#### INITIAL ENVIRONMENTAL EXAMINATION: AMENDMENT

# PESTICIDE EVALUATION REPORT AND SAFER USE ACTION PLAN (PERSUAP) FOR

### PRESIDENITAL MALARIA INITIAVE- INDOOR RESIDUAL SPRAYING (IRS) FOR MALARIA CONTROL IN RWANDA

#### PROGRAM/ACTIVITY DATA:

Program/Activity Number: Country/Region: Program/Activity Title:	GH-I-00-06-00002-00 Rwanda, Africa Bureau, East Africa 696-006.00 : SO 6: Increased use of community health services, including HIV/AIDS		
Sub-activity:	IRS for Malaria Control in R	wanda	
Funding Begin: FY07	<b>Funding End:</b> FY07	<b>LOP Amount:</b> \$ 4,068,000 (Early funding: \$ 380,000 )	
PERSUAP Prepared By: Current Date:	Melanie Biscoe and Samba Y March 12, 2007	` '	
IEE Amendment (Y/N): Filename & date of original IEE:	Y 34Rwanda2_S06_Health;doc	: June 23, 2004	
ENVIRONMENTAL ACTION R	ECOMMENDED: (Place X w	where applicable)	
Categorical Exclusion: Positive Determination:	Negative Determination: _X Deferral:		
ADDITIONAL ELEMENTS: (Pla	ce X where applicable)		
CONDITIONS: _X	PVO/NGO:		

**Other Relevant Environmental Compliance Documentation:** This IEE references the following USAID environmental compliance documentation that is already in effect for ongoing activities globally under USAID:

• Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment: 03/2007

This IEE references the following USAID environmental compliance documentation that is already in effect for ongoing activities under USAID/RWANDA SO 6:

- Amended Pesticide Evaluation Report and Safer Use Action Plan Insecticide Treated Nets: Social Marketing Rwanda: 34Rwanda3 LLITN PERSUAP SO6.doc :07:27/04
- Pesticide Evaluation Report and Safer Use Action Plan Insecticide treated Nets: Social Marketing in Rwanda: 31Rwanda1 ITN PERSUAP S06.doc:09:28/2001

#### **SUMMARY OF FINDINGS:**

The U.S. President's Initiative on Malaria (PMI) in Africa seeks to reduce malaria mortality by 50% in up to 15 countries in sub-Saharan Africa by 2010. The United States will work in partnership with host governments and build on existing national malaria control plans, policies and resources. The Initiative will support and complement efforts of the Global Fund (GFATM), the World Bank, and other members of the Roll Back Malaria (RBM) Partnership. The Initiative will include detailed reporting on inputs, outputs, and results. Rwanda was one of the first seven countries selected for this Initiative.

As part of PMI, the United States Agency for International Development (USAID) proposes to implement Indoor Residual Spraying (IRS) in Rwanda for malaria vector control during the 2007-2010 project period. Because pesticide use is proposed for this intervention, USAID is obligated to comply with the Code of Federal Regulations Title 22 Section 216 (22 CFR 216). 22 CFR 216 mandates that detailed pesticide procedures are addressed prior to direct or indirect support of pesticide use. This document fulfills this legal obligation. Additionally, this PERSUAP relies heavily upon USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment* (PEA), the primary resource for providing guidance for IRS implementation that maximizes the safety of workers and beneficiaries and minimizes environmental contamination.

The pesticide that will be used for the first spray rounds is ICON ® 10 % Wettable Powder (WP), composed of the active ingredient lambda-cyhalothrin. Rwanda is characterized by both seasonal and endemic malaria transmission, and IRS would be used primarily for epidemic prevention. The first round of IRS will be conducted in the three districts comprising Kigali City: Nyarugenge, Gasabo, and Kicukiro. The second round of spraying will cover these three districts as well as Nyanza and Kirehe districts

A **negative determination with conditions** is recommended for this project. The conditions are that USAID, USAID contractors, and the MOH implement the risk reduction actions outlined in the Pesticide Evaluation Report and Safer Use Action Plan (PERSUAP) and summarized in the section entitled REQUIRED MITIGATION MEASURES: The Safer Use Action Plan. USAID will discuss the compulsory nature of PERSUAP implementation with the MOH; and the development of an Implementation Letter between USAID and MOH assigning roles and responsibilities for these risk reduction actions.

Any expansion of IRS *exclusively using ICON* ® to cover additional districts does not require an additional PERSUAP, provided that the following occurs:

- 1. Agricultural and environmental sectors/stakeholders are consulted prior to project expansion and any concerns are addressed through discussion or through revision of project activities (this may be particularly important for conventional or organic crop production and beekeeping activities)
- 2. Malaria vectors in target districts are not resistant to lambda-cyhalothrin
- 3. IRS expansion into additional districts complies with the Required Mitigation Measures described in the present PERSUAP.

If continuation or scale-up of IRS activities requires an alternative insecticide, an additional PERSUAP must be developed.

As required by USAID's Automated Directives System (ADS) 204.5.4, the Strategic Objective (SO) team will actively monitor ongoing activities for compliance with the recommendations in this PERSUAP, and modify or end activities that are not in compliance.

#### **APPROVAL OF ENVIRONMENTAL ACTION RECOMMENDED:**

CLEARANCE:			
Mission Director, USAID/Rwanda:			Date:
		Kevin Mullally	
CONCURRENCE:			<b>.</b>
Environmental Officer, Bureau of C	flobal Health:	M. 1 17 .1.	Date:
ADDITIONAL CLEARANCES:		Michael Zeilinger	
Mission Environmental Officer			
USAID/Rwanda:	Timothy Kar	era	Date:
PMI Advisor			Date
	Karen Shelle	у	
SO6 Team Leader:			Date:
	John Dunlop		
Regional Environmental			_
Advisor, USAID/REDSO	Walter I. Kna	nusenberger	Date:
Environmental Officer	.,, .,		
Africa Bureau:			Date:
	Brian Hirsch		

# PESTICIDE EVALUATION REPORT AND SAFER USE ACTION PLAN (PERSUAP) FOR INDOOR RESIDUAL SPRAYING (IRS) FOR MALARIA CONTROL IN RWANDA

by

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March 2007

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#### **ACRONYMS**

ADS Automated Directives System
ASP Africa Stockpiles Program
CDC Centers for Disease Control

DDT Dichloro-diphenyl-trichloroethane
EIA Environmental Impact Assessment
EMP Environmental Management Plan

FAO Food and Agriculture Organization of the United Nations

GDP Gross Domestic Product

GFATM The Global Fund to Fight AIDS, Tuberculosis, and Malaria (referenced as

"Global Fund")

IEC Information, Education and Communication

IEE Initial Environmental Examination

IPCS International Program on Chemical Safety

IRS Indoor Residual Spraying ITNs Insecticide Treated Nets

IUCN International Union for Conservation of Nature and Natural Resources

LLINs Long-Lasting Insecticidal Nets IVM Integrated Vector Management

LATH Liverpool Associates in Tropical Health

MINAGRI Ministry of Agriculture

MOU Memorandum of Understanding NGOs Non-Governmental Organization

PEA for IVM Programmatic Environmental Assessment for Integrated Vector

Management

PERSUAP Pesticide Evaluation Report and Safer Use Action Plan

PMI Presidential Malaria Initiative in Africa (U.S.)

PNILP National Malaria Control Program
PPE Personal Protective Equipment

REMA Rwanda Environmental Management Authority

RBM Roll Back Malaria

RTI Research Triangle Institute

U5 Under five

USAID United States Agency for International Development USEPA United States Environmental Protection Agency

WP Wettable Powder

WHO World Health Organization

WHOPES World Health Organization Pesticide Evaluation Scheme

#### **SUMMARY**

# **REQUIRED MITIGATION MEASURES:** The Safer Use Action Plan

Table 1 summarizes the required mitigation actions according to the time that the actions should be taken. Further recommendations for monitoring and mitigation activities for IRS can be found in USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment* (2007). USAID and RTI will develop a work plan further detailing the roles and responsibilities for required mitigation measures described in Table 1. USAID will discuss the compulsory nature of PERSUAP implementation with the Ministry of Health; the Ministry of Health must be committed to the implementation of the IEE/PERSUAP. The campaign will not spray in communities that rely heavily on organic agricultural trade goods (typically stored indoors) unless agricultural stakeholders can agree on an appropriate strategy to mitigate contamination of organic crop commodities. Any expansion of IRS exclusively using Icon to cover additional districts does not require an additional PERSUAP, provided that the following occurs:

- 1. Agricultural and environmental sectors/stakeholders are consulted prior to project expansion and any concerns are addressed through discussion or through revision of project activities (this may be particularly important for conventional or organic crop production and beekeeping activities);
- 2. Malaria vectors in target districts are not resistant to lambda-cyhalothrin, and;
- 3. IRS expansion into additional districts complies with the requirements described in the above paragraph and in Table 1 below.

Table 1. Required Mitigation Activities for IRS Program, Rwanda

Potential negative impacts	Pre-Campaign	Stakeholders responsible
Exposure and Contamination Continues Without Corrective Action	Development of protocol for decision- making when environmental monitoring indicates environmental contamination as a result of IRS	RTI, District Officials (including environmental manager), PNILP, REMA and MINAGRI as needed
Fetal Exposure	Pregnancy tests to ensure pregnant women are not on the spray teams; prohibition of breastfeeding women on spray teams	District Officials, RTI
Spray Operator and Community Exposure, Environmental Contamination	Training of spray operators, team leaders and supervisors according to WHO and PERSUAP guidelines; training of storekeepers, drivers and health workers.	RTI
Spray Operator and Community Exposure, Environmental Contamination	Procurement of sprayers manufactured according to WHO specifications; procurement and proper use of PPE by spray operators, team leaders and supervisors (cotton overalls, face shield, dust mask, broad-rimmed hat, rubber gloves, gum boots)	RTI
Acute Effects of Pesticide Go	Procurement and distribution of treatment	PNILP

Untreated	medicines for insecticide exposure	
Spray Operator Exposure	Organization of a drill for carrying out and	RTI
	supervising personal hygiene, regular	
	washing of protective clothes and cleaning	
	of equipment according to WHO guidelines	
Spray Operator and Community	Procurement and distribution of barrels for	RTI
Exposure	progressive rinse, and wash-tubs for	
	personal hygiene (if appropriate);	
	inscription of program barrels and tubs as	
	District Health Office property to deter sale	
Community Fyrnaning	and domestic use in event of pilferage  Procurement of seat covers or sheets for	District Officials DNIII D
Community Exposure	covering cloth vehicle seats	District Officials, PNILP
Environmental Contamination	Locate district storage facilities on high	District Officials
	ground, outside of floodplains (if possible)	
Community Exposure	IEC Campaign, citing importance of	RTI
	removing all food, utensils and straw	
	flooring from house prior to spraying,	
	moving furniture to the center of the room	
	or outside, staying out of the house during	
	and 2-4 hours after spraying (and	
	associated risks and actions necessary to	
	treat exposure), not allowing children or	
	animals in the house until floor residue is	
	swept outside; also needs to cite	
	importance of not plastering or painting walls after the home has been sprayed.	
Potential Exposure without	Lab-testing of insecticide to ensure quality	RTI
Impact on Vector	control	KII
Potential Exposure without	Entomological monitoring	RTI, District Officials
Impact on Vector		,
	During Campaign	
Community Exposure, Fetal	Prohibition of spraying in homes where sick	Supervisors, Team Leaders
Exposure	persons or pregnant women are living and	·
	cannot move outside the home and stay	
	outside the home during and 1 hour after	
	spraying.	
Community Exposure	Prohibition of spraying in homes where	Supervisors, Team Leaders
	food, utensils and flooring have not been	
	removed from the house, and where	
	furniture has not been removed outside or	
	moved to the middle of the room and	
0	covered with a cloth by the spray operator.	
Spray Operator Exposure		
	Prohibition of eating, drinking and smoking	Supervisors, Team Leaders
	during work; prohibition of eating before	Supervisors, Team Leaders
	during work; prohibition of eating before washing	
Community Exposure	during work; prohibition of eating before washing  Prior to spraying, covering furniture that	Supervisors, Team Leaders  Spray Operators
	during work; prohibition of eating before washing  Prior to spraying, covering furniture that cannot be moved with cloths provided by	
Community Exposure	during work; prohibition of eating before washing  Prior to spraying, covering furniture that cannot be moved with cloths provided by the District Health Office, or Program	Spray Operators
	during work; prohibition of eating before washing  Prior to spraying, covering furniture that cannot be moved with cloths provided by	
Community Exposure  Spray Operator and Community	during work; prohibition of eating before washing  Prior to spraying, covering furniture that cannot be moved with cloths provided by the District Health Office, or Program  Reprimanding of spray operators that do	Spray Operators  Supervisors, District
Community Exposure  Spray Operator and Community Exposure, Environmental	during work; prohibition of eating before washing  Prior to spraying, covering furniture that cannot be moved with cloths provided by the District Health Office, or Program  Reprimanding of spray operators that do not follow proper procedure in all aspects	Spray Operators  Supervisors, District

Spray Operator and Community Exposure, Environmental	vehicles with seat cover or cloth to prevent seat contamination; procurement and use of gloves for washing interior and exterior of program vehicle  Supervisors will use the IRS Campaign Oversight Checklist (Annex 1) to record	Supervisors
Contamination	spray operator compliance with best practices (Note that this checklist is a template that will evolve based on field experience)	
Pilferage and Community Exposure, Environmental Contamination	Daily tracking of insecticide sachets used, spray-operator sign-out of sachets, return of empty sachets to supervisors, etc. (see Pesticide Procedures J)	RTI
Spray Operator and Community Exposure, Environmental Contamination	Daily sprayer maintenance, sprayer progressive rinse, spray operator bathing, washing of overalls, PPE and cloths used to cover furniture, latrine disposal of laundry wash-water	Supervisors, RTI
Community Exposure, Environmental Contamination	Triple-rinsing (and, if necessary, shredding) of contaminated packaging; local disposal	District Officials, RTI
Pilferage and Community Exposure, Environmental Contamination	Keep storage facilities up to standards described in Pesticide Procedures J; Storage of all insecticides, empty packaging, barrels and tubs in storage facilities, reducing use of contaminated goods domestically	District Officials, RTI
Potential Exposure without Impact on Vector	Entomological monitoring	RTI
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	Environmental compliance monitoring and reporting by district environmental managers, RTI and USAID	District Officials, RTI, USAID
	Post-Campaign	
Community Exposure	End-of-program cleaning/decontamination of interior and exterior of vehicles	Drivers, RTI
Community Exposure to Sachet Breakdown Products	Return empty Icon sachets to Syngenta for disposal	RTI
Inability to Use Safer WHO- Approved Insecticides in Malaria Vector Control	Development of protocol/implementation of measures to mitigate mosquito resistance to insecticides pesticide rotation or mosaicing.	PNILP
Spray Operator and Community Exposure, Environmental Contamination continue unnoticed	Submission of end-of-spraying environmental compliance reporting to USAID	RTI
Potential Exposure without Impact on Vector	Entomological monitoring	RTI

#### BACKGROUND AND PURPOSE

#### **Need for Action and the Preferred Alternative**

#### **PMI Background**

The IRS program in Rwanda is associated with the U.S. President's Initiative on Malaria in Africa, which was announced 30 June, 2005, and seeks to reduce malaria mortality by 50% in up to 15 countries (total population: 175 million) in sub-Saharan Africa by 2010. This will be accomplished by rapidly scaling up the following proven malaria prevention and treatment interventions in each country to reach 85% coverage of vulnerable groups (children under five, pregnant women, and people living with HIV/AIDS):

- treatment of malarial illnesses with artemisinin-based combination therapies (ACTs);
- intermittent preventive treatment (IPT) of pregnant women with effective antimalarial drugs, currently sulfadoxine-pyrimethamine;
- distribution of insecticide-treated bed nets (ITNs); and
- indoor residual spraying (IRS).

In implementing these interventions, the United States will work in partnership with host governments and build on existing national malaria control plans, policies and resources. The Initiative will support and complement efforts of the Global Fund (GFATM), the World Bank, and other members of the Roll Back Malaria (RBM) Partnership. The Initiative will include detailed reporting on inputs, outputs, and results. Angola, Tanzania, and Uganda were the first three countries selected for this Initiative, followed by Rwanda, Mozambique, Malawi and Senegal, then Liberia, Mali, Kenya, Ethiopia, Madagascar, Zambia, Benin, Ghana.

#### Malaria Burden in Rwanda

As mentioned in the national health policy, malaria and AIDS are the two major health problems in Rwanda given their socioeconomic impacts. Malaria is one of the leading causes of outpatient attendance (about 50% of all health center visits are due to malaria) and it is the principal cause of morbidity in every province in Rwanda.

Since 2000, about 1,000,000 cases are recorded per year countrywide. In 2004, 845,376 cases of malaria were recorded, among which over 23,790 severe cases were recorded in the district hospitals with 1,353 deaths; fifty-four percent of hospital cases and 53% of the deaths occurred among children under five. Malaria is also a significant health risk for pregnant women and their unborn children, particularly women in their first and second pregnancies, and women with HIV infection (Rwandan PMI MOP, 2006; PNILP, 2005). Country estimates indicate that the number of children under five (U5) is 1,550,000; the number of pregnant women per year is 390,000 and there are approximately 188,000 people living with HIV/AIDS.

Malaria incidence rate rose from 3.5% in 1982 to 48.16% in 2003; such an increase is attributed to several causes including climatic factors (rainfall, temperature), increased chloroquine resistance (previously the most common form of malaria treatment), greater population density and population movements, and human and economic activities such as rice farming, brick

making and mining, which increase breeding areas for mosquitoes and thus increase the risk of malaria transmission. Malaria is now evident in high altitude areas and other areas where the disease was not previously a public health problem. Often inhabitants of these areas have little or no immunity to the disease and are therefore prone to severe forms of malaria. Since 1998, severe epidemics/upsurges of malaria have been observed nationwide almost every two years (Rwandan PMI MOP, 2006).

Epidemic prone districts in all five provinces affected an estimated population of 4,215,430 inhabitants; with over 80% of the inhabitants living in the Southern, Eastern and Kigali City provinces.

*Plasmodium falciparum* is the main plasmodium species encountered in Rwanda with 95% of malaria cases, followed by *Plasmodium malariae* (4.5% of cases) and *Plasmodium ovale* (.5% of cases). Since several years *P. falciparum* is increasingly resisting to anti malaria drugs.

Several entomological studies performed since 1942 indicate that *Anopheles gambiae* and *A. funestus* are the main vectors responsible of malaria transmission in Rwanda. Susceptibility tests performed on *A. gambiae* strains that were collected in the district of Kacyiru indicate good susceptibility to deltamethrin .05% with mortality rate comprised between 80% and 98%.

Malaria is not properly taken over in many health care facilities as well as at home while the level of use of preventive methods (ITN, LLIN, larval treatment, IRS) is still very low (PNILP, 2005). The 2005 Demographic and Health Survey (DHS) conducted between February and July of 2005 showed weak case management practices for malaria in children U5. Among caregivers who reported having a child with fever in the two weeks before the survey, only 12.3% of children received an anti-malarial drug and only 2.5% had received treatment within 24 hours. In addition, only four to six percent of those children were given a recommended drug (combination amodiaquine-sulfadoxine-pyrimethamine (AQ/SP) or quinine). In three districts studied in 2005, only 21% of persons with uncomplicated malaria and 44% of patients with severe malaria were managed correctly in health facilities, and only 59% received a recommended drug.

Use of preventive measures at the household level is also inadequate. Rwanda experienced modest gains in ITN ownership between 2000 and 2005, but coverage remains relatively low. Overall ITN coverage increased from 6.6% to 14.7%, use by U5s rose from 4.3% to 13.0%, and use by all women from 3.9% to 10.5%. In 2005, 17.2% of pregnant women slept under an ITN (not queried in 2000 DHS). The 2005 DHS found only 18.2% of households with at least one net of any type, and only 14.7% with at least one ITN.

From a socioeconomic standpoint, a study in Rwanda calculated that 19% of the country's health budget was consumed by malaria treatment in public health facilities (WEF, 2006), 16% of all donor health funds, 13% of all public health funds, and 26% of all private health funds went towards malaria efforts, while the direct cost per episode of malaria treated is estimated to be \$2.09 while the indirect cost is over \$5.00 (MOP, 2006). With the majority of the children and many adults experiencing more than one episode per year, malaria impedes economic development. Donors (38%), followed by households (29%), and lastly public sources (24%) are the main financiers of malaria services (Carlson A. & Al., 2007); hence households spend more

than the government for malaria (contrary to general health care). According to the same source, overall, resources for malaria are spent on curative care rather than preventive and public health programs.

In such a context, malaria will make worse the prevailing high poverty level in Rwanda: over 60% of individuals live in poverty, 42% in absolute poverty and 57% of households live below the poverty line (UNDP Rwanda). Such a poverty level is aggravating the impacts of malaria epidemics on public health.

#### **Alternatives Considered and Not Considered**

#### **Alternatives Considered**

IRS Campaign using ICON

USAID support would include the following components:

- Purchase of insecticide, spraying equipment, and adequate amounts of personal protective clothing and equipment for spray operators and supervisors;
- Financial support for trainers and spray teams;
- Technical advisors to plan the program, train field staff, and supervise field operations;
- Entomological training and monitoring;
- Wall bioassays to determine the residual effect of pesticides;
- IEC to inform beneficiaries, raise public awareness, promote behavior change and promote cooperation;
- Financial support for renting storage facility; and
- Additional human health and environmental safety components.

#### **Alternatives Not Considered**

ITN/LLIN Program

USAID is committed to continuing support for ITN and LLIN scale-up activities within Rwanda. To that end, the following PERSUAPs and PERSUAP amendments were developed prior to this PERSUAP:

- Amended Pesticide Evaluation Report and Safer Use Action Plan
   Insecticide Treated Nets: Social Marketing Rwanda: 34Rwanda3 LLITN PERSUAP SO6.doc :07:27/04
- Pesticide Evaluation Report and Safer Use Action Plan Insecticide treated Nets: Social Marketing in Rwanda: 31Rwanda1 ITN PERSUAP S06.doc:09:28/2001

Malaria prevention through scaling up the use of treated mosquito nets (ITN, LLIN) is a key strategy of the NIMCP. With the financial support of its partners, the NIMCP has rendered the prices of treated nets affordable mostly to pregnant women and children under five. PSI, USAID, UNDP and the Global Fund are playing an important in the promotion of the use of treated mosquito nets in Rwanda.

Late 2006, PSI managed the distribution of the 1.3 million nets utilizing trucks, Land cruisers, motorcycles, bicycles, and even canoes to reach deep into the countryside. 15,000 community-based health workers were actively involved that campaign. Following on this activity, Rwanda is now planning to conduct an assessment of household ITN coverage, to reinforce communication campaigns for net usage among vulnerable groups, and to scale up combination therapy delivery for malaria treatment through public, private, and community based channels.

IRS Project using DDT or

DDT is not approved for use in malaria control in Rwanda (see Complementary and Conflicting Policies, Plans or Controls for the

other Insecticide

Areas under Consideration). Pyrethroids are currently the only IRS insecticides promoted by the NIMCP, of which lambda-cyhalothrin is the most appropriate insecticide (see *Pesticide Procedures B. The basis for selection of the requested pesticide*).

Larviciding and Environmental Management At the present time, the NIMCP is piloting the use of environmental management and Insect Growth Regulators (IGRs) to reduce mosquito breeding sites and larva survival in Kigali. Depending on the results of the pilot program, USAID may want to consider supporting this intervention in addition to LLINs and IRS. In this way, USAID may be able to further the goal of "keeping down" malaria after the initial "knock-down" phase.

Larval treatment has been identified (among health workers mainly) as a method to be used to complement IRS in the very numerous humid areas of the targeted districts; the combination of both methods may lead to better results.

No Action

According to USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment*, the no action alternative will not be considered; the risks posed by IRS are acceptable to USAID in light of the risks posed by malaria.

#### The Preferred Alternative

#### Human Health and Environmental Effects of Preferred Alternative

The total population living in the five targeted districts is estimated to be 1,365,142 inhabitants (Bureau of Statistics 2006 figures) who are distributed as follows: Kirehe, in the eastern part of the country, hosts 256,767 people; Nyanza, in the south, counts 252,001; the three districts of Kigali city host 856,374 inhabitant with 358,647 people in Gasabo, 232,543 in Kicukiro and 265,184 in Nyarugenge. The total population of the country being 8,650,000 people, about 16% of the country will benefit from the protective impact of the IRS project.

This protection will reduce the incidence of adult morbidity, miscarriages, low birth-weight, and adverse effects on fetal neurodevelopment due to malaria, etc. It will also reduce incidence of malaria-related childhood anemia, complications, organ failure, and death. Also the negative socioeconomic impacts in terms of country's health budget and/or domestic expenses as mentioned above will be reduced.

Few to no adverse human health or environmental effects are anticipated as result of occupational, residential, and/or environmental exposure to lambda-cyhalothrin due to mitigation efforts. Although lambda-cyhalothrin belongs to one of the safer classes of pesticide (pyrethroids), attention needs to be paid to the negative environmental and health impacts these products may have when they are used under unsafe conditions. Indeed, from storage to

spraying, these chemicals may cause harm through accidental spills and acute poisonings among spray operators if handled improperly. Given the fact that the use of pesticides (even in agriculture) is still very limited in Rwanda, these aspects must be analysed in detail in addition to logistics management of spraying, in order to identify practical measures to be taken to limit negative health and environmental impacts at the lowest level. Training on safe management and storage of pesticides and the management of remaining stocks will be critical in the IRS campaign.

Effects from occupational exposure could include temporary skin and eye irritation, although personal protective equipment should minimize such irritation. It is possible that the impacts of residential exposure could include effects on the neurodevelopment of unborn fetuses, but further research is necessary to test this hypothesis (Berkowitz, et al. 2003). Further information on the impacts of lambda-cyhalothrin and proposed mitigation for those impacts is discussed in the *Pesticide Procedures* section.

The impact of the operation on water resources may be the most important environmental concern in the context of the targeted area; pollution from sprayer rinse-water (when spray cans are cleaned up) may pollute water resources, and the spray operations themselves may augment water scarcity due to the huge quantities of water required to conduct IRS operations.

#### AFFECTED ENVIRONMENT

The total population living in the five targeted districts is approximately 1,365,142 inhabitants. Details on these districts are given in Table 2 below.

Table 2: Areas and	Population of	targeted districts	,
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Districts	Surface	Perimeter	# Sectors	Estimated	Population
	(km <sup>2</sup> )	(km)		# Homes	
Kirehe	1,190.28	191.43	12	46,818	256,767
Nyanza	675.32	175.72	10	45,818	252,001
Gasabo	431.24	110.16	15	65,208	358,647
Kicukiro	167.50	82.34	10	42,280	232,543
Nyarugenge	134.59	106.31	10	48,215	265,184
	259,893	66,596	57	248,339	1,365,142

In general the districts include an urban, a peri-urban and a rural part with predominance of the latter in most of them. The peri-urban and rural areas include swamps springs, brick fabrication sites and other humid areas where cropping activities (rice fields mostly) take place; these are important breeding sites for the mosquitoes.

Access to safe drinking water is a major issue in Rwanda: for the country as a whole, only 2.9% are supplied by the national water company named Electrogaz. The most commonly used source of water is the public tap, where 38.6% of the population obtain supplies, while river water takes second place, accounting for 18.7%, and other sources of supply accounting for 0.4%. In rural areas, 41.7% of the population obtain water from a public fountain and 20.2% from a nearby

river, 16.9% fetch water from exploited springs and 9.3% from unexploited springs (Min Fin. & Econ. Planning, 2002). According to these figures, large proportions of households (primarily the poorest households) rely on using water from rivers and lakes: these aquatic resources should not be affected by the insecticide given proper implementation of program requirements detailed in this PERSUAP. The spraying will also use large quantities of water, so attention should be paid to the its impacts on local communities water supply.

#### **ENVIRONMENTAL CONSEQUENCES**

#### **Unavoidable Adverse Effects**

The risk of vehicle accidents and consequent insecticide spillage is always present. Such spillage could expose both humans and aquatic environments to lambda-cyhalothrin. It is also possible that the impacts of residential exposure could include neurological effects on unborn fetuses, but further research is necessary to test this hypothesis (Berkowitz, et al. 2003). This fetal exposure in the home would be an unavoidable risk of the IRS operation. Human inhalation of toxic fumes in the event of a storehouse fire is also an unavoidable risk, as the combustion products of lambda-cyhalothrin include formaldehyde, acrolein, hydrogen cyanide, hydrogen chloride and hydrogen fluoride (UK NPIS accessed 2006).

#### Irreversible or irretrievable commitments of resources

All financial costs of this program are irretrievable. It is important to note that, after implementation of this proposal, the targeted Rwandan districts would acquire new insecticide storage facilities and sprayers that could be used in future IRS interventions with chemicals or methods that have not undergone environmental review. The storage facilities will also contain barrels or tubs used for rinsing sprayers and cleaning overalls, face shields, gloves, and boots. If not secured, these barrels or tubs may be pilfered and used for drinking water or food storage.

#### **Environmental impacts of the proposed action**

The primary environmental risks include negative impacts on bee hives and contamination of aquatic ecosystems, which could have a transitory adverse effect on freshwater fish and invertebrate species. Training and supervision of spray personnel according to best practices should adequately address this risk.

#### Direct and indirect effects and their significance

#### **Direct Effects**

USAID will directly support the use of lambda-cyhalothrin for malaria vector control in Rwanda. This support will likely have few adverse human health and environmental effects, while providing protection against malaria to a maximum of 900,000 people. This protection will reduce the incidence of adult morbidity, miscarriages, low birth-weight, and adverse effects on

fetal neurodevelopment. It will also reduce incidence of malaria-related childhood anemia, complications, organ failure, and death.

#### **Indirect Effects**

Through this action, USAID will be providing the District Health Office with backpack compression sprayers. Upon completion of this program, USAID will no longer supervise the use of this capital. As a result, USAID may be indirectly supporting activities (e.g. use of other insecticides, space spraying) that have not undergone environmental review.

# Complementary and Conflicting Policies, Plans or Controls for the Areas under Consideration

On January 4, 2007 the Rwandan Minister of Land and Environment Christophe Bazivamo, State Minister for HIV/AIDS and other Infectious Diseases Dr. Innocent Nyaruhirira, and Rwandan Environmental Management Authority (REMA) Director General Rose Mukankomejeannounced that it would not approve the use of DDT in malaria control. As a result of this Rwandan Government policy decision, DDT use for IRS in Rwanda is not considered as an alternative in this PERSUAP.

The recent Rwandan Organic Environmental Law is being enforced by the Rwandan Environmental Management Authority (REMA). An extract of the law is provided in Annex 3. Article 67 of the Organic Environmental Law states that programs and policies that may affect the environment shall be subjected to environmental impact assessment, before obtaining authorisation for their implementation. The environmental impact assessment shall be examined and approved by the Rwanda Environmental Management Authority or any other person given a written authorisation by the Authority (Article 69); the required EIA report format is indicated in article 68. So as to comply with the environmental law some information the PERSUAP should be used to draft an EIA report the MOH will submit to REMA via the NIMCP. Apart from the Rwandan Organic Environmental Law, which is intended to prevent negative impacts related to the handling of pesticides, the introduction of pesticides in the country is prone to authorization delivered by the Ministry of Agriculture (MINAGRI) following the submission of a certificate of origin and a certificate of analysis of the active ingredient. REMA and MINAGRI are the main institutions involved in the regulation of the handling of chemicals in general.

IRS campaign should comply not only with the Rwandan Organic Environmental Law and MINAGRI authorization, but it should also comply with relevant international treaties. These include the Basel, Rotterdam, and Stockholm Conventions as well as any associated Rwandan implementation plans and strategies.

#### **USAID Pesticide Procedures, 22 CFR Part 216.3(b)**

#### A. The USEPA registration status of the requested pesticide

The registration status of lambda-cyhalothrin is summarized in Table 3.

 Table 3.
 Registration Status of Suggested Pesticide

Is the pesticide	Lambda-cyhalothrin
Registered by the host country (for public health use)?	YES
Registered by EPA for "same or similar use"?	YES
WHO-recommended?	YES

ICON WP has been approved for use in IRS by the Rwanda Bureau of Standards and REMA. Lambda-cyhalothrin is also registered for use indoors in the United States. According to the US Environmental Protection Agency, lambda-cyhalothrin is low to moderately toxic, not carcinogenic, readily breaks down in the environment, and does not bio-accumulate. It is also very highly toxic to many fish and aquatic invertebrate species. It is registered for use on the following residential non-food sites: general indoor/outdoor pest control (crack/crevice/spot), as termiticide, on ornamental plants and lawns around homes, parks, recreation areas and athletic fields, and on golf course turf (USEPA 1997). WHO classifies lambda-cyhalothrin as amoderately hazardous (class II) insecticide (WHO 2005b). Lambda-cyhalothrin is among the 12 pesticides WHO registered for IRS (WHO, 2004).

USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment* includes a human health risk assessment for IRS that indicates the levels of exposure for spray operators and residents are low. In the field, ICON® has caused skin and eye irritation in residents who return to their homes immediately after spraying. IEC campaigns, community mobilization, and supervisory activities must be designed to discourage the community from entering the household within two hours of spraying, inform the community of the risk of entering the household immediately after spraying, and educate the community any action that should be taken in the event of such irritation (e.g. wash with soap and water, go to nearby health facility if available for treatment).

Each sachet of ICON® 10WP contains 6.2 g active ingredient lambda-cyhalothrin, and can provide coverage for one or two houses, depending on the size of the household. Thus the total amount of active ingredient applied per household ranges from 3.0-6.5 g. Lambda-cyhalothrin is applied to the wall at a WHO-recommended concentration of 0.02-0.03 g/m².

#### B. The basis for selection of the requested pesticide

The chemicals used in IRS all have different properties and are more or less appropriate in different circumstances. The following threshold criteria must be met in making decisions on pesticides used in malaria vector control:

- o Pesticide registration in the host country
  - As described in Pesticide Procedures A, ICON WP is registered in Rwanda.
- Acceptability of the pesticide to the National Malaria Control Program
  - *ICON WP* is one of two pyrethroid pesticides currently considered for use by the PNILP.
- Risk to human health—pesticides must be approved by the WHO and should be preferred based on their safety as described in USAID's *Programmatic Environmental Assessment for Integrated Vector Management*.
  - Lambda-cyhalothrin is approved by WHO for use in IRS and, according to USAID's Integrated Vector Management for Malaria Vector Control:
     Programmatic Environmental Assessment, poses a low health risk to both spray operators and resident beneficiaries of the IRS program.
- o Risk to environment, livestock and/or agricultural trade
  - *The risk to the environment and livestock is acceptable (see* Pesticide Procedures G).

Beyond these four threshold considerations, technical and logistical factors must be addressed in comparing and selecting insecticides for malaria vector control. The primary factor to be addressed is:

- Vector resistance
  - Based on resistance tests conducted by the PNILP, Anophelene mosquitoes should be susceptible to lambda-cyhalothrin (see Pesticide Procedures F); vector susceptibility to pyrethroids will be routinely studied during the program.

#### Secondary factors include:

- o Appropriateness of surface for spraying
  - House types in the target communities have both plastered cement and traditional mud and thatch construction. Both types of construction are appropriate for use of ICON WP and subsequent efficacy for period of up to five months, based on data from Sharp et al. (1993); however, bioassays must be conducted during the malaria transmission season to determine whether this supposition is appropriate for Rwanda.
- o Duration of effectiveness (and implications for cost)
  - The malaria transmission season lasts from September to May; transmission is bimodal with peaks occurring in November and April. Using ICON, two spray rounds per year would be needed for effective transmission reduction through the peaks of both malaria seasons.
- o Cost of insecticide

■ The cost of ICON WP is approximately 5.85 USD per sachet (covering 250 square meters of wall), which is acceptable to all involved institutions.

#### Tertiary factors include:

- o The need for an insecticide of a different class to prevent resistance
  - Based on conversations with the Liverpool Associates in Tropical Health (LATH), the pesticide initially used in the start of an IRS program (e.g. first- and second-season spraying) should not put sufficient pressure on vector populations to promote resistance in the immediate subsequent spray rounds (e.g. third- and/or fourth-season spraying). Resistance management, however, is critical for all IRS programs. If IRS is to be continued in epidemic districts of Rwanda, a resistance management plan must be developed to ensure that IRS remains effective in perpetuity.
- o Major classes of insecticides used in other vector control interventions that could promote resistance
  - Current use of ITNs by target populations (pregnant women and children under five) has been fairly low in the past, and as of 2005 reached approximately 14%. Although ITN or LLIN use is expected to increase as a result of recent distribution campaigns, there is currently little risk that this intervention in combination with IRS will promote vector resistance to pyrethroids.
- Major classes of insecticides used in the agricultural sector that could promote resistance
  - Major classes of insecticides used in the agricultural sector that could promote resistance include pyrethroids and organophosphates. Pesticides are commonly used in agriculture in Rwanda.
- o Host-country capacity to prevent pilferage
  - Pilferage is not expected to be particularly problematic, as long as proper safeguards are put in place (e.g. proper storehouse management, sachet accounting, locked and guarded storage facilities). District leaders and program managers are expected to be responsive to the needs of the program in preventing pilferage, based on prior development experiences in the country.

# C. The extent to which the proposed pesticide use is part of an integrated vector management program

The IRS program will be integrated to the other components of the NIMCP it would complement and reinforce their positive impacts (PNLP, 2005). One of the three strategies of the malaria strategic plan is to scale-up the use of treated mosquito nets; the targeted aim being that at least 60% of people at risk – particularly U5 and pregnant women- benefit from the best combination

of individual and community prevention measures. The NIMCP, with the support in the health sector donors, promotes the use of ITNs and LLIN through:

- large scale IEC campaigns;
- involvement of public and private sectors as well as civil society (Associations, NGOs) in the distribution of treated mosquito nets
- training of field actors (district staff, health moderators, NGOs, local associations) on interpersonal communication and social marketing;
- to render the treated materials accessible and affordable by lowering their prices. The discount voucher scheme is then applied for vulnerable groups;
- promote the use of mosquito net pesticide kits for at least two years;

Also, sanitation action plans aimed at improving the environmental conditions so as to avoid mosquito breeding sites will be elaborated and implemented at district level. Such plans would include larviciding.

Total budget for the implementation of the strategy is US\$ 110,679,000; the promotion of prevention measures represents 36.2% of such an amount or US\$ 40,140,000 in which US\$ 33,687,454 (84% of the cost of prevention) is allowed to scaling up of treated mosquito nets.

# D. The proposed method or methods of application, including availability of appropriate application and safety equipment

The proposed method of application is Indoor Residual Spraying, or IRS. IRS is a commonly-used malaria vector control method that is particularly effective in preventing malaria epidemics. It is implemented by the application of residual insecticides, to which *Anopheles* female mosquitoes have been demonstrated to be susceptible, to the interior walls of houses and other structures. The insecticide remains on the treated surfaces upon which the mosquitoes will rest before or after taking a blood meal. Several formulations of insecticides are available for this purpose. The residual effect of the insecticide is sufficient to kill resting mosquitoes for a period ranging from three to twelve months depending on the insecticide, the surface on which it is applied, and local conditions. The objective of IRS programs is to reduce the mean life-span of the female mosquito population below the duration required for development of the parasite life phases that occur in the mosquito and, thereby, to substantially reduce the population's ability to sustain malaria transmission. IRS is most effective in areas with seasonal malaria transmission and is typically implemented by teams of spray operators who spray houses in at-risk localities prior to the rainy season, as heavy rains prompt increases in the *Anopheles* vector population. To be effective, IRS must attain coverage rates of at least 85% of the houses in a target area.

The spray operators who implement IRS use compression sprayers to apply a measured amount of insecticide on the interior walls of houses and structures. A water-soluble insecticide is added to the sprayer containing a pre-measured amount of water, the prayer is pressurized, and the material is then carefully applied to the interior walls of targeted homes and structures. After the day's spraying is complete, spray operators must clean the sprayer following the manufacturer's recommendations to ensure their proper operation and calibration.

The spray equipment used for IRS will be manufactured according to WHO specifications for compression sprayers for IRS operations. District Health Officers will determine mechanisms by which potential spray operators will be chosen; in a few sectors in Kigali City, military personnel may be used. Spray operators will initially be chosen based on their completion of primary school and their ability to read, write and make calculations. Pregnancy tests will be conducted to ensure pregnant women are not included on the spray teams.

These individuals recruited for IRS campaigns will receive intensive training on the use, operation, calibration and repair of the sprayer and practical exercises during a 14 day period prior to the beginning of the spraying campaign. They will also receive training to understand proper hygiene, to recognize the signs and symptoms of poisoning, and to understand the referral procedure for any incidents involving poisoning. This training will be conducted in accordance with WHO's "Manual for Indoor Residual Spraying" (WHO 2002). Potential spray operators must also pass written and practical tests at the end of training. In this way, spray operators will be prepared to conduct appropriate application of the insecticide.

Each spray team will consist of six or seven spray operators. Each spray operator will be provided with the following safety equipment, in accordance with WHO specifications:

- Overalls
- Broad-rimmed hat
- Face shield
- Dust mask
- Rubber gloves
- Rubber boots

Supervisors will observe two spray teams to ensure spraying occurs according to best practices. Supervisors will travel between spray teams and will observe spray operators and team leaders in the preparation, spray technique, and sprayer and PPE cleanup during the IRS campaign, as well as compile all data collected by their respective teams. Supervisors will receive training according to WHO best professional practices, and will also receive additional training on personnel management, environmental aspects, entomological monitoring, geographical reconnaissance, and data recording and analysis. After each day's spray activities, supervisors will collect sachet packing material to track the amount of insecticide used, and ensure that spray operators practice proper personal hygiene to avoid prolonged insecticide exposure. The insecticide is packaged in water-soluble sachets, minimizing pesticide exposure to spray operators during sprayer preparation.

Scrupulous attention to personal hygiene is an essential component of the safe use of pesticides. For spray operators, safety precautions will depend largely on personal hygiene, including washing and changing clothes. A drill for carrying out and supervising personal hygiene, regular washing of protective clothes and cleaning of equipment should be organized along the following lines (WHO 2006):

- Spraying staff should be provided with at least two uniforms to allow for frequent changes.
- Washing facilities with sufficient water and soap should be made available in the field at appropriate locations.

- All working clothes must be removed at the end of each day's operations and a shower or bath taken.
- Working clothes must be washed regularly, the frequency depending on the toxicity of the formulation used.
- Particular attention should be given to washing gloves, as wearing contaminated gloves can be more dangerous than not wearing gloves at all.
- Spray operators must wash before eating.
- Eating, drinking and smoking during work must be strictly forbidden.
- When work involves insecticides or relatively high toxicity, the hours of work must be arranged so that exposure to the material is not excessive; transport should be arranged so that there is not a long delay between the end of the day's operations and return to base for washing.

It is recommended that an overalls wash-person should be hired and provided with his/her own protective gear (e.g. apron and gloves). However, if hiring of such a person is not feasible, spray operators should wash their own overalls at a central location in tubs used exclusively for overall washing. Spray operators must also wash themselves after each day's operations. Spray operators should never wash themselves, their overalls, or their PPE in water bodies, and all wash-water should be disposed of in a concrete evaporation tank covered with a locked grate and/or latrine pits.

# E. Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use and measures available to minimize such hazards

For acute and long-term toxicological hazards, see the toxicological profile for lambda-cyhalothrin from USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment*, located in Annex 2.

Residential Exposure. The steps to mitigate, to the fullest extent possible, occupational exposure to pyrethroids are mentioned in the preceding section and described fully in the WHO's "Manual for Indoor Residual Spraying" (WHO 2002). However, as in all IRS operations, the risk of residential exposure is also present. District authorities and program staff will work with relevant boards, committees, and non-governmental organizations to carry out an IEC campaign to sensitize residents to IRS activities, in accordance with WHO guidelines. The IEC campaign (as well as IRS Program team leaders and supervisors will also instruct residents on best practices prior to spraying) should focus on the following elements of residential safety during an IRS program:

- clear homes of mats or rugs, furniture, cooking implements and foodstuffs prior to spraying
- if furniture cannot be moved out of the home, then move it to the center of the room if possible
- stay outside the home during spraying and for two to four hours after spraying
- move and keep all animals outside the home during spraying, and for two to four hours after spraying
- sweep floors free of any residual insecticide that may remain from the spraying

- do not replaster or paint over the sprayed walls after spraying
- keep using bednets for protection against malaria

The IEC component for IRS will coordinate closely with other PMI IEC initiatives.

<u>Pesticide Poisoning</u>. Training of doctors in pesticide poisoning treatment varies from hospital to hospital throughout Rwanda. In Gasabo District, Kibagabaga Hospital doctors have been trained in pesticide poisoning; however, activated charcoal is the only antidote available for pesticide poisoning treatment. In Nyarugenge District, Muhima Hospital and the Nyarugenge health centers refer poisoned patients to National University of Rwanda. Doctors in the Nyanza Hospital have not been trained in pesticide poisoning recognition and treatment. Hospital directors in Kicukiro and Kirehe could not be contacted for this assessment.

Training of clinicians in pesticide poisoning will not be needed for the three districts in Kigali City, as a referral system for poisoning cases has been established in the districts (and can likely be established in Kicukiro, if it has not been already). However, USAID will likely have to support the training of doctors in more rural districts such as Nyanza and Kirehe so that any incidents involving pesticide poisoning can be treated in an appropriate and timely fashion. USAID will provide any technical support necessary to achieve this end. The MOH will also distribute the six medicines necessary for diagnosing/treating symptoms of lambda-cyhalothrin to relevant health facilities, hospitals and health centers. These six medicines are the following:

- Topical vitamin E (tocopherol acetate) for dermal exposure
- Topical anaesthetic for ocular exposure
- Flourescein stain for ocular exposure
- Atropine for ingestion exposure
- Diazepam for ingestion exposure
- Phenytoin for ingestion exposure

<u>Safe Pesticide Transport</u>. Prior to long-distance transport of the insecticide from the customs warehouse/central storage facility to the District, drivers should be informed about general issues surrounding the insecticide and how to handle emergency situations (e.g. road accidents). Training for long-distance transport will include the following information:

- For what use the insecticide is intended
- Toxicity of the insecticide
- Understanding security issues, implications of the insecticide getting into the public
- Handling an accident or emergency (according to FAO standards)
- Combustibility and combustion byproducts of insecticide

Drivers hired specifically for the two-month spray campaign period will receive

- Training provided to spray operators (with the exception of sprayer operation and spray practice)
- Handling an accident or emergency (according to FAO standards)
- Handling vehicle contamination (see below)

Because vehicles will be rented for the program, it is important to ensure that pesticide contamination in the vehicle does not have negative impacts when the vehicle is subsequently

used for another purpose (e.g. food transport). Drivers will be responsible for taking care that any cloth vehicle seats are covered to prevent contamination from transportation of spray operators. To prevent pesticide runoff from vehicle washing, drivers will also be responsible for wiping the vehicle bed with a damp cloth prior to washing the exterior of the vehicle. Finally, drivers will be responsible for cleaning and decontaminating the interior of the vehicle and exterior bed at the end of the spray campaign. Drivers will be provided with gloves to wear for cleaning the vehicle. All cloths used in wiping down the interior and bed of the vehicle should be washed with spray operator overalls.

#### F. The effectiveness of the requested pesticide for the proposed use

Because large scale spray operations occur during a two-month period and the peak malaria transmission seasons in Rwanda last approximately three to four months after the start of the rainy season, the insecticide chosen must remain effective for at least five or six months. Studies conducted by Sharp et al. (1993) as well as Brutus et al. (2001) indicate that Icon can be effective on mud walls for at least five months. Additionally, lambda-cyahalothrin has been used in Rwanda in an IRS trial project and in malaria epidemics control projects involving BTC and NIMCP. Even if these operations were at small scale, the results of spraying indicate a satisfactory effectiveness of the pesticide. Thus, Icon is appropriate to protect the population throughout the malaria transmission season.

#### G. Compatibility of the proposed pesticide with target and nontarget ecosystems

<u>Outside Environment</u>. Lambda-cyhalothrin is toxic to bees, and fish and other aquatic organisms. Thus the primary concern in lambda-cyhalothrin use for IRS would be the following scenarios:

- Release of sprayer rinse-water into water bodies. Sprayer rinse-water should be reused for the next day's operations. If this is not logistically possible, supervisors and spray operators must be trained to dispose of sprayer rinse-water in pit latrines.
- Spray operators washing themselves, overalls and PPE in water bodies. Spray operators should wash themselves, and wash persons should wash overalls and PPE at the local or central meeting point for IRS operations. If this is not feasible, spray operators will be instructed to do the following:
  - o Never wash yourself, overalls or PPE in natural water bodies
  - Instead, collect water from the water source and wash yourself, overalls and PPE in an area far away from the water body
  - Dump excess water in a cement evaporation tank covered with a locked gate and/or latrine pit
  - o Thoroughly wash any washtubs that may be used with soap/detergent
- Accidental spraying of apiaries (beehives). Accidental spraying of apiaries would kill bees residing therein.

Use of lambda-cyhalothrin for IRS is not expected to adversely impact beehives for the following reasons:

- Lambda-cyhalothrin will be sprayed on the inside walls of houses where bees are unlikely to land (compared with use in agriculture, where bees may come into frequent contact with pesticides)
- o Bee hives are typically not present near or on sprayed homes.
- o Preliminary data from the International Union for Conservation of Nature and Natural Resources (IUCN) environmental monitoring in Uganda indicate that even beehives in close proximity to pesticide storage facilities, sprayer clean-up sites, and targeted households were not be affected by use of lambda-cyhalothrin.

The primary route of beehive contamination from IRS would likely be from insecticide residue contaminating implements used in collecting honey. Additional risk to the honey export market may exist from contamination of honey storage containers that were not removed from the household prior to spraying. The IEC campaign will address these issues and emphasize the importance of removing all household goods prior to spraying so that such contamination does not occur.

According to United States Code of Federal Regulations Title 22 Section 216, "to the extent feasible and relevant, projects and programs for which Environmental Impact Statements or Environmental Assessments have been prepared should be designed to include measurement of any changes in environmental quality, positive or negative, during their implementation." Monitoring of changes in environmental quality as a result of this IRS activity is not relevant for the following reasons:

- Lambda-cyhalothrin does not bioaccumulate or persist in the environment.
- Lambda-cyhalothrin will not be sprayed on agricultural fields or in the environment, and substantial releases of the pesticide into the environment as a result of project activities are improbable.
- Impacts of lambda-cyhalothrin on non-target organisms are acute and transitory.
- No area within the District has been defined as a national park or conservation area.

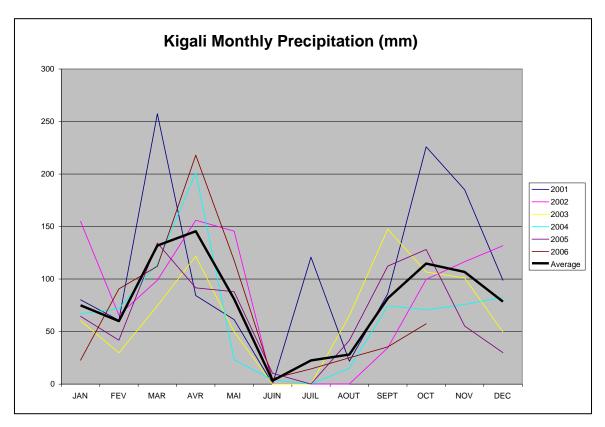
Monitoring should be considered, however, for pesticide residues in organic crops (see paragraph below). This type of monitoring should be discussed among stakeholders and can be carried out by the Tropical Pesticides Research Institute (TPRI).

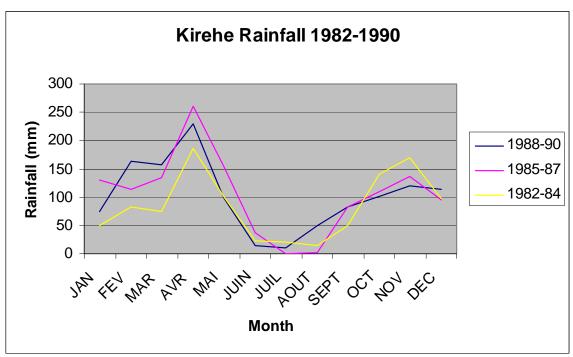
<u>Organic Crop Exports</u>. Lambda-cyhalothrin is expected to be compatible with households in the target districts.

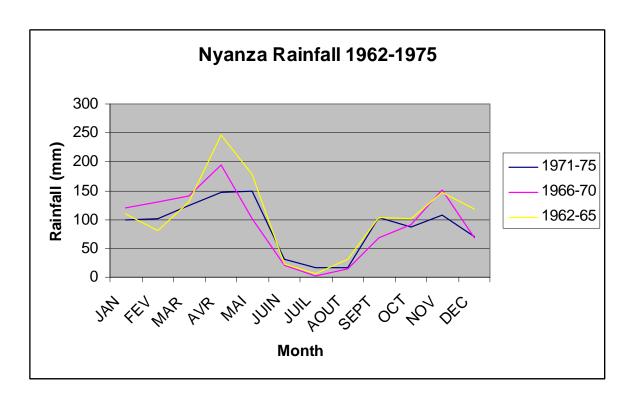
# H. The conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils

As previously indicated, Rwanda has two rainy seasons; the long rains last from September to

December and the short rains last from March to May. Yearly and average precipitation data for Kigali, Kirehe and Nyanza are illustrated in the graphs below.







Rwanda's national park system consists of Akagera National Park, Nyungue National Park, and Parc Nationale des Volcans. One of the target districts, Kirehe, borders Akagera National Park. The park covers over 2500 square kilometers of savannah west of the Kagera River, which denotes the frontier with Tanzania. Akagera National Park has a variety of wildlife and is a habitat for over 500 different species of birds (Great Lakes Safaris 2006). IRS will not take place in Akagera National Park, and any IRS activities surrounding the Park are not expected to negatively impact wildlife within the park due to the limited quantities of insecticide used, the extensive training of spray operators in responsible pesticide management, and the ephemeral and transitory nature of environmental impacts as a result of lambda-cyhalothrin exposure.

Busoro, Kibirizi, and Ntyazo sectors in Nyanza District border the wetland areas of Burundi Lake. Currently, no NGOs are doing conservation work in the district. NGOs in Nyanza are primarily active in the health and education sectors. 40% of Nyanza land is low altitude, 50% of the Nyanza land is plateau (1700 m above sea level), and less than 10% of Nyanza is composed of high mountains. IRS activities are not expected to negatively impact the wetland areas of Burundi lake due to the factors listed in the previous paragraph.

Ferrasols and Kastaznozems comprise the majority of Rwanda's soils. A soil map of Rwanda is included in Annex 4.

Every effort will be made to mitigate these potential environmental impacts, including:

• Securing storage areas to prevent pilferage.

- Supervision of spray teams to ensure proper insecticide handling and prevent pilferage.
- Counting used insecticide sachets to account for proper use of the insecticide.
- Re-use of sprayer rinse-water throughout the Program (if feasible).
- Triple-rinsing of any contaminated packaging prior to disposal.

## I. The availability and effectiveness of other pesticides or non-chemical control methods

ITNs and LLINs (using pyrethroids) are so far the predominant methods for vector control in Rwanda. Susceptibility tests performed recently (2002) on *A. gambiae* strains reveal their susceptibility to deltamethrin .05% with mortality rate comprised between 80% and 98%, indicating the effectiveness of ITNs and LLINs. The PNILP is beginning trials of environmental management combined with insect growth regulators to control malaria and other vector-borne diseases. Many stakeholders of the IRS project consulted for this PERSUAP suggested that larval treatment be considered as a method to be used to complement IRS in the districts hosting humid areas; they believe that the combination of both methods may lead to better results. Alternative insecticides that could be used for IRS include any other insecticides approved by WHO for IRS, provided that the vectors are not resistant to the insecticide and that the insecticide is effective on mud walls for at least five to six months.

# J. The requesting country's ability to regulate or control the distribution, storage, use and disposal of the requested pesticide

<u>Supply Chain</u>. Rwanda has substantial ability to control the distribution, storage, use and disposal of lambda-cyhalothrin. The supply chain of insecticide will be as follows:

```
Syngenta (Icon)

Customs (Icon)

Customs (Icon)

Camerwa Storage (Icon)

District Storage (Storekeeper and Supervisor) (Icon)

Spray Operators (spray operators must sign out all Icon received daily and return empty sachets at the end of the day)

District Storage (empties)

Camerwa Storage (empties)

Syngenta (empties)
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Distribution. Icon will primarily be stored at Camerwa (see below) with small quantities distributed to temporary storage facilities in the Kigali districts. With future expansion of the

program, it will be necessary to transport larger quantities of insecticide to district storage facilities.

Currently there is no safety training for drivers on insecticide transport. Drivers transporting insecticide will be trained according to the guidelines listed in *Pesticide Procedures E* of this document and USAID's *Integrated Vector Management for Malaria Vector Control: Programmatic Environmental Assessment*.

Storage. The central storage facility will be provided by Camerwa (Centrale d'Achats des Médicaments Essentiels du Rwanda or essential drugs purchasing group), which is well equipped and qualified to support the project in storing pesticides that will be used in Rwanda. The Camerwa storage facilities themselves will not need any additional renovation to suit environmental compliance requirements for the IRS program—in fact, Camerwa is already upgrading its storage facilities, which will provide increased capacity for IRS insecticide. The Camerwa facilities have the following components which are essential to insecticide storage according to the Food and Agriculture Organization of the United Nations:

- Secure
- Well-Ventilated
- Temperature Recorded
- Stock Records Well-Kept
- Stores Organized
- Impermeable Flooring
- Ability to separate medicine from insecticide storage (solid and grated wall sections)
- Offices kept separate from storage facility itself

The IRS program will need to make sure that Camerwa accommodates insecticide storage by acquiring equipment for emergencies (e.g. fire extinguisher, soap and clean water, eye wash set, full set of protective equipment, a shovel, broom, pan and container to use in case of spillage). Ideally, a grated sump and bunds should be installed in the area where insecticide is to be stored, in order to more easily contain the insecticide in the event of a spill. If any central storage facility is designated apart from Camerwa, the facility must also meet the standards outlined above and that have been set by Camerwa. Neither the Rwandan Government nor Camerwa have any formal guideline on the safe use of chemicals.

Temporary storage facilities will be identified for each district where IRS operates. District officials confirm the availability of warehouses that can be used to store the products and expressed willingness to support the project to that end. These temporary storage facilities must follow the minimum standards:

- Presence of a dedicated and trained storekeeper
- Thermometer installed/temperature recorded
- Insecticide stored separately from food and medicine
- Stock records up-to-date
- Facility double-padlocked and guarded
- Soap and clean water available at all times
- Shower/bathing facilities available for spray operators

<u>Disposal</u>. RTI will work with Crown Agents and Syngenta to negotiate a contract whereby empty Icon sachets will be returned to Syngenta for disposal.

#### K. The provisions made for training of users and applicators

Provisions made for training of users and applicators are described under *Pesticide Procedures D*. Training for spray operators and supervisors will be conducted over a 7 to 14 day period. Training will be conducted according to the WHO's "Manual for Indoor Residual Spraying" (WHO 2002).

#### L. The provisions made for monitoring the use and effectiveness of the pesticide

Monitoring Use. Monitoring appropriate use of the insecticide will be carried out in multiple ways. First, RTI will provide training to district environmental managers or other select authorities such that they are capable of evaluating the quality of spraying activities and associated environmental compliance actions within the program. RTI will work with USAID to determine appropriate funding and reporting mechanisms for these managers. RTI itself will also conduct an inspection to assess compliance with this PERSUAP and develop a plan of action to achieve complete compliance if deficiencies are found. RTI is already conducting inspections in IRS programs in Zambia, Uganda, Zanzibar, and Angola. Beyond the capacity building for environmental managers and the RTI inspection, the Chief of Party and other program staff will be responsible for documenting and reporting safety and environmental compliance issues to RTI to acquire technical assistance as needed and address compliance issues in a timely fashion. The objective of these activities is not only to ensure environmental compliance in the short term, but also to integrate safety and environmental standards into the program such that those standards carry forward beyond the timeframe for USAID support of IRS. An additional objective of these activities is to establish a Rwandan "checks and balances" system to ensure program quality.

Results of environmental compliance monitoring and subsequent mitigation activities from these three sources—district environmental managers, RTI environmental compliance staff, and Rwanda program staff—will be summarized in each final project report submitted to USAID. Finally, USAID's Automated Directives System (ADS) 204.5.4 requires that the Strategic Objective (SO) team actively monitor ongoing activities for compliance with the recommendations in this PERSUAP, and modify or end activities that are not in compliance.

Monitoring Effectiveness. The primary function of entomological monitoring associated with vector management is to assure that interventions are effective. Such monitoring is essential for IRS and larval control and, though not as critical, should also be implemented in areas where only ITNs have been deployed. The monitoring program must include at least the first two types of tests described below; the third category should also be included when possible.

- Determine vector susceptibility to available insecticides. Susceptibility studies detect the presence of individuals in the vector population that are physiologically resistant to the insecticide being tested. For IRS, susceptibility studies can be carried out using WHO test strips or CDC bottle assays on wild-caught adults or adults reared from immatures. While the CDC bottle assays have the advantage of testing a sample of the same chemical batch being applied, the WHO test strips enable more comparability across countries and time. Where possible, both should be done. Larvicides are generally tested for efficacy in small-scale field trials. In addition to the above "in vivo" resistance information, it is also possible to collect large numbers of the vector species for analysis by polymerase chain reaction (PCR) to determine the frequency of genetic markers coding for pesticide resistance in the local vector population.
- Verify that the insecticide was applied properly and had an immediate effect. This involves routine follow-up observations. For IRS, wall bioassays are used to verify there is sufficient residual pesticide on the walls of sampled structures to kill vector mosquitoes, and to monitor the loss of residual efficacy over time. A analogous assay may be done for ITNs, either with the same type of cone used on the wall, or by forming a "basket" with the treated netting. For larviciding, routine inspection of treated breeding sites will verify that mosquito larvae are no longer present immediately after larvicide treatment and will detect new larvae when they are present.
- Measure the impact of the intervention on the vector population and/or malaria transmission intensity. Several different techniques are used to monitor the vector population and/or the frequency and infectivity of vector biting. In general, the intention is to determine whether the vector management program has substantially reduced the vector population or survivorship, as indicated either by a reduction in the number of mosquitoes that can be collected, a reduction in mosquito biting, or, as detected through mosquito dissections, the proportion parous (the proportion that have laid at least one batch of eggs). Methods are available for human landing catches, CDC light traps, cattlebaited hut or net collections, non-baited hut or net collections, pyrethrum spray catches (PSCs), and window exit traps.

#### PREPARATION METHODOLOGY

The contents of this PERSUAP are based on direct communication with the National Malaria Control Program, the Rwanda Environmental Management Authority (REMA), the Ministry of Agriculture (MINAGRI), Balton CP, UNICEF, Camerwa, Belgian Technical Cooperation (BTC), Tulane University, MINITERE, MINALOC, Rwanda Bureau of Statistics, Rwanda Meteorological Services, and elected and appointed officials from Nyarugenge, Gasabo, Kicukiro, Kirehe and Nyanza districts. The individuals employed by these entities graciously provided information on pesticide and vector control practices to a three-person team consisting of:

Ms. Melanie Biscoe RTI International

Mr. Samba Yade RTI International (consultant)

Mr. Joaquim Canelas RTI International

Additionally, government documents concerning pesticide use, the environment, and malaria control were reviewed and incorporated into this PERSUAP. Research for this PERSUAP was conducted over a period from December 4-17, 2006.

#### **OTHER SECTIONS**

The following sections are typically included in an EA, but are not applicable in this circumstance:

 Relationship between short-term uses of the environment and maintenance/enhancement of long-term productivity

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## **ANNEX 1: IRS Campaign Oversight Checklist**

Activity	Best Practice	Best		Corrective
		Practices		Action Taken
Haves Drangustian	Francisco Marcad	Follo		
House Preparation	Furniture Moved Foodstuffs/Utensils not moved	Yes	No	
		Yes	No	
PPE Worn	Cloth covering furniture	Yes	No	
PPE Worn	Hat Gloves	Yes Yes	No	
	Facemask		No	
		Yes	No	
	Overalls	Yes	No	
<b>.</b>	Boots	Yes	No	
Personal Hygiene	No eating/chewing	Yes	No	
	No drinking	Yes	No	
	No smoking	Yes	No	
	No wiping part of body with contaminated clothing	Yes	No	
	No touching nozzle to mouth	Yes	No	
Sprayer Calibrated		Yes	No	
Spraying	Correct distance from wall	Yes	No	
	Correct rhythm	Yes	No	
	Proper surface sprayed	Yes	No	
	Gaps in sprayable surface	Yes	No	
Maintenance of Sprayers	Body rinsed (progressive rinse)	Yes	No	
•	Nozzle rinsed (progressive rinse)	Yes	No	
	Nozzle does not need replacing	Yes	No	
	Filter/strainer cleaned	Yes	No	
	Filter present	Yes	No	
	Hose not worn	Yes	No	
	Hose connection tight	Yes	No	
	Trigger operation smooth	Yes	No	
	Seal or washer condition good	Yes	No	
	No leaks	Yes	No	
	Trigger valve/pressure release valve	Yes	No	
Wash-up		Yes	No	
Storage Facility	Orderly	Yes	No	
	Double-padlocked	Yes	No	
	Guarded	Yes	No	
	No spills or leaks	Yes	No	
	Stock record sheet up-to-date	Yes	No	
	Emergency equipment present	Yes	No	
Decontamination/ Disposal	Progressive rinse or decontamination/latrine disposal	Yes	No	(If no, was the water dumped in latrine or body of water?)

# ANNEX 2: Toxicological Profile for Lambda-Cyhalothrin, *PEA for IVM*

### **Chemical History**

The synthetic pyrethroid lambda-cyhalothrin is a relatively new addition to this insecticide group. It was developed in 1977 and consists of one enantiomeric (i.e., nonsuperimposable, mirror image) pair of isomers and is a more biologically active form than cyhalothrin (IPCS, 1990a). It is used in the control of pests, including mosquitoes, in agricultural and public and animal health settings (EXTOXNET, 1996). The risks of occupational exposures and exposures to the general public are expected to be very low if proper precautions are followed. At the recommended application rates, lambda-cyhalothrin is not expected to cause adverse environmental effects. As is typical of synthetic pyrethroids, the typical symptoms for acute exposure are neurological and include tingling, burning, or numbness sensations (particularly at the point of skin contact), tremors, incoordination of movements, paralysis or other disrupted motor functions. These effects are generally reversible because lambda-cyhalothrin beaks down rapidly in the body (IPCS, 1990a; EXTOXNET, 1996).

### **Description of Data Quality and Quantity**

Lambda-cyhalothrin and cyhalothrin are basically the same chemical and differ only in their stereo chemistry and the number of isomers in each mixture (U.S. EPA, 2002a). Cyhalothrin consists of four stereo isomers while lambda-cyhalothrin is a mixture of only two isomers. The two lambda-cyhalothrin isomers are contained in cyhalothrin and they represent 40 percent of the cyhalothrin mixture. The majority of toxicity studies available were conducted using cyhalothrin as the test chemical. Evidence based on subchronic studies in rats suggests that the two mixtures are not biologically different with respect to their mammalian toxicity (U.S. EPA, 2002a).

EPA and ATSDR have developed quantitative human health benchmarks for cyhalothrin (EPA's acute and chronic oral RfDs and short-, intermediate-, and long-term dermal and inhalation benchmarks, and ATSDR's acute and subchronic oral MRLs).

### Recommended resources include:

Environmental Health Criteria 99: Cyhalothrin (IPCS, 1990a)

Toxicological Profile for Pyrethrin and Pyrethroids (ATSDR, 2003a)

Pesticide Information Profiles (PIP) for Lambda-cyhalothrin (EXTOXNET, 1996)

Specifications and Evaluations for Public Health Pesticides for Lambda-cyhalothrin (WHO, 2003)

Integrated Risk Information System (IRIS) summary review for cyhalothrin (U.S. EPA, 2005a).

### **Summary Table**

Duration	Route	Benchmark Value	Units	Endpoint	Reference
Acute, Subchronic, Chronic	Inhalation	0.0008	mg/kg/day	Inhalation NOAEL for neurotoxicity in rats at 0.08 mg/kg/day (0.3 µg/L) with uncertainty factor (UF) of 100 applied	U.S. EPA (2002a)
Acute	Oral	0.005	mg/kg/day	Acute RfD based on neurotoxicity in dogs	U.S. EPA (2002a)
Subchronic	Oral	0.001	mg/kg/day	Adopt chronic RfD for subchronic duration	
Chronic	Oral	0.001	mg/kg/day	Chronic RfD based on neurological effects in dogs	U.S. EPA (2002a)
Acute, Subchronic, Chronic	Dermal	0.1	mg/kg/day	Dermal NOAEL in rats with UF of 100 applied	U.S. EPA (2002a)

For inhalation exposure, a NOAEL of  $0.3~\mu g/L$  (0.08~mg/kg/day) was identified for neurotoxicity, decreased body weight, and slight changes in urinalysis parameters in rats exposed to lambda-cyhalothrin via inhalation for 21 days. An uncertainty factor of 100 was applied, for an inhalation benchmark value of 0.0008~mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 2002a).

For oral exposure, an acute RfD of 0.005 mg/kg/day was derived based on a NOAEL of 0.5 mg/kg/day for neurotoxicity (ataxia) observed in dogs exposed to lambda-cyhalothrin, with an uncertainty factor of 100 applied (U.S. EPA, 2002a). A chronic oral RfD of 0.001 mg/kg/day was derived based on a NOAEL of 0.1 mg/kg/day for gait abnormalities in dogs exposed to lambda-cyhalothrin, with an uncertainty factor of 100 applied (U.S. EPA, 2002a). The chronic RfD was adopted to represent subchronic exposures.

For dermal exposure, a NOAEL of 10 mg/kg/day was identified in rats dermally exposed to lambda-cyhalothrin for 21 days. An uncertainty factor of 100 was applied, for a dermal benchmark value of 0.1 mg/kg/day. This value is appropriate for all exposure durations (U.S. EPA, 2002a).

### **Insecticide Background**

CAS #: 91465-08-6

Synonyms: none (WHO, 2003)

Chemical Group: synthetic pyrethroid

Registered Trade Names: Charge, Excaliber, Grenade, Karate, Hallmark, Icon, OMS 0321,

PP321, Saber, Samurai, Sentinel, and Matador (EXTOXNET, 1996)

### **Usage**

Lambda-cyhalothrin is a synthetic pyrethroid (IPCS, 1990a) most commonly used for pest control, especially mosquitoes; the insecticide is usually sprayed on interior walls or used to impregnate bed nets (EXTOXNET, 1996). This insecticide is a restricted use pesticide, so it can be purchased and used only by certified applicators (EXTOXNET, 1996). Lambda-cyhalothrin has adulticidal, ovicidal, and larvicidal activity (IPCS, 1990a). In addition to mosquitoes, it is effectively used to control: cockroaches, ticks, fleas, aphids, Colorado beetles, cutworms and butterfly larvae (EXTOXNET, 1996; IPCS, 1990a).

### **Formulations and Concentrations**

There are several formulations for lambda-cyhalothrin, each containing varying amounts of the active ingredient. The typical formulations for lambda-cyhalothrin are

Technical grade (not less than 810 g/kg lambda-cyhalothrin)

Emulsifiable concentrate (at 20 +/-  $2^{\circ}$ C: up to 25 g/l +/- 15% declared content; > 25 g/l to 100 g/l +/- 10% of declared content)

Wettable powder (up to 25 +/- 15% of declared content: > 25-100 +/- 10 % of declared content)

Slow release capsule suspension (at 20 +/- 2°C: up to 25 g/l +/- 15% declared content).

The main formulation used for agricultural purposes is the emulsifiable concentrate. The wettable powder formulation is mainly used for public health reasons (WHO, 2003). Lambda-cyhalothrin is commonly mixed with buprofezin, pirimicarb, dimethoate, or tetramethrin, resulting in the usual product (WHO, 2003; EXTOXNET, 1996).

### **Shelf-Life**

This insecticide, like many others, needs to be stored in a cool, dry, and well-ventilated facility (IPCS, 1990a). Lambda-cyhalothrin should not be stored or transported with foodstuffs and household supplies to the limit the potential for cross contamination and human exposure (IPCS, 1990a).

### **Degradation Products**

In the environment, lambda-cyhalothrin degrades through biological and photochemical reactions (IPCS, 1990a). Biological reactions are thought to be more important. Lambda-cyhalothrin will degrade rapidly in soils, remain relatively stable in water, and is usually not found in air due to its low vapor pressure. The main degradation products are 3-(2-chloro-3,3,3-trifluoroprop-1-enyl)-2, 2-dimenthyl-cyclopropanecorboxylic acid, the amide derivative of cyhalothrin, and 3-phenoxybenzoic acid. The degradation is a result of the cleavage of the ester linkage to give two main degradation products, which are further degraded to carbon dioxide. Lambda-cyhalothrin degrades fairly quickly in alkaline conditions, in comparison to neutral or

acidic media. It is strongly absorbed in soils and sediments with little tendency for bioaccumulation (IPCS, 1990a).

In water, lambda-cyhalothrin is stable at pH 5. Racemization at the alpha-cyano carbon occurs at pH 7 to pH 9, creating a one to one mixture of enantiomer pairs A and B. The ester bond is hydrolysed at pH 9. Additionally, a moderately high rate of photolysis is seen in dilute aqueous solutions (IPCS, 1990a).

### **Environmental Behavior**

### **Fate and Transport in Terrestrial Systems**

In most soil types, lambda-cyhalothrin is not very mobile. Its high reported organic carbon partitioning coefficient (Koc) value reflects its strong affinity for soil. It is retained more in soil with low sand content or high organic matter content (EXTOXNET, 1996). Studies have shown that lambda-cyhalothrin and its degradation products do not leach through soils into groundwater nor are they transported to other compartments of the environment following agricultural uses (IPCS, 1990a).

Lambda-cyhalothrin is moderately persistent in soil with a soil half-life ranging from 4 to 12 weeks. A longer in-field half-life of approximately 30 days is reported for most soils (EXTOXNET, 1996). The half-life is variable because it is dependent on the availability of sunlight, which speeds degradation (IPCS, 1990a).

### **Fate and Transport in Aquatic Systems**

Lambda-cyhalothrin is not expected to be prevalent in surface or groundwater because it has extremely low water solubility and binds tightly to soil. Lambda-cyhalothrin enters surface water largely through surface runoff. Even so, lambda-cyhalothrin is most likely to stay bound to sediment and settle to the bottom. Studies have shown that hydrolysis of lambda-cyhalothrin occurs rapidly at a pH of 9 but not at a pH of 7, though isomerization was observed at a pH of 7. No hydrolysis or isomerization was seen at a pH of 5.

### **Human Health Effects**

### **Acute Exposure**

### Effects/Symptoms

No data on accidental human poisonings have been reported. Additionally, no quantitative epidemiological studies are available (IPCS, 1990a). However, under normal use conditions, acute exposure to lambda-cyhalothrin is not expected to represent a hazard in humans. Transient skin sensations such as periorbital facial tingling and burning have been reported following direct skin exposure in laboratory workers and manufacturing workers handling synthetic pyrethroids. This sensation is possibly due to repetitive firing of sensory nerve terminals and usually lasts for a few hours up to 72 hours post-exposure. No neurological abnormalities have been observed upon medical examination (IPCS, 1990a). Lambda-cyhalothrin can irritate the

eyes, skin, and upper respiratory tract. Additionally, oral exposure can cause neurological effects, including tremors and convulsions. Ingestion of liquid formulations may result in aspiration of the solvent into the lungs, resulting in chemical pneumonitis. Based on the acute oral toxicity data, lambda-cyhalothrin has been classified as "Moderately Hazardous" (Class II) (WHO, 2003).

In animals, the technical form of lambda-cyhalothrin is moderately toxic; however, toxicity depends on both the formulation (concentration of active ingredient and solvent vehicle) and the route of exposure (EXTOXNET, 1996). Laboratory data indicate that acute oral exposure to lambda-cyhalothrin is moderately to highly toxic in rats and mice and that mice are more susceptible to the toxic effects than rats (WHO, 2003). The oral LD<sub>50</sub> for lambda-cyhalothrin in corn oil has been reported to range from 56 mg/kg in female rats up to 79 mg/kg in males. A similar LD<sub>50</sub> is reported for technical grade lambda-cyhalothrin in rats at 64 mg/kg (EXTOXNET, 1996). The oral LD<sub>50</sub> in mice is reported as 20 mg/kg (IPCS, 1990a). The effects of acute oral exposure are typical of pyrethroid toxicity, including abnormal motor function (WHO, 2003).

Acute inhalation exposures are also highly toxic to animals (WHO, 2003). In the formulated product Karate, the 4-hour LC<sub>50</sub> in rats is reported as 0.175 mg/L in females and 0.315 mg/L in males (EXTOXNET, 1996).

Lambda-cyhalothrin is less toxic in animals via acute dermal exposure (WHO, 2003). In rats, dermal LD $_{50}$ s of 632 mg/kg for males and 696 mg/kg for females have been reported for the technical product. Studies have also shown the technical product produced no skin irritation to rabbits and is nonsensitizing in guinea pigs. Mild eye irritation was observed in rabbits. However, dermal exposure to the formulated product Karate causes severe primary skin irritation in rabbits and mild skin sensitization in guinea pigs. Other acute dermal effects are related to the nervous system and include tingling, burning sensations, or numbness (EXTOXNET, 1996).

#### **Treatment**

Lambda-cyhalothrin and its breakdown products can be detected in blood and urine, but only within a few days of the last exposure (ATSDR, 2003a). Dermal exposure to lambda-cyhalothrin exposure should be treated by removing contaminated clothing and washing the exposed areas with soap and water. If lambda-cyhalothrin gets into the eyes, they should be rinsed with water for several minutes. Contact lenses should be removed if possible and medical attention should be sought. Vomiting should not be induced following ingestion of lambda-cyhalothrin, and medical attention sought. Inhalation exposures require removal to fresh air and rest (IPCS, 1990b)

### **Chronic Exposure**

### Noncancer Endpoints

Based on the available data, it is unlikely that lambda-cyhalothrin would cause chronic effects in humans under normal conditions. No specific target organs have been identified in the available

chronic studies (EXTOXNET, 1996). Decreased body weight gain and mild neurological effects have been observed in some animal studies (EXTOXNET, 1996; IPCS, 1990a).

Lambda-cyhalothrin is not expected to be teratogenic, mutagenic, or genotoxic in humans. Studies in animals have found no teratogenic or fetotoxic effects in rats or rabbits. Additionally, it was negative in five test strains in the Ames mutagenicity assay (IPCS, 1990a). No mutagenic or genotoxic effects were seen in other in vitro cytogenic assays or chromosomal aberration tests (EXTOXNET, 1996).

### Cancer Endpoints

Data on the carcinogenic potential suggest that lambda-cyhalothrin is not carcinogenic in humans. In rats and mice exposed to cyhalothrin, no carcinogenic effects were observed. EPA has classified lambda-cyhalothrin as a Group D chemical, "not classifiable as to human carcinogenicity" (U.S. EPA, 2002a).

#### **Toxicokinetics**

Animal studies have been have been conducted in various species to investigate the toxicokinetics of cyhalothrin and lambda-cyhalothrin. Oral cyhalothrin is readily absorbed, metabolized thoroughly, and eliminated as polar conjugates in the urine (IPCS, 1990a). Studies with lambda-cyhalothrin have shown that it also is rapidly metabolized into less toxic water-soluble compounds and excreted in the urine and feces (EXTOXNET, 1996). In mammals, cyhalothrin is metabolized as a result of ester cleavage to cyclopropanecarboxylic acid and 3-phenoxybenzoic acid, and eliminated as conjugates. Tissue levels decline after exposure stops and residues in the body are low (IPCS, 1990a).

### **Ecological Effects**

### **Acute Exposure**

### Toxicity to Non-Target Terrestrial Organisms

Like other synthetic pyrethroids, lambda-cyhalothrin has been shown to be toxic to honey bees but has little effect on birds and domestic animals (EXTOXNET, 1996). In birds, the toxicity of lambda-cyhalothrin ranges from nontoxic to slightly toxic. Oral LD<sub>50</sub> values in mallard duck are reported as greater than 3,950 mg/kg. Dietary LC<sub>50</sub> values of 5,300 ppm are reported in bobwhite quail. Additionally, there is no evidence of lambda-cyhalothrin accumulation in bird tissues or in eggs (EXTOXNET, 1996). Lambda-cyhalothrin has shown mixed toxicity to other non-target terrestrial organisms. It is extremely toxic to honey bees, with a contact LD<sub>50</sub> of 0.9  $\mu$ g/bee and an oral LD<sub>50</sub> of 38 ng/bee (EXTOXNET, 1996), but has no adverse effect on earthworms (IPCS, 1990a).

### Toxicity to Aquatic Organisms

Like other synthetic pyrethroids, lambda-cyhalothrin has been shown to be quite toxic under laboratory conditions to both cold and warm water fish. Acute 96-hr  $LC_{50}$  values range from 0.2 to 1.3  $\mu$ g/L. It is also highly toxic to aquatic arthropods with 48-hr  $LC_{50}$  ranging from 0.008 to

 $0.4~\mu g/L$  (IPCS, 1990a; WHO, 2003). In the field, however, these effects are not likely to occur under the recommended use scenarios (WHO, 2003). No serious adverse effects have been observed due to the low rates of application and the lack of persistence in the environments (IPCS, 1990a). Accumulation studies have shown that although bioaccumulation is possible in fish, it is unlikely due to the rapid metabolism of lambda-cyhalothrin (EXTOXNET, 1996).

### **Chronic Exposure**

### Toxicity to Non-Target Terrestrial Organisms

No data were located on the chronic toxicity to non-target terrestrial organisms.

### Toxicity to Aquatic Organisms

No data for chronic duration exposures of aquatic organisms were located; however, a subchronic study in Sheepshead minnow embryos and larvae showed no effect on hatchability or larval survival when exposed to up to  $0.25~\mu g/L$  through 28 days post hatching. A significant effect on larval weight was observed at  $0.38~\mu g/L$ . In an additional subchronic exposure study, survival, growth, and reproduction of *Daphnia magna* were seen at 40 ng/L but not at 2.5~ng/L (IPCS, 1990a).

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### **ANNEX 3:** National Organic Law

#### **GENERAL**

**Article 32:** No one is permitted to dispose waste in an inappropriate place, except where it is destroyed from or in a treatment plant and after being approved by competent authorities.

**Article 33:** Any waste<sup>1</sup>, especially from hospitals, dispensaries and clinics, industries and any other dangerous waste, shall be collected, treated and changed in a manner that does not degrade the environment in order to prevent, eliminate or reduce their adverse effects on human health, natural resources, flora and fauna and on the nature of the environment.

### Article 51: The State shall establish:

- 1° measures to control soil erosion;
- 2° measures to control soil pollution by chemical substances, fertilisers, medicines and others which are allowed to be used:
- 3° measures to prevent diffusion of soil pollution as well as concrete measures to rehabilitate degraded soils;
- 4° measures to protect and reserve catchment areas around wells from where drinking water is drawn.

### **Article 54:** The State shall establish the list of following:

1° species of animals and plants that shall be protected depending on their role in ecosystems, their scarcity, their aesthetic value, their extinction as well as their economic, cultural and scientific role. The list shall be established by an order of the Minister having environment in his or her attributions;

2° historical sites ....

**Hazardous wastes** are any substances whether solid, liquid or gaseous that causes a serious harm to human health, security and other biodiversity together with the quality of the environment.

<sup>&</sup>lt;sup>1</sup> **Waste** is any substance whether solid, liquid or gaseous resulting from household activities, from manufacturing plants or any abandoned movable or immovable property, and which may be harmful.

**Article 60:** Generally, <u>decentralised entities</u> are responsible for the implementation of laws, policies, strategies, objectives and programmes relating to protection, conservation and promotion of the environment in Rwanda.

**Article 64:** The <u>population</u> has the obligation to conserve the environment by individual action or through collective activities, associations of the environment, in preparing green spaces and reserved areas and other activities that promote environment.

Article 65: In the framework of implementation of this organic law, there is hereby established:

1° the Rwanda Environment Management Authority abbreviated in English as "REMA", a public establishment with legal personality and shall enjoy financial and administrative autonomy;

2° the National Fund for Environment in Rwanda, abbreviated as "FONERWA" in French, which is responsible for soliciting and managing financial resources.

The organisation, functioning and their responsibilities shall be determined by specific laws.

**Article 66:** There is hereby established <u>committees</u> responsible for conservation and protecting the environment at the Provincial, City of Kigali, District, Town, Municipality, Sector and the Cell levels.

The organisation, functioning and their responsibilities are determined by Prime Minister's Order.

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EIA

**Article 67:** Every project shall be subjected to <u>environmental impact assessment</u>, before obtaining authorisation for its implementation. This applies to *programmes and policies that may affect the environment*. An order of the Minister having environment in his or her attributions shall determine the list of projects mentioned in this organic law.

Article 68: The environmental impact assessment shall at least indicate the following:

1° a brief description of the project and its variants;

2° a study of direct or indirect projected effects on a place;

3° analysis relating to the initial state of a place;

4° measures envisaged to reduce, prevent or compensate for the damage;

5° reasons based on in selecting such a place;

6° a brief description of points from 1° to 5° of this article;

7° an explanation of the methods that will be used in monitoring and evaluating the state of the environment before, during the activities of the project, in using the installation but particularly after completion of the project;

8° an estimation of the cost of the measures recommended to prevent, reduce or compensate for the negative effects the project may cause on the environment as well as the measures for examining and controlling the status of the environment.

An order of the Minister having environment in his or her attributions shall specify the details of the provisions of this article.

**Article 69:** The environmental impact assessment shall be examined and approved by the Rwanda Environmental Management Authority or any other person given a written authorisation by the Authority. The promoter pays a levy reduced from the operating cost of his or her project excluding the working capital. This tax is determined by the law establishing the National Fund for the Environment. The environment impact assessment shall be carried out at the expense of the promoter.

**Article 70:** An order of the Minister having environment in his or her attributions establishes and revises the list of planned works, activities and projects, and of which the public administration shall not warrant the certificate, approve or authorise without an environmental impact assessment of the project. The environmental impact assessment shall describe direct and indirect consequences on the environment.

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#### PREVENTIVE AND PUNITIVE PROVISIONS

**Article 81**: The following are prohibited:

1° dumping or disposal of any solid, liquid waste or hazardous gaseous substances in a stream,

river, lake and in their surroundings;

2° damaging the quality of air and of the surface or underground water;

3° ....

**Article 82:** It is prohibited to dump any substances, in any place, which may:

1° destroy sites and buildings of scientific, cultural, tourist or historic interest;
2° kill and destroy flora and fauna;
3° endanger the health of biodiversity;
4° ...

#### **Article 83:** It is prohibited to dump in wetlands:

1° waste water, except after treatment in accordance with instructions that govern it;

2° any hazardous waste before its treatment;

Any activity that may damage the quality of water is prohibited.

### Article 88: It is prohibited:

- 1° to dump, make flow, dispose of and store any substance in a place where it may cause or facilitate water pollution on the national territory;
- 2° to use natural resources in a degrading and illegal manner;
- 3° release into the atmosphere poisonous gases, smoke, waste, soot, dust and any other chemical substances in an illegal manner.

**Article 89:** In accordance with regulations provided for by International Conventions signed and ratified by Rwanda, it is prohibited to dump, eliminate, immerse any chemical substance in water and in any other place where it may:

- 1° threaten general public health and biological resources;
- 2° harm navigation, fishing and others;
- 3° deteriorate the beauty of a place which is potential for its aquatic tourist interest.

### **Article 90:** It is prohibited:

1° to pile waste on unauthorised public places including public lands defined by law;

2° to import waste in the country;

3° to immerse burn or eliminate waste in wetlands by any process without respecting rules applied in Rwanda.

**Article 91:** Acts related to purchase, sale, import, export, transit, store and pile chemicals, diversity of chemicals and other polluting or dangerous substances are prohibited in the whole country. An order of the Prime Minister determines a list of chemicals and other polluting substances that are not permitted.

**Article 92:** It is prohibited to sell, import, export, store ordinary drugs or chemical substances with intention to sell or distribute even if it is free of charge except authorisation or temporary permission is issued by competent authorities.

An order of Prime Minister shall determine a list of prohibited drugs mentioned in this article.

#### **Article 93:** It is prohibited:

1° to use explosives, drugs, poisonous chemicals and baits in water that may intoxicate or even kill fish;

 $2^{\circ}$  to use drugs, poisonous chemical substances and baits that may kill wild animals and which may render them unfit for consumption.

### **Article 94:** It is prohibited:

1° to kill injure and capture animals of the endangered species;

2° to destroy or damage habitats, larvae, pupae and the young animals of the endangered species;

3° to cause death, destroy protected plants, harvest and tear them a part;

4° to transport or sale the remains of a whole or part of an animal as well as plants of the protected species;

5° to fell trees in forests and protected areas and in national parks.

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**Article 95:** Any one or association that does not carry out environmental impact assessment prior to launching any project that may have harmful effects on the environment is punished by suspension of his or her activities and closure of his or her association and without prejudice to be ordered to rehabilitate the damaged property, the environment, people and the property.

Falsification and alteration of documents of environmental impact assessment is punished in the same manner as what is provided for in paragraph one of this article.

**Article 102:** Any one who dumps in unaccepted manner or without authourisation any waste that is subject to prior authorisation provided for by this organic law is punished by a fine ranging from one million Rwandan francs (1,000,000) to five million (5,000,000) Rwandan francs and an imprisonment ranging from six (6) months to two (2) years or one of these two penalties.

**Article 103:** Any one who pollutes inland water masses by dumping, spilling or depositing chemicals of any nature that may cause or increase water pollution is punished by a fine ranging from two million (2,000,000) to five million (5,000,000) Rwandan francs and an imprisonment ranging from two (2) months to two (2) years or one of these penalties.

In case of recidivism, such a penalty is doubled. The offender may be required to rehabilitate the polluted place.

Competent authorities may, in case of negligence, refusal or resistance, proceed to rehabilitate it but at the expense of the offending party.

**Article 118:** This law comes into force on the day of its publication in the Official Gazette of the Republic of Rwanda.

Kigali, on 08/04/2005

ANNEX 4: Soils of Rwanda



- A -ACRISOLS
- Af-Ferric Acrisols
- Ag-Gleyic Acrisols
- Ah-Humic Acrisols
- Ao- Orthic Acrisols
- Ap-Plinthis Acrisols
- B- CAMBISOLS
- Bc- Chromic Cambisols
- Bd-Dystric Cambisols
- Be-Eutric Cambisols
- Bf- Ferralic Cambisols
- Bg- Gleyic Cambisols
- Bh-Humic Cambisols
- Bk- Calcic Cambisols
- Bv- Vertic Cambisols
- Bx- Gelic Cambisols
- E- RENDZINAS
- C- CHERNOZEMS
- Cq- Glossic Chernozems
- Ch- Haplic Chemozems
- Ck- Calcic Chemozems
- Cl- Luvic Chemozems
- D-PODZOLUVISOLS
- Dd Dystric Podzoluvisols
- De- Eutric Podzoluvisols
- Dg- Gleyic Podzoluvisols
- F-FER RALSOLS
- Fa- Acric Ferrlsols
- Fh-Humic Ferralsols
- Fo-Orthic Ferralsols
- Fp Plinthic Ferralsols
- Fr-Rhodic Ferralsols
- Fx-Xanthic Ferralsols
- G-GLEYSOLS
- Gc-Calcaric Gleysols
- Gd-Dystric Gleysols
- Ge- Eutric Gleysols
- Gh-Humic Gleysols
- Gm- Mollic Gleysols
- Gp-Plinthic Gleysols
- Gx-Gelic Gleysols
- H- PHAEOZEMS
- Hc- Calcaric Phaeozems
- Hg- Gleyic Phaeozems
- Hh- Haplic Phaeozems
- Hl- Luvic Phaeozems
- I- Lithosols
- J- FLUVISOLS
  - Jc- Calcaric Fluvisols
- Jd- Dystric Fluvisols
- Je Eutric Fluvisols
- Jt-Thionic Fluvisols
- K-KASTAZNOZEMS
- Kh- Haplic Kastanozems
- Kk- Calcic Kastanozems Kl- Luvic Kastanozems