



PRESIDENT'S MALARIA INITIATIVE



The PMI Africa IRS (AIRS) Project

Indoor Residual Spraying (IRS) 2

Task Order Six

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

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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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ZAMBIA

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

2015-2020

August 2017

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ACRONYMS

AIRS	Africa Indoor Residual Spraying project
BMPs	Best management practices
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
DDT	Dichlorodiphenyltrichloroethane
EMA	Environmental Management Act
IRS	Indoor Residual Spraying
IVM	Integrated Vector Management
PQ	WHO Prequalification Team
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
ZEMA	Zambia Environmental Management Agency

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 Zambia. That SEA authorized the use of the pyrethroid, carbamate, organochlorine, and organophosphate classes of insecticides, and chlorfenapyr (when approved by WHOPES/PQ) for IRS in Zambia. 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 Letter Report for Zambia.

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 Zambia, 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 Zambia and in the United States.

Zambia has been implementing IRS for malaria control as part of an integrated vector management (IVM) strategy consistently since 2003. In 2017, PMI proposes to spray the same thirty six high burden malaria districts as in 2016. A long-lasting insecticide in the organophosphate class, Actellic 300CS will be used in thirty four districts and clothianidin is proposed to be used in two districts that were previously sprayed using Actellic 300 CS. However, this SEA is seeking approval to authorize the use of clothianidin in any area of the country.

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, organophosphates, or, DDT, 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 Zambia will be performed according to the protocols and procedures found therein.

APPROVAL

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

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 Zambia responds to the needs of the community and country as it relates to managing malaria in Zambia, 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 (2017), is consistent with the Government of Zambia's and USAID's goal of reducing malaria incidence in Zambia while minimizing negative impact to the environment and to human health.

The proposed actions recommended for approval in this SEA Amendment are:

The continuation of IRS programming for 2017-2020 using pyrethroids, carbamates, organophosphates, or, DDT, 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.

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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I. BACKGROUND AND PURPOSE

I.1 OBJECTIVES

PMI's IRS activities in Zambia operate under a Supplemental Environmental Assessment (SEA), which was approved in September 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 the four classes of WHOPES-recommended pesticides (pyrethroid, carbamate, organophosphate and organochlorine), 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 Zambia, 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 Zambia, 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 Zambia and the Ministry of Health are seeking authorization to spray clothianidin insecticide in two of the 36 target districts during the 2017 IRS season. The rest of the target districts (34) 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 Zambia Environmental Management Authority (ZEMA), but they have authorized a clothianidin trial during IRS operations between October and December, 2017. For USAID/PMI to conduct the trial, it is necessary to amend the current 2015-2020 Supplemental Environmental Assessment for IRS in Zambia. Registration of clothianidin for future use in IRS in Zambia will partially depend on the trial findings and final recommendations by WHOPES/PQ.

I.2 AREA AND SCOPE OF CLOTHIANIDIN USE FOR IRS IN ZAMBIA IN 2017

In 2017, if this SEA is approved, IRS will be conducted using clothianidin in Chembe and Shiwang'andu Rural Districts of Luapula and Muchinga Provinces, respectively. Chembe is one of the newly created districts, and it is the site of the Chembe Bridge across the Luapula River dividing Zambia and the Congo Pedicle territory of Democratic Republic of Congo. Shiwang'andu is among the seven districts of Muchinga Province, with a total surface area of approximately 9,837 square km and shares boundaries with Mpika, Chinsali, Chama and Kasama districts.

Chembe and Shiwang'andu districts were selected due to their capacity to conduct the requisite entomological activities. These districts have appropriate facilities to sustain mosquitoes after cone bioassays to evaluate their mortality up to day five because clothianidin is slow acting. Additionally, out of the 36 PMI IRS supported districts, Chembe and Shiwang'andu districts are two of the smallest districts. The total targeted number of structures in both Chembe and Shiwang'andu districts are 5,713 and 4,433, respectively. The total amount of clothianidin that will be used is approximately 2,537 sachets, estimating that one sachet covers an average of 4 structures.

1.3 ENTOMOLOGICAL MONITORING

1.3.1 QUALITY OF SPRAY AND RESIDUAL PERFORMANCE OF CLOTHIANIDIN

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 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.

1.3.2 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 Chembe and Showang'andu rural districts and in two neighboring unsprayed sites in each of the districts.

2. PROPOSED ACTION AND ALTERNATIVES

This section describes the alternatives for the clothianidin pilot 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 Zambia for IRS. 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 Zambia National Malaria Elimination Program (NMEP).

2.3 ALTERNATIVE IRS GEOGRAPHICAL SITES CONSIDERED

All provinces and districts in Zambia 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 NMEP 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 Zambia and the Zambia NMEP 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 Zambia. Thereafter, clothianidin will be an available alternative insecticide.

3. PESTICIDE PROCEDURES

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 Zambia. 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 2017 PMI Zambia spray campaign. PMI will only utilize clothianidin if/when recommended by WHO.

Registration for use in the Zambia: Clothianidin is currently not registered for IRS use in Zambia. However, a ZEMA license to conduct field trials and evaluation has been amended to authorize PMI Zambia to spray clothianidin in two districts as part of PMI’s 2017 IRS operations. Full authorization and registration of clothianidin for IRS use in Zambia will depend in part on its performance in these districts.

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 IVM PEA 2017 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 4.3) 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

¹ <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.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 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 wild mosquitoes 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 Chembe or Shiwang'andu 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.

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

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 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 Zambia 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

Zambia insecticide and toxic substance regulations provide the guidelines and measures for management of insecticides, including storage, transport, usage and disposal. ZEMA provides the regulation on 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 chemical 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. A ZEMA license to conduct field trials and evaluation has been extended to include MoH and PMI as holders so that clothianidin can be used in the 2017 IRS operations. The full authorization and registration of clothianidin in Zambia will depend on the results of 2017 IRS, and the anticipated recommendation by WHO.

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 Zambia project, and is used for IVM decision-making.

4. ENVIRONMENTAL & HEALTH IMPACTS

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.⁴

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

⁴ United States EPA assessment report (2003),

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.

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 Zambia 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

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. 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. Most interventions will have to be provided by medical professionals at the nearest health clinic. Annex A provides additional information on symptoms and treatment protocols for exposure to clothianidin.

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

Clothianidin	
Human side effects	Treatment
<p>Clothianidin is a systemic insecticide belonging to the nitroguanidine subgroup of nicotinoid insecticides. It is also referred to as a chloronicotinyl or neonicotinoid.⁵ 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 suggest 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.⁶ 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.⁷</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.⁸</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 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.⁹</p>

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

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

⁷ Ibid

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

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

ANNEX B: BIBLIOGRAPHY

Abt Associates. August 2012. *Assessment and Recommendations: Storage, Stock Control, and Inventory Management*. USAID.

Abt Associates. December, 2016. *Zambia End of Spray Operations Report 2014*. USAID

Abt Associates. January, 2017. *PMI/Africa IRS Project, Zambia Work Plan and Budget, March 2, 2017 – February 28, 2017*. USAID

EMA (2011). *Environmental Management Act. 2011*. EMA, Lusaka Zambia.

IVM PEA, 2017. *Integrated vector management programs for malaria vector control (version 2017)*. USAID

USEPA, 2003. *Assessment Report. Pesticides Facts sheets*. Office of Prevention, Pesticide and Toxic Substances (7501C)

WHO (2012). *Global plan for insecticide resistance management in malaria vectors*. World Health Organization, Geneva.

WHO. (2013) *Test procedures for insecticide resistance monitoring in malaria vectors*. World Health Organization, Geneva.

WHO-UNEP *Sound Management of Pesticides and Diagnosis and Treatment of Pesticide Poisoning: A Resource Tool*. World Health Organization, Geneva.