



PRESIDENT'S MALARIA INITIATIVE



## The PMI Africa IRS (AIRS) Project

Indoor Residual Spraying (IRS) 2

Task Order Six

# AMENDMENT I TO THE TANZANIA SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL 2015 – 2020

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**Submitted to:** The United States Agency for International Development/President's Malaria Initiative

*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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TANZANIA

SUPPLEMENTAL ENVIRONMENTAL  
ASSESSMENT: AMENDMENT I FOR  
INDOOR RESIDUAL SPRAYING  
FOR MALARIA CONTROL

2015-2020

September 2017

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# ACRONYMS

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<b>AIRS</b>	Africa Indoor Residual Spraying project
<b>BMPs</b>	Best management practices
<b>CDC</b>	Centers for Disease Control and Prevention
<b>CFR</b>	Code of Federal Regulations
<b>DDT</b>	Dichlorodiphenyltrichloroethane
<b>IRS</b>	Indoor Residual Spraying
<b>IVM</b>	Integrated Vector Management
<b>NEMC</b>	National Environmental Management Council
<b>NMCP</b>	National Malaria Control Program
<b>PQ</b>	WHO Prequalification Team
<b>SEA</b>	Supplemental Environmental Assessment
<b>SUAP</b>	Safer Use Action Plan
<b>TPRI</b>	Tropical Pesticide Research Institute
<b>USAID</b>	United States Agency for International Development
<b>USEPA</b>	United States Environmental Protection Agency
<b>WHO</b>	World Health Organization
<b>WHOPES</b>	World Health Organization Pesticide Evaluation Scheme
<b>ZEMA</b>	Zanzibar Environmental Management Authority

# 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 Tanzania. That SEA authorized the use of the pyrethroid, carbamate, and organophosphate classes of insecticides, and chlorfenapyr (when approved by WHOPES/PQ) for IRS in Tanzania. This amendment to the SEA authorizes the use of clothianidin, a new IRS insecticide currently under WHO review, once a PQ listing is obtained. This amendment also serves as the 2017-18 Letter Report for Tanzania.

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 Tanzania, new viable insecticides must be introduced for use. In order to add clothianidin as an IRS alternative, this amendment to the existing SEA must be approved.

This SEA amendment outlines the characteristics, benefits, and potential hazards of clothianidin, as well as the legal and regulatory status of this active ingredient in Tanzania and in the United States.

Tanzania has been implementing IRS for malaria control as part of an integrated vector management (IVM) strategy consistently since 2007. In 2018, PMI proposes to spray the same nine high burden malaria districts in Mainland Tanzania and nine districts of Zanzibar as in 2017. A long-lasting insecticide in the organophosphate class, Actellic 300CS will be used in seventeen districts and clothianidin is proposed to be used in one district (Musoma Rural) that was previously sprayed using Actellic 300 CS. However, this SEA is seeking authorization for the use of clothianidin in any area of the country, once recommended by WHO.

Therefore the proposed actions analyzed in this document are:

The continuation of IRS programming for 2017-2020, implementing a rotational or mosaic technique, using pyrethroids, carbamates, or organophosphates, in addition to chlorfenapyr or clothianidin (when recommended by WHOPES/PQ) where appropriate, based on pesticide resistance patterns throughout the country, and other critical factors.

All conditions of the existing 2015 SEA, including the Safer Use Action Plan (SUAP) and the Environmental Mitigation and Monitoring Plan (EMMP), will remain valid, and all PMI IRS operations in Tanzania will be performed according to the protocols and procedures found therein.

# APPROVAL

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## **APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED 2015-2020 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR PRESIDENT'S MALARIA INITIATIVE INDOOR RESIDUAL SPRAYING (IRS) FOR MALARIA CONTROL IN TANZANIA**

The United States Agency for International Development, Global Health Bureau has determined that the proposed IRS effort, as described in Amendment I of the 2015-2020 Supplemental Environmental Assessment: Indoor Residual Spraying for malaria control in Tanzania responds to the needs of the community and country as it relates to managing malaria in Tanzania, and also conforms to the requirements established in 22 CFR 216.

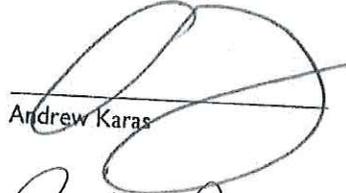
This document does not mandate the execution of the proposed IRS, rather, it documents the environmental planning and impact analysis executed by the IRS team in preparation for the proposed action. The design and standards of operation of the IRS program are established to avoid and reduce any potential impact. USAID has concluded that the proposed action, when executed as described in the Supplemental Environmental Assessment and the Programmatic Environmental Assessment for PMI IVM (2012), is consistent with the Government of Tanzania's and USAID's goal of reducing malaria incidence in Tanzania while minimizing negative impact to the environment and to human health.

The proposed actions recommended for approval in this 2017 SEA amendment are:

The continuation of IRS programming for 2017-2020, implementing a rotational or mosaic technique, using pyrethroids, carbamates, organophosphates, or chlorfenapyr or clothianidin (when recommended by WHOPES/PQ) where appropriate, based on pesticide resistance patterns throughout the country, and other critical factors.

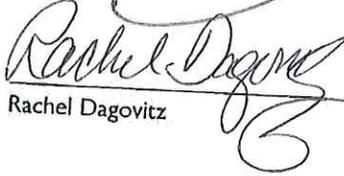
The Safer Use Action Plan in chapter 6 of the SEA and the PMI BMP manual provide detailed guidance on the performance of all activities associated with IRS.

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Date: 9/24/17

**CONCURRENCE:**  
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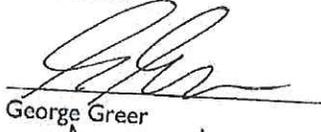
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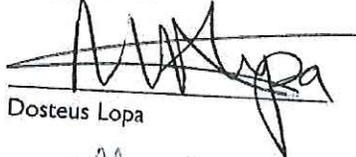
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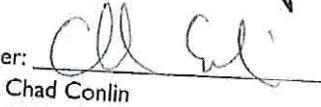
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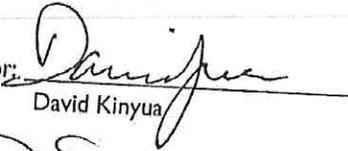
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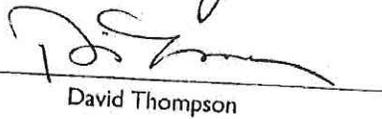
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# I. BACKGROUND AND PURPOSE

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## I.1 OBJECTIVES

PMI's IRS activities in Tanzania operate under a Supplemental Environmental Assessment (SEA), which was approved in November 2015. The SEA, which was prepared in accordance with the provisions of USAID 22 Code of Federal Regulations (216) regarding the use and application of pesticides, is nationwide in scope and authorizes the use of three classes of WHOPES-recommended pesticides (pyrethroid, carbamate, and organophosphate), and additionally authorizes the use of chlorfenapyr when recommended by WHOPES/PQ. This document has been prepared to serve as an amendment to that SEA, and proposes to authorize the use of clothianidin for IRS in all areas in Tanzania (including Zanzibar), once a PQ listing is obtained (expected in Sept 2017).

In order to expand the insecticide options for IRS to manage vector insecticide resistance in Tanzania, new viable insecticides must be introduced for use. Changing insecticides classes over time and space is a leading way to manage resistance, and having more alternatives available increases the chances of mitigating resistance. It's against this background that PMI Tanzania and the National Malaria Control Programme are seeking authorization to spray clothianidin insecticide in one of the 18 target districts during the 2018 IRS season. The rest of the target districts (17) will continue using Actellic 300 CS.

Sumishield 50WG is a new insecticide formulation from Sumitomo Chemical, Japan that is currently under review by WHO. The active ingredient in Sumishield 50WG is the neonicotinoid clothianidin. Clothianidin has not yet been fully authorized by the National Environmental Management Council (NEMC). For USAID/PMI to conduct the pilot, it is necessary to amend the current 2015-2020 Supplemental Environmental Assessment for IRS in Tanzania. Registration of clothianidin for future use in IRS in Tanzania will partially depend on the pilot findings and final recommendations by WHOPES/PQ.

## I.2 AREA AND SCOPE OF CLOTHIANIDIN USE FOR IRS IN TANZANIA IN 2018

In 2018, if this SEA is approved, IRS will be conducted using clothianidin in Musoma Rural District, one of seven districts of Mara region in the Lake Zone. Based on the 2012 national census, the district had a population of 178,356. Geographically, the district is bordered by Butiama District on the north, Bunda District on the south, and Lake Victoria on the west and north. For IRS purposes, the district has 43,880 spray-able structures according to 2017 IRS data, the average insecticide usage rate is 3.1 structures per bottle/sachet which amounts to 14,155 sachets of clothianidin (Sumishield) required to spray all available structures, as per 2017 IRS findings.

The National Malaria Control Program (NMCP) in consultation with PMI selected Musoma Rural district for the clothianidin pilot. Factors contributing to the selection of the district include previous good history of IRS acceptance by households and the relatively small district size as compared to other IRS benefiting districts within the Lake Zone. These two factors make the implementation of the pilot relatively easier.

## **I.3 ENTOMOLOGICAL MONITORING**

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

To determine the quality of spray and residual performance of clothianidin on walls, cone bioassays will be conducted within two weeks of IRS and continued monthly. Bioassays will be conducted using the WHO cone bioassay in five randomly selected houses with mud plaster walls, five houses with concrete walls, and five houses with burnt brick walls.

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

To monitor changes in mosquito populations, the following activities will be performed: monthly Prokopack aspiration collections, CDC light trap (CDC-LT) and human landing catches at two sites within the clothianidin sprayed areas in Musoma rural district and in two neighboring unsprayed sites in Musoma urban district.

# **2. PROPOSED ACTION AND ALTERNATIVES**

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

## **2.1 DESCRIPTION OF PROPOSED ACTION**

The preferred action is to authorize the use of clothianidin nationwide in Tanzania for IRS (including Zanzibar). If clothianidin is recommended by WHO and authorized for PMI use in IRS by this SEA, it will provide an additional option for implementing IRS in selected communities while balancing current entomological, epidemiological, logistical, environmental, and economic priorities. The pesticide to be used in an IRS season will be determined by a process fully explained in the 2015 SEA under Pesticide Procedures part b. (Section 4.2)

## **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 reduce the available alternatives, and possibly result in increasing resistance to the available insecticides. A consequence of that could be rising rates of infections, transmissions, mortality and morbidity due to the increased prevalence of resistant and infected vectors. Therefore, the “no action” alternative does not meet the overall goals of USAID/PMI, or the Tanzania National Malaria Control Program (NMCP).

## **2.3 ALTERNATIVE IRS GEOGRAPHICAL SITES CONSIDERED**

All provinces and districts in Tanzania are eligible for PMI support for IRS according to the current SEA. This amendment seeks to maintain nationwide coverage and add clothianidin as an IRS option. 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 result in reducing the effectiveness of the intervention.

## 2.4 USE OF ALTERNATIVE INSECTICIDE (S)

Only pesticides recommended by WHO may be selected for use in PMI-supported IRS. PMI Tanzania and the Tanzania NMCP regularly conduct entomological testing to help determine the best choice of insecticide for use. This amendment proposes to add clothianidin as an alternative insecticide in anticipation that this new insecticide – currently under WHO review – will be fully recommended by WHOPES/PQ for IRS, and registered for public health use in Tanzania. Thereafter, clothianidin will be an available alternative insecticide.

# 3. PESTICIDE PROCEDURES

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Title 22 of the United States 22 CFR 216 mandates the consideration of twelve factors when a project includes “assistance for the procurement or use, or both, of pesticides”. The existing SEA addresses the twelve factors for the IRS Malaria Control Program in Tanzania. This section of the amendment addresses any clothianidin-specific aspects of those twelve factors.

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

Clothianidin was registered with USEPA in 2003.

## 3.2 THE BASIS FOR SELECTION OF THE REQUESTED PESTICIDES

**Recommended by WHO:** It is anticipated that clothianidin will be recommended by WHOPES/PQ prior to the 2018 PMI Tanzania spray campaign. PMI will only utilize clothianidin if/when recommended by WHO.

**Registration for use in the Tanzania:** Clothianidin is currently not registered for IRS in Tanzania. Since the Musoma Rural District is included in the available ESIA certificate for organophosphate, AIRS Tanzania, on behalf of the NMCP, will apply for a certificate of variation. The application will involve submitting a duly filled variation application form along with the updated ESIA report with additional details on the use of clothianidin, its mechanisms of action, intended spray area, and updated Environmental and Social Management Plan. Further, AIRS Tanzania, on behalf of NMCP, will apply for a permit to conduct the pilot from the Tanzania Pesticide Research Institute (TPRI). Full authorization and registration of clothianidin for IRS use in Tanzania will depend partly on its performance in the pilot district.

**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 on the primary wall surface types is expected 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 Best Management Practices (BMPs) for IRS are strictly followed, the release to the environment, and therefore the impact to the environment, should be negligible. More information on the potential ecological impact of clothianidin is found in the 2017 Programmatic Environmental Assessment (PEA) for IVM.

**Human health impact:** The 2017 IVM PEA also assessed cancer and non-cancer risks associated with clothianidin by process (e.g., mixing insecticide, spraying, residing in sprayed house, etc.) 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 (IPM/IVM) PROGRAM

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

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

Clothianidin will be applied using the same compression spray equipment and techniques as other WHO-recommended insecticides, and the same cautions apply. The Safer Use Action Plan (SUAP) in Chapter 6 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 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.<sup>1</sup> Refer to the Environmental and Health Impact section of this amendment (Section 4.3) 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

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

USEPA (USEPA 2012), is 0.0098 mg/kg/day. This value was calculated using an Uncertainty Factor (UF) of 100 to account for differences in intra-species sensitivity (10), and the lack of human exposure studies (10). In addition, a Modifying Factor (MF) of 10 was also applied to capture uncertainty associated with the lack of a developmental immuno-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 dermal contact, and the physiological response to shorter exposures allows for recovery (in contrast with chronic exposures). Based on the risk screening results and the inherently conservative nature of the calculation, adverse human health effects for workers or residents are not expected from the use of clothianidin.<sup>2</sup> Clothianidin does not damage genetic material nor is there evidence that it causes cancer in rats or mice; it is unlikely to be a human carcinogen.<sup>3</sup>

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

To determine the quality of spray and residual performance of clothianidin on the walls, cone bioassays will be conducted within two weeks of IRS and this will be continued monthly. Bioassays will be conducted using the WHO cone bioassay in five randomly selected houses with mud plaster walls, five houses with concrete walls, and five houses with burnt brick walls. Cone bioassays will be performed according to WHO standard protocols with one cone each at 0.5, 1.0 and 1.5m height. Cone bioassays will continue monthly until mortality is below 80% for two consecutive months based on the 5 days holding period.

Testing with laboratory reared mosquitoes of a susceptible colony will be conducted in five houses with mud plaster walls, five houses with concrete walls, and five houses with cement walls. Mortality of test mosquitoes will be recorded every 24 hrs. at 1, 2, 3, 4, and 5 days after exposure, with Abbott's correction implemented if mortality is between 5 percent and 20 percent in the negative controls after 5 days. If mortality is >20% after 5 days in untreated controls, tests should be repeated.

To monitor changes in mosquito populations the following will be performed: monthly Prokopack aspiration collections; CDC light trap (CDC-LT); and human landing catches at two sites within the clothianidin spray area and in two neighboring unsprayed sites in each of the districts. Neighboring unsprayed sites will be located within 20km of Musoma Rural district sprayed areas and be as similar in characteristics as possible.

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

Clothianidin is compatible with the target environment (walls, ceilings, eaves of homes) in that it dries on these surfaces, and is not released to receptors or the general environment to any great extent. The dried pesticide remains on the sprayed surfaces, and performs as designed, killing vector mosquitoes that rest on them, and the exposure to non-target organisms and ecosystems is very limited.

Clothianidin is incompatible with the non-target ecosystems (humans, animals, and the environment), in that, if they are released to the environment in large quantities, they could have negative effects on land

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

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

and water based flora and fauna. However, the IRS implementation process is designed to ensure that to the maximum extent possible, pesticides are deliberately and carefully applied to the walls and ceilings of dwellings, and do not come in contact with humans, animals, or the environment. IRS implementation is also planned to minimize and responsibly manage insecticide-contaminated liquids through the reuse of leftover pesticides and contaminated water, the triple rinsing of equipment, and the daily washing of personal protective equipment and, at a minimum, face and hands of spray team members.

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

Chapter 3 of the 2015 SEA provides a detailed account of the environmental conditions in Tanzania under which clothianidin is to be used. During IRS operations, particular attention is paid to any sensitive areas identified in the environmental assessment, including water bodies, schools, hospitals, any area where organic farming is practiced, or where bee-keeping or natural bee habitats are established. Bird-nesting and bee habitat will be protected, and clothianidin will not be stored near water habitats and resources. IRS will be prohibited within 30 meters of all sensitive ecosystems.

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

Only WHO-recommended pesticides may be used for PMI-supported IRS. Other non-chemical control methods are covered under the 2015 SEA recommendations for IVM.

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

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

For mainland Tanzania, the Industrial and Consumer Chemicals Management and Control Act No 3 of 2003 provides the legal framework for the regulation of pesticide use. TPRI is mandated to regulate the use of pesticides for agriculture, horticulture, forestry, gardening and public health and other uses, as well as monitoring the use of pesticides and taking 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 USERS AND APPLICATORS**

Training of spray operators will be provided in like fashion as for other classes of pesticides, using training procedures and materials as indicated in the SUAP 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 Tanzania project, and is used for IVM decision-making.

# 4. ENVIRONMENTAL & HEALTH IMPACTS

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## 4.1 POTENTIAL POSITIVE EFFECTS OF CLOTHIANIDIN

### 4.1.1 DIRECT POSITIVE EFFECTS

The direct positive impacts of the approval of clothianidin use in IRS program will include the capacity for improved insecticide resistance management, as it will serve as an additional option for rotation of insecticides to prevent resistance. Other positive direct impacts of clothianidin in IRS derive from the expected health, economic, and environmental benefits provided by IRS (Refer to section 4.1 in the 2015 SEA).

### 4.1.2 INDIRECT POSITIVE EFFECTS

The indirect positive impacts regarding the use of clothianidin in IRS are the same as the positive impacts of the four WHOPEs recommended classes of pesticides, (Refer to section 4.1.2 of the 2015 SEA).

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

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

Important clothianidin characteristics are listed below.

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

The acute health risks to humans from exposure to clothianidin are minimal due to its low mammalian toxicity. 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. 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. 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 (NMP)) of the insecticide as opposed to the neonicotinoid itself.

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

## 4.2.2 AQUATIC LIFE

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

## 4.2.3 BIRDS

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

## 4.2.4 BEES

Bee keeping in Tanzania is mainly conducted away from the household and the sale of honey provides some income to the residents. Spraying in areas near beehives can lead to the death of the bees, which are vulnerable to clothianidin. 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.

## 4.2.5 CUMULATIVE IMPACT

No cumulative impacts are expected as a result of using clothianidin in IRS if PMI BMPs are followed,

# 5. SAFER USE ACTION PLAN

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The procedures and protocols of the SUAP in the 2015 SEA remain in effect, and will be used for clothianidin. Clothianidin-specific considerations are discussed below. See Annex A of this amendment for health and safety impacts of clothianidin and treatment recommendations.

## 5.1.1 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 in the district hospital where clothianidin is used receives appropriate training on administering emergency treatment to pesticide exposure. Annex A provides additional information on symptoms and treatment protocols for exposure to clothianidin.

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

<b>Clothianidin</b>	
<b>Human side effects</b>	<b>Treatment</b>
<p>Clothianidin is a systemic insecticide belonging to the nitroguanidine subgroup of nicotinoid insecticides. It is also referred to as a chloronicotinyl or neonicotinoid.<sup>5</sup> Clothianidin and other neonicotinoids act on the <a href="#">central nervous system</a> of insects as an agonist of <a href="#">acetylcholine</a>, the neurotransmitter that stimulates <a href="#">nAChR</a>, targeting the same receptor site (<a href="#">AChR</a>) and activating post-synaptic acetylcholine receptors but not inhibiting <a href="#">AChE</a>. The acute health risks to humans from exposure to clothianidin are minimal due to its low mammalian toxicity. Extrapolation from test results on animals to humans suggests that clothianidin is moderately toxic through oral exposure, but toxicity is low through skin contact or inhalation. Mild to moderate poisoning can cause nausea, vomiting, diarrhea, abdominal pain, dizziness, headache, and mild sedation.<sup>6</sup> While clothianidin may cause slight eye irritation, it is not expected to be a skin sensitizer or irritant. 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 (NMP)) of the insecticide as opposed to the neonicotinoid itself.<sup>7</sup></p> <p>Clothianidin does not damage genetic material nor is there evidence that it causes cancer in rats or mice; it is unlikely to be a human carcinogen. Submitted data also indicate that no significant adverse environmental impacts are expected to occur from the use of clothianidin.<sup>8</sup></p>	<p><b>MANAGEMENT OF MILD TO MODERATE TOXICITY</b> - Treatment is symptomatic and supportive. Administer IV fluids for hypotension.</p> <p><b>MANAGEMENT OF SEVERE TOXICITY</b> - Treatment is symptomatic and supportive. Treat hypotension with IV fluids; add vasopressors if hypotension persists. Treat dysrhythmias per ACLS 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 these insecticides are frequently mixed with organophosphate and carbamate pesticides.<sup>9</sup></p>

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

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

<sup>7</sup> Ibid

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

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

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# ANNEX C: ENVIRONMENTAL MITIGATION AND MONITORING PLAN

Category of Activity	Describe specific environmental threats of your organization's activities	Description of Mitigation Measures	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
Use of insecticides	I. Occupational risks for workers involved in IRS campaigns (e.g., risks from insecticide exposure and vehicular accidents), especially women of child-bearing age	<p>a. Inspect and certify vehicles used for pesticide or spray team transport prior to contract.</p> <p>b. Train drivers</p> <p>c. Provide cell phone, personal protective equipment (PPE) and spill kits during pesticide transportation.</p> <p>d. Initial and 30-day pregnancy testing for female candidates for jobs with potential pesticide contact.</p> <p>e. Health test all spray team members for duty fitness.</p> <p>f. Procure, distribute, and train all workers with potential pesticide contact on the use of PPE.</p> <p>g. Train operators on mixing pesticides and the proper use and maintenance of spray pumps.</p> <p>h. Provide adequate facilities and supplies for end-of-day cleanup.</p> <p>i. Enforce spray and clean-up procedures.</p>	<p>a-d. Environmental Compliance Officer (ECO).</p> <p>e-g. Operations Manager (OM).</p> <p>h. ECO</p> <p>i. Chief of Party (COP), Technical Project Managers (TPM) and headquarters environmental staff.</p>	<p>a. Transport vehicles have a valid inspection certificate on-board.</p> <p>b. Drivers have a certificate of training completion.</p> <p>c. Transport vehicles are equipped with cell phone, spill kit, and PPE.</p> <p>d. Storekeeper has records of pregnancy testing for all female team members.</p> <p>e. Storekeeper has medical exam results for all team members.</p> <p>f. Spray operators wear complete PPE during spraying and clean-up.</p> <p>g. Operators mix pesticide properly, and the pump 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>	<p>a-c. ECO inspection of vehicles in the field.</p> <p>d-e. ECO inspection of health records at IRS operational sites.</p> <p>f-h. ECO performs pre-spray inspections of inventories and training records, and mid-spray inspections of PPE use and spray operator performance.</p> <p>i. Monitoring of on-line database for submission of inspection reports.</p>	<p>a-c. 2 inspections per week.</p> <p>d-e. One inspection per campaign, additional inspection if new hires or more than 30 spray days.</p> <p>f-h. ECO pre-spray inspections 2/campaign, ECO mid-spray inspections 5 times/week.</p> <p>i. Weekly</p>

Category of Activity	Describe specific environmental threats of your organization's activities	Description of Mitigation Measures	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
	2. Safety risks for residents of sprayed houses (e.g., risks from inhalation and ingestion of insecticides)	<ul style="list-style-type: none"> <li>a. IEC campaigns to inform homeowners of responsibilities and precautions.</li> <li>b. Prohibit spraying houses that are not properly prepared.</li> <li>c. Two-hour exclusion from house after spraying</li> <li>d. Instruct homeowners to wash itchy skin and go to health clinic if symptoms do not subside.</li> </ul>	<ul style="list-style-type: none"> <li>a-b. IEC officers, OM, ECO</li> <li>c. ECO</li> <li>d. Spray operators (SO) and Team Leaders (TL)</li> </ul>	<ul style="list-style-type: none"> <li>a. Pre-spray IEC campaigns were executed. Homeowners know responsibilities.</li> <li>b. All houses being sprayed are properly prepared.</li> <li>c. Homeowners observe 2 hour exclusion.</li> <li>d. Lack of incident reports, or incident reports with proper response noted.</li> </ul>	<ul style="list-style-type: none"> <li>a. OM- IEC work records, ECO- mid-spray inspections.</li> <li>b-d. ECO mid-spray inspections</li> </ul>	<ul style="list-style-type: none"> <li>a. Inspect work records 1/campaign,</li> <li>b-d. ECO mid-spray inspections 3/wk.</li> </ul>
	3. Ecological risk to non-target species and water bodies from use of insecticides (during transport, mixing and spraying)	<ul style="list-style-type: none"> <li>a. 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. 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.</li> <li>b. Operators will not spray within 30 meters of bee hives.</li> <li>c. Train operators on proper spray technique.</li> <li>d. Spray indoors only.</li> <li>e. Maintain pumps.</li> </ul>	<ul style="list-style-type: none"> <li>a. ECO,</li> <li>b-e. TL, District Coordinator (DC), OM, ECO</li> </ul>	<ul style="list-style-type: none"> <li>a. Insecticide is packed in barrels prior to shipment over water.</li> <li>b. Locations of bee hives have been identified, and operators do not spray within 30 meters.</li> <li>c. Operators are trained and know and use proper spray techniques.</li> <li>d. Operators spray only inside of house</li> <li>e. Pumps are maintained and operated to eliminate leaks and erratic spraying.</li> </ul>	<ul style="list-style-type: none"> <li>a. ECO pre-shipment inspection</li> <li>b. ECO pre- and mid-spray inspections. TL daily</li> <li>b-e. Training records, ECO and DC mid-spray inspections, TL daily</li> </ul>	<ul style="list-style-type: none"> <li>a. Once before shipping.</li> <li>b. TL daily, ECO and DC weekly.</li> <li>b-e Inspection of training records 1/campaign.. TL daily.</li> <li>b-e. ECO and DC mid-spray inspections 5/wk.</li> </ul>

Category of Activity	Describe specific environmental threats of your organization's activities	Description of Mitigation Measures	Who is responsible for monitoring	Monitoring Indicator	Monitoring Method	Frequency of Monitoring
	4. Environmental risk from disposal of insecticide (both liquid and solid waste)	<p>a. Choose sites for disposal of liquid wastes, including mobile soak pit sites according to PMI BMPs.</p> <p>b. Construct fixed and mobile soak pits with charcoal to adsorb pesticide from rinse water.</p> <p>c. Maintain fixed and mobile soak pits as necessary during season.</p> <p>d. Inspect and certify solid waste disposal sites before spray campaign.</p> <p>e. Monitor waste storage and management during campaign.</p> <p>f. Monitor disposal procedures post-campaign.</p>	<p>a-c. Abt OM, ECO, DC</p> <p>d-f. Abt ECO</p>	<p>a. Operations sites meet PMI BMPs.</p> <p>b. Fixed and mobile soak pits are sited and constructed according to the PMI BMP manual.</p> <p>c. Fixed and mobile soak pits perform properly throughout the spray season.</p> <p>d. Disposal sites have the capacity and policies to properly dispose of wastes.</p> <p>e. Solid wastes are stored and managed according to PMI BMPs.</p> <p>f. Waste disposal has taken place as agreed and certificates of disposal received.</p>	<p>a-b. ECO Pre-spray inspections</p> <p>c-f. ECO mid- and post-spray inspections and monitoring.</p>	<p>a.2/campaign</p> <p>b.1/campaign</p> <p>c. 5/week</p> <p>d. 1/campaign</p> <p>e. 3/week</p> <p>f. Continuous during disposal</p>
	5. Risk of diversion of insecticides for unintended or uncontrolled use	<p>a. Maintain records of all pesticide receipts, issuance, and return of empty sachets/bottles.</p> <p>b. Reconcile number of houses sprayed vs. number of sachets/bottles used.</p> <p>c. Examine houses sprayed to confirm spray application.</p> <p>d. Perform physical inventory counts during the spray season.</p>	<p>a-d. Storekeepers, District coordinators, sector managers, logistics coordinator, OM, ECO</p>	<p>a-d. All pesticide management records are reconciled.</p>	<p>a-b, d. Inspection of pesticide management records. Storekeeper performance checklists.</p> <p>c. ECO mid-spray inspections.</p>	<p>a-b, d. Daily monitoring by storekeeper or site supervisor. Weekly monitoring by District Coordinators</p> <p>c. 1/campaign by country headquarters.</p> <p>2/campaign by ECO</p> <p>d. 2/campaign/ store-room</p>

# ANNEX D: EMMR FORM

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Please see **Annual Environmental Mitigation and Monitoring Report (EMMR) Form** next page

**PMI IRS Rwanda**  
**ENVIRONMENTAL MITIGATION AND MONITORING REPORT (EMMR)**  
**ANNUAL REPORTING FORM**

Implementing Organization:

Geographic location of USAID-funded activities:

Period covered by this Reporting Form and Certification:

<b>Mitigation Measure</b>	<b>Status of Mitigation Measures</b>	<b>Outstanding issues relating to required conditions</b>	<b>Remarks</b>
<b>Ia. Pre-contract inspection and certification of vehicles used for pesticide or spray team transport.</b>			
<b>Ib. Driver training</b>			
<b>Ic. Cell phone, personal protective equipment (PPE) and spill kits on board during pesticide transportation.</b>			
<b>Id. Initial and 30-day pregnancy testing for female candidates for jobs with potential pesticide contact.</b>			
<b>Ie. Health fitness testing for all operators</b>			

Mitigation Measure	Status of Mitigation Measures	Outstanding issues relating to required conditions	Remarks
If. Procurement of, distribution to, and training on the use of PPE for all workers with potential pesticide contact.			
Ig. Training on mixing pesticides and the proper use and maintenance of spray pumps.			
Ih. Provision of adequate facilities and supplies for end-of-day cleanup,			
Ii. Enforce spray and clean-up procedures.			
2a. IEC campaigns to inform homeowners of responsibilities and precautions.			
2b. Prohibition of spraying houses that are not properly prepared.			
2c. Two-hour exclusion from house after spraying			
2d. Instruct homeowners to wash itchy skin and go to health clinic if symptoms do not subside.			

Mitigation Measure	Status of Mitigation Measures	Outstanding issues relating to required conditions	Remarks
3a. Packaging for pesticide shipments over water			
3b. Protection of bees/pollinators			
3c. Use of proper spray techniques			
3d. Spraying indoors only			
3e. Maintenance of pumps			
4a. Choose sites for disposal of liquid wastes, including mobile soak pit sites, according to PMI BMPs.			
4b. Construct fixed and mobile soak pits with charcoal to adsorb pesticide from rinse water.			
4c. Maintain soak pits as necessary during season.			
4d. Inspection and certification of solid waste disposal sites before spray campaign.			

Mitigation Measure	Status of Mitigation Measures	Outstanding issues relating to required conditions	Remarks
4e. Monitoring waste storage and management during campaign.			
4f. Monitoring disposal procedures post-campaign.			
5a. Maintain records of all pesticide receipts, issuance, and return of empty sachets/bottles.			
5b. Reconciliation of number of houses sprayed vs. number of sachets/bottles used.			
5c. Visual examination of houses sprayed to confirm pesticide application.			
5d. Perform physical inventory counts during the spray season.			