<ul style="list-style-type: none"> <li>• 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.</li> <li>• Procurement and inventory logs must be maintained.</li> <li>• Ensure storage facility and personal protective equipment (PPE) are appropriate for the active ingredient used and in accordance with approved SOPs.</li> <li>• 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)</li> </ul>	District Coordinator (DC), Operations Manager (OM), Abt Environmental 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.)	<ul style="list-style-type: none"> <li>• PMI BMPs reviewed and implemented</li> <li>• Procurement and inventory logs maintained</li> <li>• Proper PPE used by workers, if needed.</li> <li>• Operations facilities are sited appropriately</li> <li>• All insecticide management records are reviewed and maintained</li> </ul>	<ul style="list-style-type: none"> <li>• Inspection of facilities, conditions, PPE use, and logs</li> <li>• Review of waste management records and storekeeper performance checklists.</li> <li>• Verify that inspection reports and storage records are properly maintained and document verification in the annual EMMR.</li> <li>• ECO performs mid-application inspections.</li> </ul>	<ul style="list-style-type: none"> <li>• Daily monitoring by storekeeper or site supervisor</li> <li>• Weekly monitoring by DC</li> <li>• Monthly review of procurement logs and inventories by OM</li> </ul>

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
					Verify that inspection reports are properly maintained and document verification in the annual EMMR	
	2. Occupational risks for workers involved in IRS campaigns.	<ul style="list-style-type: none"> <li>• Inspect and certify vehicles used for insecticide or team transport prior to contract.</li> <li>• Train drivers</li> <li>• Ensure availability of cell phone, personal protective equipment (PPE) and spill kits during insecticide transportation.</li> <li>• Initial and 30-day pregnancy testing for female candidates for jobs with potential insecticide contact.</li> <li>• Health test all spray team members for duty fitness.</li> <li>• Procure, distribute, and train all workers with potential insecticide contact on the use of PPE.</li> </ul>	DC, OM, ECO, Chief of Party, and Abt Associates technical experts within the respective country	<ul style="list-style-type: none"> <li>a. Transport vehicles have a valid inspection certificate on-board.</li> <li>b. Drivers have a certificate of training completion.</li> <li>c. Transport vehicles are equipped with cell phone, spill kit, and PPE.</li> <li>d. Storekeeper has records of pregnancy testing for all female team members.</li> <li>e. Storekeeper has medical exam results for all team</li> </ul>	<ul style="list-style-type: none"> <li>a-c. ECO inspection of vehicles in the field.</li> <li>d-e. ECO inspection of health records at operations sites.</li> <li>f-h. ECO performs pre-application inspections of inventories and training records, and mid-application inspections of PPE use and operator performance.</li> <li>i. Monitoring of on-line database</li> </ul>	<ul style="list-style-type: none"> <li>a-c. 2 inspections per week.</li> <li>d-e. One inspection per campaign, additional inspection if new hires or more than 30 application days.</li> <li>f-h. ECO pre-application inspections 2 per campaign, ECO mid-application inspections 5 times per week.</li> </ul>

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		<ul style="list-style-type: none"> <li>• Train operators on mixing insecticides and the proper use and maintenance of application equipment.</li> <li>• Provide adequate facilities and supplies for end-of-day cleanup.</li> <li>• Enforce application and clean-up procedures.</li> </ul>		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, corrective action is taken as needed.	for submission of inspection reports.	i. Weekly
	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	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	a. Review IEC materials once per campaign

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		b. Ensure health facility staff are aware of insecticide poisoning management			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.	<ul style="list-style-type: none"> <li>• Storage facilities and transportation vehicles must be physically secured to prevent theft.</li> <li>• Maintain records of all insecticide receipts, issuance, and return of empty containers.</li> <li>• Conduct analysis comparing number of houses treated vs. number of containers used.</li> <li>• Examine houses treated to confirm application</li> <li>• Perform physical inventory counts during the application season.</li> </ul>	Storekeepers, District coordinators, sector managers, logistics coordinator, OM, ECO	<ul style="list-style-type: none"> <li>• Storage facilities and transportation vehicles are secured.</li> <li>• All insecticide management records are reconciled.</li> </ul>	<ul style="list-style-type: none"> <li>• Inspection of storage facilities and transportation vehicles.</li> <li>• Inspection of insecticide management records. Storekeeper performance checklists.</li> <li>• ECO mid-campaign inspections.</li> </ul>	<ul style="list-style-type: none"> <li>• Daily monitoring by storekeeper or site supervisor. Weekly monitoring by District Coordinator</li> <li>• Examine houses during campaign according to schedule in SOPs.</li> <li>• Physical inventory counts twice per campaign per store room.</li> </ul>
	5. Ecological risk to non-target species and water bodies	<ul style="list-style-type: none"> <li>• For shipments of insecticide over water, sachets/ bottles will be packed in 220 liter open top</li> </ul>	DC, OM, ECO	<ul style="list-style-type: none"> <li>• Training materials and records</li> </ul>	<ul style="list-style-type: none"> <li>• Review training materials and records to verify</li> </ul>	<ul style="list-style-type: none"> <li>• Inspect work records once per campaign</li> </ul>

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	from use of insecticides	<p>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> <ul style="list-style-type: none"> <li>• 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</li> <li>• Ensure application equipment and PPE are appropriate for the active ingredient used and in accordance with approved SOPs, and maintain equipment to avoid leaks.</li> <li>• Maintain application equipment</li> <li>• No application of insecticides within 30 yards of beekeeping sites</li> </ul>		<ul style="list-style-type: none"> <li>• Equipment is maintained and operated to eliminate leaks.</li> <li>• Applicators only mix and apply insecticides according to SOPs</li> </ul>	<p>trainings were conducted</p> <ul style="list-style-type: none"> <li>• Conduct inspections during operations.</li> <li>• Verify that inspection and incident reports are properly maintained and document verification in the annual EMMR. Include any issues identified during inspections in the annual EMMR</li> </ul>	<ul style="list-style-type: none"> <li>• Inspections during operations 3 times per week</li> <li>• Review training materials once per campaign</li> </ul>

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	6. Environmental risk from disposal of liquid and solid wastes	<ul style="list-style-type: none"> <li>• 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</li> <li>• Choose sites for disposal of liquid wastes, including fixed and mobile soak pit sites according to PMI BMPs</li> <li>• Construct fixed and mobile soak pits with charcoal according to the BMPs to adsorb insecticide from rinse water</li> <li>• Maintain soak pits as necessary during season</li> <li>• Monitor waste storage and management during campaign</li> <li>• Monitor disposal procedures post-campaign</li> </ul>	DC, OM, ECO	<ul style="list-style-type: none"> <li>• WMP implemented and disposal sites inspected and certified before campaigns.</li> <li>• Disposal sites near operations sites are appropriate according to PMI BMPs</li> <li>• Soak pits are constructed according to PMI BMPs</li> <li>• Soak pits perform properly throughout the application season</li> <li>• Wastes are stored and managed according to PMI BMPs</li> <li>• Waste disposal is conducted in</li> </ul>	<ul style="list-style-type: none"> <li>• Review WMP/SOPs to ensure it conforms to PMI BMPs and WMP is available on site</li> <li>• Pre-application 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</li> <li>• Mid- and post-application inspections and monitoring. Verify disposal</li> </ul>	<ul style="list-style-type: none"> <li>• Pre-application inspections: once per campaign</li> <li>• Mid- and post-application inspections: twice per campaign</li> <li>• Review of WMP/SOPs during campaign</li> </ul>

<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>
				accordance with the WMP/SOPs and records maintained	practices in inspection reports and document in the annual EMMR. Include any issues identified during inspections in the annual EMMR. <ul style="list-style-type: none"> <li>• Review WMP/SOPs to for effectiveness and maintain on site</li> </ul>	

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	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 hazards.	<ul style="list-style-type: none"> <li>Wastes will only be disposed in incinerators that comply with PMI BMPs Collect and maintain treatment and disposal documents and records on file</li> <li>Country-level USAID EC documentation must contain guidance on proper disposal of wastes</li> </ul>	COR, Abt ECO, Abt Technical Experts	<ul style="list-style-type: none"> <li>Incinerator specifications</li> <li>Maintenance of treatment and disposal records</li> <li>Reg 216 documentation for incinerator procurement and management services reviewed by COR and GH BEO.</li> </ul>	<ul style="list-style-type: none"> <li>Review incineration records and document in the annual EMMR</li> </ul>	<ul style="list-style-type: none"> <li>Review incinerator specifications prior to disposal arrangement</li> <li>Annual review of disposal records</li> </ul>
<b>8. Testing of Insecticide-Treated Nets</b>	<ol style="list-style-type: none"> <li>Risk of theft from storerooms, followed by unintended use.</li> <li>Pollution from improper disposal of packaging.</li> <li>Risk of toxic exposure from chewing on or licking nets.</li> <li>Surface or groundwater pollution from</li> </ol>	<ol style="list-style-type: none"> <li>Store nets only in storerooms secured with sturdy doors, double locks, and barred windows.</li> <li>Dispose of waste materials according to PMI BMPs.</li> </ol>	1-5 Environmental Compliance Officer, USAID Mission	<ol style="list-style-type: none"> <li>Storerooms are built or modified to meet PMI BMPs.</li> <li>Evidence of a compliant disposal program in place.</li> </ol>	<ol style="list-style-type: none"> <li>Inspection of storeroom using checklists.</li> <li>Inspection of disposal/destruction records.</li> </ol>	1-5. Once per fiscal quarter.

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	<p>improper disposal of wastewater from washing nets</p> <p>5. Risk of the use of nets for purposes for which they are not designed.</p>					
<b>8. Emergency Response</b>	N/A	N/A	N/A	N/A	N/A	N/A

# ANNEX C: ENVIRONMENTAL MITIGATION AND MONITORING REPORT

Implementing organization:

Geographic location of USAID-funded activities:

Period covered by this Reporting Form and Certification:

## Environmental Mitigation and Monitoring Report

List each Mitigation Measure from column 3 in the EMMP	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. Rehabilitation			
5. Small-Scale Water and Sanitation			
6. Nutrition			

List each Mitigation Measure from column 3 in the EMMP	Status of Mitigation Measures	List any outstanding issues relating to required conditions	Remarks
7. Vector Control			
8. Emergency Response			

Prepared by:

\_\_\_\_\_

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

\_\_\_\_\_

# ANNEX D: BIBLIOGRAPHY

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