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AMENDMENT 1 TO THE GHANA SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL 2015–2020

Recommended Citation: Amendment 1 to the Ghana Supplemental Environmental Assessment for Indoor Residual Spraying for Malaria Control: 2015–2020. Bethesda, MD. Abt Associates.

Contract and Task Order Number: AID-OAA-I-17-00008/AID-OAA-TO-17-00027

Submitted to: U.S. President's Malaria Initiative/U.S. Agency for International Development

Submitted: February 2018

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

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AMENDMENT 1 TO THE 2015 GHANA SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL

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ACRONYMS

BMP	best management practice
ECO	Environmental Compliance Officer
IRS	indoor residual spraying
IVM	integrated vector management
NMCP	National Malaria Control Program
PEA	Programmatic Environmental Assessment
PMI	President's Malaria Initiative
PPE	personal protective equipment
SEA	Supplemental Environmental Assessment
SUAP	Safer Use Action Plan
USAID	United States Agency for International Development
USEPA	United States Environmental Protection Agency
WHO	World Health Organization
WHOPES	World Health Organization Pesticide Evaluation Scheme

EXECUTIVE SUMMARY

This document has been prepared to serve as an amendment to the 2015–2020 Supplemental Environmental Assessment (SEA) for indoor residual spraying (IRS) in Ghana. That SEA authorized the use of the pyrethroid, carbamate, and organophosphate classes of insecticides, and also chlorfenapyr—when approved by the World Health Organization (WHO) Prequalification Team—for IRS in Ghana. This amendment to the SEA authorizes the use of clothianidin, a new IRS insecticide that was Prequalification Team-listed in 2017. This amendment also serves as the 2018 Letter Report for Ghana.

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 Ghana, new viable insecticides must be introduced for use. In order for clothianidin to be added as an IRS alternative, 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, as well as the legal and regulatory status of this active ingredient in Ghana and in the United States. PMI has consistently supported implementation of IRS for malaria control in Ghana as part of an integrated vector management (IVM) strategy since 2007. In 2018, PMI proposes to spray the same seven high-burden malaria districts in the Northern Region of Ghana as in 2017. A long-lasting insecticide in the organophosphate class, Actellic 300 CS, will be the insecticide predominantly used. Clothianidin is proposed to be used in one district (Mamprugu Moaduri District) that was previously sprayed using Actellic 300 CS. This SEA amendment is, however, seeking authorization for the use of clothianidin in any area of the country during the validity of the parent SEA, in anticipation of future needs.

Therefore, the proposed action analyzed in this document is:

- Continue IRS programming for 2018–2020, implementing a rotational or mosaic technique, using pyrethroids, carbamates, organophosphates, or clothianidin, in addition to chlorfenapyr (when recommended by the WHO Prequalification Team) 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 Ghana will be performed according to the protocols and procedures found therein.

APPROVAL

APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED

AMENDMENT OF THE 2015–2020 SUPPLEMENTAL ENVIRONMENTAL ASSESSMENT FOR THE U.S. PRESIDENT'S MALARIA INITIATIVE INDOOR RESIDUAL SPRAYING FOR MALARIA CONTROL IN GHANA

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 2015–2020 SEA, responds to the needs of the community and country as it relates to managing malaria in Ghana, and also conforms to the requirements established in the 22 Code of Federal Regulations 216.

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

The action recommended for approval in this 2018 SEA amendment is to continue IRS programming for 2018–2020 using a rotational or mosaic technique, involving pyrethroids, carbamates, organophosphates, clothianidin, or chlorfenapyr (when recommended by the WHO Prequalification Team), 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 best management practice (BMP) manual provide detailed guidance on the performance of all activities associated with IRS.

CLEARANCE:

Mission Director: approved via Action memo Date: 2/26/18
USAID/Ghana Sharon Cromer

CONCURRENCE:

Acting Bureau Environmental Officer/GH: Dennis Durbin Date: 2/28/18
Dennis Durbin

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PMI Advisor: _____ Date: _____
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Regional Environmental Advisor: _____ Date: _____
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Mission Environmental Officer: _____ Date: Feb. 12/2018
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Emmanuel Odotei

Regional Environmental Advisor: _____ Date: Feb 12/2018
USAID/West Africa
Henry Aryeetey

Ag. Deputy Mission Director: _____ Date: 2/12/18
USAID/Ghana
Kevin Brown

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Action Memorandum

TO: Sharon L. Cromer, Mission Director

THROUGH: Steven E. Hendrix, Deputy Mission Director Steve 2/23/2018

FROM: Akua Kwateng-Addo, HPNO Office Director AKwateng

DATE: February 23, 2018

SUBJECT: Approval of the Supplemental Environmental Assessment (SEA) amendment #1 to include a new insecticide "Sumishield" (clothianidin) for indoor residual spraying (IRS) operations in Ghana

I. ACTION REQUESTED

That you approve the accompanying amendment#1 to the Supplemental Environmental Assessment (SEA).

II. BACKGROUND

The Supplemental Environmental Assessment (SEA) was approved in 2015 and covered all insecticide classes for all regions in Ghana for Indoor Residual Spraying (IRS). A new insecticide – clothianidin – from a new insecticide class has received World Health Organization (WHO) approval and Ghana Environmental Protection Agency (EPA) approval for IRS. The President's Malaria Initiative (PMI) Ghana would like to amend the 2015 SEA to include the new insecticide class to mitigate insecticide resistance in IRS

III. AUTHORITY

The use of pesticides is subject to specific provisions of 22 CFR 216.3(b)(v). "Where identification of the pesticides to be procured or used does not occur until after [project] approval, neither the procurement nor the use of the pesticides shall be undertaken unless approved, in writing, . . in the case of projects authorized at the Mission level, [by] the Mission Director.

SUBJECT: Approval of the Supplemental Environmental Assessment (SEA) amendment #1 to include a new insecticide "Sumishield" (clothianidin) for indoor residual spraying (IRS) operations in Ghana

IV. RECOMMENDATION

That you approve this SEA amendment #1 to allow the use of a new insecticide to be rotated into IRS operations.

Approved ☒ Disapproved ☐

Mission Director:
USAID/Ghana

Sharon L. Cromer

Date: 2/26/18

SUBJECT: Approval of the Supplemental Environmental Assessment (SEA) amendment #1 to include a new insecticide "Sumishield" (clothianidin) for indoor residual spraying (IRS) operations in Ghana

CLEARANCE PAGE

Drafted: Eric Tongren

Cleared:

PMI Advisor: Sixte Zigirumugabe	e-clearance	Date: 02/15/2018
PPDO: Clare Masson	e-clearance	Date: 02/21/2018
Mission Environmental Officer USAID/Ghana: Emmanuel Odotei	e-clearance	Date: 02/12/2018
Mission Environmental Officer USAID/West Africa: Henry Aryeetey	e-clearance	Date: 02/12/2018
Regional Legal Advisor USAID/Ghana: Warren Leishman	e-clearance	Date: 02/22/2018

I. Background and Purpose

1.1 Objectives

PMI's IRS activities in Ghana operate under an SEA, which was approved in March 2015. The SEA was prepared in accordance with the provisions of the USAID 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 WHOPES-recommended pesticides: pyrethroid, carbamate, and organophosphate. It additionally authorizes the use of chlorfenapyr when recommended by the WHO Prequalification Team. This document has been prepared to serve as an amendment to that SEA, and proposes to also authorize the use of clothianidin for IRS in all areas of Ghana.

In order to expand the insecticide options for IRS to manage vector insecticide resistance in Ghana, new viable insecticides must be introduced for use. Changing insecticides classes over time and space is a leading way to manage resistance, and having more alternatives available increases the chances of mitigating resistance. For these reasons, PMI Ghana and the National Malaria Control Programme are seeking authorization to spray clothianidin insecticide in in Mamprugu Moaduri District, in the Northern Region of Ghana, one of the seven target districts during the 2018 IRS season. The rest of the target districts (six) will continue using Actellic 300 CS.

Sumishield 50WG is a new insecticide formulation from Sumitomo Chemical, Japan that was approved for IRS by the WHO prequalification team in October 2017. The active ingredient in Sumishield 50WG is the neonicotinoid clothianidin. Clothianidin has not yet been fully authorized by the Ghana Environmental Protection Agency (Ghana EPA), but the manufacturer is in the process of registering this insecticide with the Ghana EPA. For USAID/PMI to be able to use it, this registration needs to be completed, and the current 2015–2020 SEA has to be amended.

1.2 Area And Scope of Clothianidin Use For IRS in GHANA in 2018

In 2018, if this SEA amendment is approved, IRS will be conducted using clothianidin in Mamprugu Moaduri District, one of seven PMI target districts in the Northern Region of Ghana. Based on the 2017 spray data from PMI AIRS Ghana, the district has 59,835 people; in the 2010 national census, the population was recorded as 46,894 (Ghana Statistical Service, 2014). Geographically, the district is bordered by Sisala District (Upper West Region) and Builsa South District (Upper East Region) on the north, Kumbungu District on the south, North Gonja District on the west, and West Mamprusi District on the east. For IRS purposes, the district has 22,371 sprayable structures according to 2017 IRS data, and the average insecticide use rate is 4.5 structures per bottle (or sachet). Therefore, a total of 4,971 sachets (5,220 sachets, including a 5% buffer stock) of clothianidin (Sumishield) will be required to spray all available structures, as per 2017 IRS findings.

The National Malaria Control Program (NMCP), in consultation with PMI, selected the Mamprugu Moaduri District as the IRS beneficiary district to receive spraying with clothianidin in 2018. Factors contributing to the selection of the district include a long history of spraying with pirimiphos-methyl, with the need to rotate to a different IRS insecticide for resistance management, and the relatively small size of the district compared to other IRS target districts in the Northern Region of Ghana. These two factors make using Sumishield in this district for the first time in Ghana a priority, and relatively easier. Additionally, insecticide susceptibility tests indicate that the predominant vector, *An. gambiae* s.l., is susceptible to clothianidin.

1.3 Entomological Monitoring

1.3.1 Quality of Spraying and Residual Performance of Clothianidin

In 2018, to determine the quality of spraying and the residual performance of clothianidin on walls, WHO bioassays will be conducted within two weeks of IRS, and continued monthly. These bioassays will indicate how long the insecticide persists in killing or knocking down at least 80% of vector mosquitoes. This will be done in randomly selected houses: five with mud plaster walls; five with concrete, painted walls; and five with concrete walls that have not been painted.

1.3.2 Vector Density Surveillance

To monitor changes in mosquito populations, the following activities will be performed: monthly Prokopack aspiration collections, pyrethrum spray collections, human landing catches, and exit trap collections. These tests will be performed at two sites within the clothianidin-sprayed areas (Kunkwa and Yagaba) in Mamprugu Moaduri District, and in two neighboring unsprayed sites (Tugu and Kulaa in the Tamale Metro area).

2. Proposed Action and Alternatives

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

2.1 Description of Proposed Action

The preferred action is to authorize the use of clothianidin nationwide in Ghana for IRS. Clothianidin is Prequalification Team-listed by WHO. If authorized for PMI use in IRS, 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 may reduce the number of available alternatives IRS insecticides, and possibly result in increasing resistance to the available insecticides. This could raise rates of infections, transmission, mortality, and morbidity, due to the increased prevalence of resistant and infected vectors. Therefore, the "no action" alternative does not meet the overall goals of USAID/PMI, or of Ghana (the NMCP).

2.3 Alternative IRS Geographical Sites Considered

All regions and districts in Ghana 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 reduce 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 Ghana and the Ghana NMCP regularly conduct entomological testing to help determine the best choice of insecticide. This amendment proposes to add clothianidin as an alternative insecticide, as it has now been Prequalification Team-listed by WHO for IRS, and in anticipation of it being registered for public health use in Ghana. Thereafter, clothianidin will be an available alternative insecticide.

3. Pesticide Procedures

Title 22 of the United States 22 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 Ghana; this section of the amendment addresses any clothianidin-specific aspects of those factors.

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

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

3.2 The Basis for Selection of the Requested Pesticides

Recommended by WHO: Clothianidin was included on the WHO Prequalification Team list in 2017. PMI plans to use clothianidin, as it is now recommended by WHO.
Registration for use in Ghana: Clothianidin is currently not registered for IRS in Ghana, but the needed registration process is ongoing. PMI will spray with clothianidin only when Sumishield has been registered for use in Ghana, and not before. Since the Mamprugu Moaduri District is included in the available Environmental Impact Assessment certificate for IRS in Ghana, VectorLink Ghana can conduct IRS with clothianidin upon registration of Sumishield in Ghana.
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 formulation to be used (Sumishield) on the primary wall surface types is reported to be greater than the duration of the transmission season (about eight months), but these properties will be investigated further in upcoming operations if this amendment is approved.
Ecological impact: If PMI 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) and pathway (e.g., inhalation, dermal, ingestion, etc.). Based on the risk screening results, adverse human health effects for workers or residents are not expected from the use of clothianidin.

3.3 The Extent to Which the Proposed Pesticide Use Is Part of an Integrated Pest Management/IVM Program

IVM for the control of the malaria vector population is practiced using two primary interventions, insecticide-treated nets and indoor residual spraying. Environmental management for malaria control is limited to some common-sense safeguards, such as eliminating standing water, which can serve as a breeding ground for

mosquitoes. PMI does not support environmental management as a vector control method, because the life-cycle requirements and the adaptability shown by IRS vectors limit the large-scale effectiveness of these measures. PMI strategy has been that IRS will be implemented as a component of IVM for malaria control.

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

Clothianidin will be applied using the same compression spray equipment and techniques as other WHO-recommended insecticides, and the same cautions apply. The SUAP in Chapter 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.[1] Refer to the environmental and health impact section of this amendment (Section 4.2) and the PEA for greater detail about its toxicity.

3.5.1 Human Health Hazards

Clothianidin: The risk results for clothianidin are based on a two-generation reproduction study on rats, in which the rats were exposed through normal feeding; endpoints included weight gain, sexual maturation, and stillbirths. The health benchmark derived from this study, and recommended by the USEPA (USEPA 2012), is is 0.0098 mg/kg/day. 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 immunotoxicity 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.[2] 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.[3]

3.6 The Effectiveness of Clothianidin for the Proposed Use

To determine the quality of spray and residual performance of clothianidin on the walls, cone bioassays will be conducted within two weeks of IRS, and this will be continued monthly. Bioassays will be conducted using the WHO cone bioassay method in five randomly selected houses with mud plaster walls, five houses with painted concrete walls, and five houses with unpainted concrete 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 vector mortality is below 80% for two consecutive months, based on the 5 days' holding period.

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[1] http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf Accessed 7/14/17.
[2] IVM PEA, 2017. Integrated vector management programs for malaria vector control (version 2017). USAID.
[3] https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281 Accessed 7/14/17.

Testing with laboratory-reared mosquitoes of a susceptible colony will be conducted in two houses with mud plaster walls, two houses with painted concrete walls, and two houses with unpainted concrete 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% and 20% in the negative controls after 5 days. If mortality is >20% after 5 days in untreated controls, tests will be repeated.

To monitor changes in mosquito populations, the following will be performed: monthly human landing catches and pyrethrum spray collections at sentinel sites within the clothianidin spray area (Kunkwa and Yagaba) and in two neighboring unsprayed sites in Tugu and Kulaa in Tamale Metro area. Neighboring unsprayed sites will be located within 120 km of the Mamprugu Moaduri District sprayed areas, and be as similar in characteristics to the treated sites as possible.

3.7 Compatibility of Clothianidin with Target and Non-Target Ecosystems

Clothianidin is suited for use with the target areas (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 thus 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 it is released to the environment in large quantities it could have negative effects on land- and water-based flora and fauna. However, the IRS implementation process is designed to ensure that, to the maximum extent possible, pesticides are deliberately and carefully applied to the walls 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 (PPE) and, at a minimum, faces 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 Ghana 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, and any area where organic farming is practiced or where beekeeping or natural bee habitats are established. Bird-nesting and bee habitat will be protected, and clothianidin will not be stored near water habitats and resources. IRS will be prohibited within 30 meters of all sensitive ecosystems.

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

Only WHO-recommended pesticides may be used for PMI-supported IRS. Other non-chemical control methods are covered under the 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 Ghana, the Pesticides Control and Management Act of 1996 (Act 528) deals with pesticide importation, licensing, permitting procedures, and sale, among other concerns. The Chemicals Control and Management

Centre regulates the use of pesticides for agriculture, horticulture, forestry, gardening, and public health, and monitors the use of pesticides, taking enforcement action against illegal use. It also provides permitting of chemical imports and exports, as well as pesticides registration and licensing.

3.11 The Provisions Made for Training of Spray Operators

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

4. Environmental and Health Impacts

4.1 Potential Positive Effects of Clothianidin

4.1.1 Direct Positive Effects

The direct positive impacts of approving the use of clothianidin in IRS will include improved capacity for insecticide resistance management, as clothianidin will serve as an additional option for rotation of insecticides to prevent resistance. Carefully chosen rotations of insecticides (switching classes each round) reduce the rate at which operationally significant levels of insecticide resistance will be selected among vector mosquitoes. Other positive direct impacts of clothianidin in IRS derive from the expected health, economic, and environmental benefits provided by IRS itself. (Refer to Section 4.1 in the 2015 SEA.)

4.1.2 Indirect Positive Effects

The indirect positive impacts of using clothianidin in IRS are the same as the positive impacts of using the four WHO-recommended classes of pesticides. (Refer to section 5.1.2 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: for rabbits, slight (barely perceptible) transient skin irritation; and it is an eye irritant.
- Inhalation LC50 (4h): for male and female rats >2.3mg/L.

- Other: Not mutagenic. Not oncogenic in rats and mice. Not teratogenic in rats and rabbits.[4]

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 exposure to individuals would principally be via skin contact with insecticide treated indoor surfaces. 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 in rodents have caused agitation, seizures, metabolic acidosis, coma, hypothermia, pneumonitis, respiratory failure, hypotension, ventricular dysrhythmias, and death in rodents. 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 itself. Overall, when used properly, the product does not pose significant risks to residents.

4.2.2 Aquatic Life

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

4.2.3 Birds

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

4.2.4 Bees

In Ghana, beekeeping is only a supplementary economic activity in most areas. Very little attention is paid to the use of bees as pollinators for the agricultural sector.[5] 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. Messages on the potential toxicity of clothianidin 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 negative environmental cumulative impacts are expected as a result of using clothianidin in IRS if PMI BMPs are followed. IVM, including the use of clothianidin, should reduce the spread of mosquito-borne diseases.

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[4] United States EPA factsheet: https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-044309_30-May-03.pdf.

[5] Very little is known about domestic beekeeping in the Mamprugu Moaduri District in Ghana. However, some beekeeping projects have been initiated in some communities in the West Mamprusi District. Before extending Sumishield use to other districts, a survey will be conducted to estimate the prevalence of beekeeping in those districts.

5. Safer Use Action Plan

The procedures and protocols of the SUAP of 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 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 Ghana Health Service in the IRS district hospital and clinics where clothianidin is used receive appropriate training on administering emergency treatment to pesticide exposure. Annex A provides additional information on symptoms and treatment protocols for exposure to clothianidin.

Annex A: Summary Of Acute Exposure Symptoms and Treatment Of Clothianidin

Clothianidin	
Human side effects	**Treatment**
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.[6] 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.[7] 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 of the insecticide (N-methyl-2-pyrrolidone) as opposed to the neonicotinoid itself.[8] 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.[9]	Management of mild to moderate toxicity—Treatment is symptomatic and supportive. Administer IV fluids for hypotension. 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.[10]

[6] http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf Accessed 7/14/17.
[7] https://toxnet.nlm.nih.gov/cgi-bin/sis/search/a?dbs+hsdb:@term+@DOCNO+7281 Accessed 7/14/17.
[8] Ibid.
[9] http://www.cdpr.ca.gov/docs/registration/ais/publicreports/5792.pdf Accessed 7/14/17.
[10] 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	1. Occupational risks for workers involved in IRS campaigns (e.g., risks from insecticide exposure and vehicular accidents), especially women of child-bearing age	a. Inspect and certify vehicles used for pesticide or spray team transport prior to contract. b. Train drivers. c. Provide cell phone, PPE, and spill kits during pesticide transportation. d. Initial and 30-day pregnancy testing for female candidates for jobs with potential pesticide contact. e. Health-test all spray team members for duty fitness. f. Procure and distribute PPE, and train all workers with potential pesticide contact on the use of PPE. g. Train operators on mixing pesticides and the proper use and maintenance of spray pumps. h. Provide adequate facilities and supplies for end-of-day cleanup. i. Enforce spray and clean-up procedures.	a-d. Environmental Compliance Officer (ECO) e-g. Operations manager h. ECO i. Chief of Party, technical project managers and headquarters environmental staff	a. Transport vehicles have a valid inspection certificate on board. b. Drivers have a certificate of training completion. c. Transport vehicles are equipped with cell phone, spill kit, and PPE. d. Storekeeper has records of pregnancy testing for all female team members. e. Storekeeper has medical exam results for all team members. f. Spray operators wear complete PPE during spraying and clean-up. g. Operators mix pesticide properly, and the pump 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.	a-c. ECO inspection of vehicles in the field d-e. ECO inspection of health records at IRS operational sites f-h. ECO performs pre-spray inspections of inventories and training records, and mid-spray inspections of PPE use and spray operator performance i. Monitoring of on-line database for submission of inspection reports	a-c. 2 inspections per week d-e. One inspection per campaign, additional inspection if new hires or more than 30 spray days f-h. ECO pre-spray inspections 2/campaign, ECO mid-spray inspections 5 times/week i. Weekly

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)	a. IEC campaigns to inform homeowners of responsibilities and precautions. b. Prohibit spraying of houses that are not properly prepared. c. Two-hour exclusion from house after spraying. d. Instruct homeowners to wash itchy skin and go to health clinic if symptoms do not subside.	a-b. IEC Officers, operations manager, ECO b. ECO c. Spray operators and team leaders	a. Pre-spray IEC campaigns were executed. Homeowners know responsibilities. b. All houses being sprayed are properly prepared. c. Homeowners observe 2-hour exclusion. d. Lack of incident reports, or incident reports with proper response noted.	a. Operations manager-IEC work records, ECO-mid-spray inspections b-d. ECO mid-spray inspections	a. Inspect work records 1/campaign. b-d. ECO mid-spray inspections 3/wk.
	3. Ecological risk to non-target species and water bodies from use of insecticides (during transport, mixing, and spraying)	a. For shipments of insecticide over water, sachets/bottles will be packed in 220 liter 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. b. Operators will not spray within 30 meters of bee hives. c. Train operators on proper spray technique. d. Spray indoors only. e. Maintain pumps.	a. ECO b-e. Team leader, district coordinator, operations manager, ECO identified	a. Insecticide is packed in barrels prior to shipment over water. b. Locations of beehives have been identified, and operators do not spray within 30 meters. c. Operators are trained, and know and use proper spray techniques. d. Operators spray only inside of house. e. Pumps are maintained and operated to eliminate leaks and erratic spraying.	a. ECO pre-shipment inspection b. ECO pre- and mid-spray inspections, team leader daily inspections b-e. Training records, ECO and district coordinator, mid-spray inspections, team leader daily inspections	a. Once before shipping b. Team leader daily inspection, ECO and district coordinator weekly b-e. Inspection of training records 1/campaign. Team leader daily. b-e. ECO and district coordinator mid-spray inspections 5/wk.

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)	a. Choose sites for disposal of liquid wastes, including mobile soak pit sites, according to PMI BMPs. b. Construct fixed and mobile soak pits with charcoal to adsorb pesticide from rinse water. c. Maintain fixed and mobile soak pits as necessary during season. d. Inspect and certify solid waste disposal sites before spray campaign. e. Monitor waste storage and management during campaign. f. Monitor disposal procedures post-campaign.	a-c. Abt operations manager, ECO, district coordinator d-f. Abt ECO	a. Operations sites meet PMI BMPs. b. Fixed and mobile soak pits are sited and constructed according to the PMI BMP manual. c. Fixed and mobile soak pits perform properly throughout the spray season. d. Disposal sites have the capacity and policies to properly dispose of wastes. e. Solid wastes are stored and managed according to PMI BMPs. f. Waste disposal has taken place as agreed and certificates of disposal have been received.	a-b. ECO Pre-spray inspections c-f. ECO mid-and post-spray inspections and monitoring.	a. 2/campaign b. 1/campaign c. 5/week d. 1/campaign e. 3/week f. Continuous during disposal
	5. Risk of diversion of insecticides for unintended or uncontrolled use	a. Maintain records of all pesticide receipts, issuance, and return of empty sachets/bottles. b. Reconcile number of houses sprayed vs. number of sachets/bottles used. c. Examine houses sprayed to confirm spray application. d. Perform physical inventory counts during the spray season.	a-d. Storekeepers, district coordinators, sector managers, logistics coordinator, operations manager, ECO	a-d. All pesticide management records are reconciled.	a-b., d. Inspection of pesticide management records, and storekeeper performance checklists; ECO mid-spray inspections	a-b., d. Daily monitoring by storekeeper or site supervisor; weekly monitoring by district coordinators c. 1/campaign by country headquarters; 2/campaign by ECO; 2/campaign/ storeroom

ANNEX D: ENVIRONMENTAL MITIGATION AND MONITORING REPORT

Implementing organization:
Geographic location of USAID-funded activities:
Period covered by this Reporting Form and Certification:

Mitigation Measure	Status of Mitigation Measures	Outstanding Issues Relating to Required Conditions	Remarks
1a. Pre-contract inspection and certification of vehicles used for pesticide or spray team transport			
1b. Driver training			
1c. Cell phone, personal protective equipment (PPE) and spill kits on board during pesticide transportation			
1d. Initial and 30-day pregnancy testing for female candidates for jobs with potential pesticide contact			
1e. Health fitness testing for all operators			
1f. Procurement and distribution of PPE, and training on the use of PPE for all workers with potential pesticide contact			

Mitigation Measure	Status of Mitigation Measures	Outstanding Issues Relating to Required Conditions	Remarks
1g. Training on mixing pesticides and the proper use and maintenance of spray pumps			
1h. Provision of adequate facilities and supplies for end-of-day cleanup			
1i. 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			
3a. Packaging for pesticide shipments over water			
3b. Protection of bees/pollinators			

Mitigation Measure	Status of Mitigation Measures	Outstanding Issues Relating to Required Conditions	Remarks
3c. Use of proper spray techniques			
3d. Indoor spraying 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			
4e. Monitoring of waste storage and management during campaign			
4f. Monitoring of disposal procedures post-campaign			

Mitigation Measure	Status of Mitigation Measures	Outstanding Issues Relating to Required Conditions	Remarks
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			