U.S. AGENCY FOR INTERNATIONAL DEVELOPMENT
BUREAU FOR ASIA AND THE NEAR EAST
WASHINGTON, D.C. 20523

ENVIRONMENTAL THRESHOLD DECISION

File No: ANE 08-10 RDMA SO3 ROD PERSUAP & ETD AI, Amended

PROGRAM/ACTIVITY DATA

Country Code-SO: 486-003

SO Name: SO3, Increased Effectiveness to Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS) and Infectious Diseases (ID)

Country or Region: Regional Development Mission/Asia (RDMA)

Activity Name: Record of Decision (ROD), Pesticide Evaluation Report and Safe Use Action Plan (**PERSUAP**), Avian Influenza (AI) & Initial Environmental Examination, Amended

Funding Begin: October 1, 2005 **Funding End:** September 30, 2010 **LOP Amount**: $65,629,000

IEE Prepared by: Molly Brady, Office of Public Health **Date:** October 5, 2007
IEE Amendment (Y/N): Y If "Yes," Number @ Date of Original: ANE 06-56, IEE approved March 26, 2006; ANE 06-67, May 17, 2006

ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion:	☒	Deferral:	☐
Positive Determination:	☐	Negative Determination:	☒
With Conditions:	☒	Exemption:	☐

PERSUAP APPROVED WITH CONDITIONS

SUMMARY OF FINDINGS

USAID/RDMA amends its ANE BEO-approved Initial Environmental Examination (IEE), ANE 06-67, approved May 17, 2006 (which amends an earlier ANE 06-56, IEE approved March 26, 2006), to include a Pesticide Evaluation and Safe Use Action Plan (PERSUAP), which was a condition of the original IEE. Other than the submission of the PERSUAP, all previous activities remain the same, namely:

USAID's RDM/A supports its "Avian Influenza (AI)" program to control the spread of highly pathogenic avian influenza (HPAI) in animals and humans through: 1) strengthening preparedness, surveillance, and control activities; 2) strengthening animal and human health capacity; 3) developing behavior change communication strategies; and 4) developing public-private partnerships. Activities will be implemented in the Greater Mekong Sub-Region (GMS), including Burma, China, Thailand, and Vietnam. Relevant activities in Bangladesh, Cambodia, Indonesia, and Mongolia are also anticipated under this program. AI activities include technical assistance and training in capacity building; communications; collaboration; linkages with public and private sectors; contact with and disposal of contaminated animal waste; treatment for include infection control; storage, use, and disposal of medical supplies, equipment and contaminated sharps; biological waste disposal; and potential procurement and use of pesticides.

ENVIRONMENTAL DECISIONS

USAID/RDMA's **Amended IEE** activities remain the same as in the initial IEE and therefore:
SO3 activities (ANE 06-56, IEE approved March 26, 2006) are primarily technical assistance, and AI activities under SO3 continues to be primarily technical assistance and training in capacity building; communications; collaboration; and linkages with public and private sectors. These AI activities will not have an impact on the natural or physical environment and qualify for **Categorical Exclusion** per 22 CFR 216.2 (c) (2)(i), (v), and (viii).

However, those AI activities which involve contact with and disposal of contaminated animal waste, treatment for infection control, storage, use, and disposal of medical supplies, equipment and contaminated sharps, and biological waste disposal for **Negative Determination with Conditions** per 22 CFR 216.3 (2) (iii). The **Conditions** are that program implementation includes biological and medical waste management for animal and health care workers and laboratory technicians in standardized protocols and support for procurement of items required for proper safety precautions to ensure maximum safety and minimal adverse impact on the environment and human health; and procurement and use of pesticides requires that a Pesticide Evaluation and Safe Use Action Plan (PERSUAP) shall be prepared prior to any procurement or use of pesticides under SO3, to address USAID's Pesticides Procedures per 22 CFR 216.3 (b)(1).

Finally, the submitted PERSUAP is **APPROVED with Conditions**, the Conditions being: 1) annual worker training and documentation; 2) annual auditing of PERSUAP implementation; and 3) to the extent feasible, return of unused or obsolete pesticides to the vendor or supplier, including used and unused packaging, bottles, bags, drums and other pesticide containers.

APPROVAL OF RECOMMENDED ENVIRONMENTAL ACTION

Bureau Environmental Officer: Michael Schimpp for John O. Wilson

Date: 11/14/07

Approved: ☒

Disapproved: ☐

File No: ANE 08-10 RDMA SO3 ROD PERSUAP & ETD AI, Amended

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Mission Environmental Officer
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ANE 08-10 RDMA SO3 - ROD Request - PERSUAP IEE - AI, Amended

INITIAL ENVIRONMENTAL EXAMINATION
IEE RDMA SO 486-003 (AI)

PROGRAM/ACTIVITY DATA:

Country Code-SO: 486-003
SO Name: SO3, Increased Effective Responses to Human Immunodeficiency Virus (HIV)/ Acquired Immune Deficiency Syndrome (AIDS) and Infectious Diseases
Country or Region: Regional Development Mission/Asia (RDMA)
Activity Name: Avian Influenza

Funding Begin: October 1, 2005 **Funding End:** September 30, 2010
LOP Amount: $65,629,000 **Sub-Activity Amount:** N/A

IEE Prepared by: Molly Brady, Office of Public Health **Date:** October 5, 2007
IEE Amendment (Y/N): Y Original IEE dated May 17, 2006 (ANE 06-67)

ENVIRONMENTAL ACTION RECOMMENDED: (Place X where applicable)

Categorical Exclusion:	☒	Deferral:	☐
Positive Determination:	☐	Negative Determination:	☒
With Conditions:	☒	Exemption:	☐

BACKGROUND

This is the amendment to the Initial Environmental Examination for SO 486-003 for Avian Influenza activities, approved on May 17, 2006. It includes a Pesticide Evaluation and Safer Use Action Plan (PERSUAP) as shown in Appendix A.

The program being implemented by the Regional Development Mission/Asia (RDM/A) Office of Public Health (OPH) provides support to control the spread of highly pathogenic avian influenza (HPAI) in animals and humans. OPH plans to support: a) strengthening of preparedness, surveillance and control activities, b) strengthening animal and human health capacity to detect and respond to outbreaks and suspected cases, c) developing behavior change communication strategies, and d) developing public-private and other partnerships. Activities will be implemented in the Greater Mekong Sub-Region (GMS), including Burma, China, Laos, Thailand and Vietnam. OPH might also provide technical assistance to the relevant activities in Bangladesh, Cambodia, Indonesia and Mongolia.

In 1997, the first known instance of human infection with influenza A virus subtype H5N1 occurred in Hong Kong, in an outbreak which infected 18 and killed six people. Authorities contained the spread by culling an estimated 1.5 million birds in three days. However, in December 2003, highly pathogenic avian influenza was detected in Vietnam and in 2004 Cambodia, China, Indonesia, Japan, Laos, and Thailand all reported H5N1 outbreaks in poultry. Since then, H5N1 avian influenza viruses have killed millions of domestic fowl in Asia (>250 million have been culled), spread beyond Asia infecting poultry in such countries as Azerbaijan, Croatia, Germany, Iraq, Nigeria, Russia, and Turkey, and resulted in a global total of 329 persons infected with H5N1 with 201 attributed deaths (WHO: 2OCT07)

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In FY2005, in response to the growing crisis, the U.S. Congress appropriated USD 25 million in emergency supplemental funding to support H5N1 HPAI prevention and control activities in Asia. Of this, USAID received $10 million for avian influenza activities, as well as $3.7 million in reprogrammed funds from country missions. In FY 2006 and FY 2007, RDM/A received $12.5 million and $18 million, respectively, to continue AI interventions. All activities are being implemented based on recommendations laid out in the *Avian and Human Pandemic Influenza Strategic Guideline* issued by the USAID Avian and Pandemic Influenza Management and Response Unit in Washington.

The avian influenza activities under this SO aim to achieve the goal of an effective regional response to avian influenza. Activities will focus on preparedness and planning, animal and human surveillance, animal and human response, communications, and the development of public-private and other partnerships. To achieve this goal, the SO3 consists of activities in support of pandemic preparation, surveillance and laboratory strengthening, and behavior change communication. Illustrative examples include: support of preparedness and planning development; promotion of cross-sectoral coordination and communication; and support of national and regional simulation activities. Other activities include development of standardized guidelines for reporting animal and human cases; development of viral surveillance strategies at central and community levels; training for laboratory workers; and provision of laboratory equipment and reagents. In the area of communication, activities will focus on communication including collaboration with partners in development and dissemination of preventive messages and appropriate monitoring and evaluation of communication messages.

SUMMARY OF FINDINGS

USAID RDM/A's "SO 3, Increased Effective Responses to HIV/AIDS and Other Infectious Diseases" programs previously received a Categorical Exclusion under its predecessor "SO 498-022 Increase Effective Regional Response to HIV/AIDS and Other Infectious Diseases." Avian influenza activities under SO3 continue to be primarily technical assistance and training in the areas of capacity building, communications, collaboration, and linkages with public and private sector. These activities will not have an impact on the natural or physical environment and are recommended for a **Categorical Exclusion** per 22 CFR 216.2 (c)(2)(i).

However, the avian influenza activities under SO 3 will include support for response activities that will involve contact with and disposal of contaminated animal waste, and treatment activities that will include infection control for suspected human cases. The avian influenza activities will also support surveillance activities that will involve the storage, use, and disposal of medical supplies, equipment and contaminated sharps, as well as generation of biological waste. These activities are recommended for a **Negative Determination with Conditions** pursuant to 22 CFR 216. The Conditions are that program implementation includes biological waste management training for animal and health care workers and laboratory technicians in standardized protocols and support for the procurement of items required for proper safety precautions and disposal to ensure maximum safety and minimal impact on the environment.

In addition, SO 3's outbreak response activities will also potentially involve procurement and use of pesticides, which may have significant adverse impacts on the environment, and therefore these activities qualify for a **Negative Determination with Conditions** pursuant to USAID's pesticide procedures (22 CFR 216.3(b)). The **Conditions** are that a Pesticide Evaluation and Safer Use Action Plan (PERSUAP) shall be prepared prior to any procurement or use of pesticides under SO 3. The PERSUAP addresses USAID's Pesticide Procedures pursuant to 22 CFR 216.3(b)(1)(i)(a-l), and, with its approval, explicitly

permits the acquisition and use of pesticide, according to the best practices identified in the PERSUAP." (See Appendix A.)

Given the nature of the disease that can change quickly, it is anticipated that program adjustment might be required to effectively respond to the situation and in that case, the IEE document will be amended as appropriate.

APPROVAL OF RECOMMENDED ENVIRONMENTAL ACTIONS:

CLEARANCE:

Mission Director Approval: _____ Olivier Carduner — Date: 11/6/07

Deputy Mission Director Approval: _____ Richard W. Whelden — Date: 10/3/07

Regional Legal Advisor Approval: _____ Mary Alice Kleinjan — Date: 10/31/07

Mission Program Development Officer Approval: _____ Sara Walter — Date: 10/20/07

Mission Environmental Officer Approval: _____ Winston Bowman — Date: 10/19/07

Mission Public Health Director Approval: _____ Cathy J. Bowes — Date: 10/15/07

Mission Infectious Disease Advisor Approval: _____ Dr. John MacArthur — Date: 10 OCT 07

CONCURRENCE:

Bureau Environmental Officer _____ John O. Wilson — Date: 11/14/07

Approved: ☒

Disapproved: ☐

PERSUAP RDMA OPH SO 486-003

DISTRIBUTION:

Mission Environmental Officer

IEE File

Appendix A
Pesticide Evaluation and Safer Use Action Plan (PERSUAP)

BACKGROUND

In response to the growing avian influenza crisis, RDM/A received $12.5 million in FY06 and $18 million in FY07 funds to support H5N1 highly pathogenic avian influenza (HPAI) prevention and control activities in Asia countries. All activities will be implemented based on recommendations laid out in the *Avian and Human Pandemic Influenza Strategic Guidelines* issued by the USAID Avian and Pandemic Influenza Management and Response Unit in Washington (see http://ghintranet.usaid.gov/AIUnit/guidance/strategic.html).

One of the RDM/A's avian influenza intervention activities is to support Food and Agricultural Organization of the United Nations (FAO) to implement preparedness/planning, surveillance, response (control & outbreak containment) and communications activities. Under the outbreak response, the activity will involve procurement/use of pesticide disinfectant to decontaminate the affected areas. In addition, through the USAID global stockpile, USAID/Washington donates HPAI commodities, including disinfectant, to RDM/A countries for use in outbreak response. Therefore, these activities qualify for a **Negative Determination with Conditions** pursuant to USAID's pesticide procedures (22 CFR 216.3(b)). The **Conditions** are that a Pesticide Evaluation and Safer Use Action Plan (PERSUAP) shall be prepared prior to any procurement or use of pesticides under SO 3. The PERSUAP addresses USAID's Pesticide Procedures pursuant to 22 CFR 216.3(b)(1)(i)(a-l) as follows:

Pesticide procedures element a: The USEPA registration status of the requested pesticide

The main pesticide disinfectant RDM/A will support FAO to procure and use is Dupont Virkon™ Multi-purpose Disinfectant Cleaner, which is also registered and marketed as Dupont RelyOn™ Multi-purpose Disinfectant Cleaner or Dupont Virkon/RelyOn™ Multi-purpose Disinfectant Cleaner. (See Appendix B.) For the purposes of this document, Virkon™ will be used to represent all three names. The disinfectant included in the HPAI decontamination kits provided by USAID/W is Virkon™ as well. Virkon™ is currently an EPA-registered disinfectant product (see http://www.epa.gov/pesticides/factsheets/avian_flu_products.htm). As EPA states on this site, "Although there are no antimicrobial products registered specifically against the H5N1 subtype of avian influenza A viruses, EPA believes that the currently registered avian influenza A products, when applied in strict accordance with the label directions, will be effective against the H5N1 strain".

In the rare case that FAO may need to purchase a disinfectant that is not included on the list of EPA-registered disinfectants above, RDM/A will only consider its use if the product is identical in formulation to one of the products on the list above, and an amendment to the IEE can show that none of the 100 EPA-approved pesticides are available in the country, it does not infringe on any patents, it can be shown to meet required quality control to be fully effective and not contain harmful contaminants, and they have approval from the appropriate host government authorities. Prior to seeking to use such a product, RDM/A will directly contact the REA and BEO to discuss the need to use the unregistered product in question. RDM/A will assemble all the information they can about the product in question, including a product label.

Pesticide procedures element b: Basis for selection of the pesticide

The main factors USAID/W, USAID RDM/A, and its partners use to select Virkon™ and potential other EPA-approved disinfectants include availability, efficacy (effectiveness at killing the virus), and price. Other factors under consideration are relative safety to human health and quality control considerations, such as the reliability of the manufacturer.

In the Asia region, FAO imports most AI disinfectant products from major international firms like DuPont, Dow, and others. FAO will ensure that all products used are manufactured by the owner of a proprietary formulation or are under a license to produce this formulation.

Pesticide procedures element c: Extent to which the proposed pesticide use is, or could be, part of an Integrated Pest Management (IPM) program:

The international—as well as many national—strategies being implemented to deal with HPAI already form an integrated program. In addition to control of the HPAI viruses, most initiatives include monitoring and

surveillance, zoning and compartmentalization, regulations and quarantine, vaccination, disinfection and disposal of waste (see http://www.oie.int/eng/info_ev/en_AI_avianinfluenza.htm).

Pesticide procedures element d: Proposed method or methods of application, including the availability of application and safety equipment.

Products will be applied according to the directions on the EPA-required label. For Virkon™, the supplemental label is attached as Appendix C and the RelyOn™ labels as Appendix D. Product will be applied by staff trained in appropriate application, including use of backpack and regular sprayers, and wearing appropriate personal protective equipment.

For areas in which disinfectant is being used as a preventive measure, appropriate PPE includes protective clothing such as long sleeve shirts and long pants, socks and shoes, rubber gloves, a particle mask, and goggles. Hands should be washed before eating, drinking, chewing gum, using tobacco or using the toilet. Contaminated clothing should be removed and washed before reuse.

For areas in which disinfectant is being used as a response to suspected cases of avian influenza, appropriate PPE includes protective suits, booties over shoes, 2 pairs of gloves, a N-95 mask, and goggles. Hands should be washed before eating, drinking, chewing gum, using tobacco, or using the toilet. PPE gear should be used one time only and discarded in appropriate biosafety bags.

Pesticide procedures element e: Any acute and long-term toxicological hazards, either human or environmental, associated with the proposed use, and measures available to minimize such hazards:

Most disinfectants that might be used by FAO are inorganic compounds that are only very toxic and can cause harm to people, equipment and the environment in the concentrated form in which they are sold. Once the purchased products are diluted with water, their toxicity decreases measurably so as to not pose a great acute risk to the health of users and others who come into contact with the diluents. Most have few long-term or chronic effects. However, they should be used with care around open water as they may kill aquatic organisms.

As mentioned above, USAID's product of choice, Dupont Virkon™ Multi-purpose Disinfectant Cleaner is registered in the USA as Dupont Virkon™ Multi-purpose Disinfectant Cleaner, Dupont Virkon/RelyOn™ Multi-purpose Disinfectant Cleaner, and Dupont RelyOn™ Multi-purpose Disinfectant Cleaner. All the Virkon™ products come formulated in tablet and powder forms. They contain 77.09% inert ingredients, as well as a mixture of 1.50% sodium chloride (salt) and 21.41% potassium peroxymonosulfate, which are corrosive, and are Class I (Danger) products in the concentrated form. Therefore, people coming in contact with concentrated forms must use care. The Virkon™ powder in concentrated form is corrosive and can cause skin burns, lung burns and irreversible eye damage. Workers coming into contact with this form must use rubber gloves, full protective clothing, a particle mask, goggles, and avoid breathing the powder.

USAID will **not** approve the use of highly dangerous or cancer causing alternatives such as hydrochloric acid, formaldehyde liquid or formaldehyde gas.

Pesticide procedures element f: Effectiveness of the requested pesticide for the proposed use:

As noted above, both EPA and FAO have lists of chemicals and products that work against HPAI. (See http://www.epa.gov/pesticides/factsheets/avian_flu_products.htm and http://www.fao.org/avianflu/en/factsheets.html.) The EPA and FAO recommend the use of Virkon™ as an HPAI disinfectant for animal housing, cages, and equipment; human housing; and clothing.

To achieve maximum effectiveness, it will be important to ensure that the disinfectant contains the appropriate quantity of the active ingredient, is stored properly, and is used before expiration date.

Pesticide procedures element g: Compatibility of the proposed pesticide use with target and non-target ecosystems:

None of the compounds on the FAO list of recommended chemicals and products, including Virkon™, are persistent; in the environment they break down rapidly. None of the disinfectants will be sprayed over large areas like insecticides might, and therefore will be locally contained. The end result of controlling the virus and saving wild birds by using disinfectants to contain transmission of HPAI will outweigh the risks to wild birds.

Pesticide procedures element h: Conditions under which the pesticide is to be used, including climate, flora, fauna, geography, hydrology, and soils:

There is little likelihood that disinfectants used by FAO will spread far from the place where they are used because of the small quantities used and the fact that disinfectants rapidly break down and are diluted in the environment. Application of disinfectants is likely to be limited to indoor or limited-size outdoor settings. In addition, training of those applying the disinfectants will include the direction to not discharge effluent from the disinfectants into lakes, streams, ponds, estuaries, oceans, or other waters.

Pesticide procedures element i: Availability of other pesticides or non-chemical control methods:

Both FAO and EPA have lists of other chemicals and/or disinfectants that can be used for HPAI control, and they include relatively safe compounds as soaps, detergents and citric acid. See http://www.fao.org/avianflu/en/factsheets.html for a list of chemicals for disinfecting different items and risk avoidance. Virkon™ is listed as an 'excellent disinfectant' with a known concentration that is effective against avian influenza viruses. Soap and detergent is not as highly recommended because the exact concentration needed to be effective at killing avian influenza viruses is unknown and could therefore lead to misuse in disinfecting the contaminated areas.

Pesticide procedures element j: Host country's ability to regulate or control the distribution, storage, use, and disposal of the requested pesticide.

As part of preparedness and planning activities, RDM/A supports FAO to assist the host country government in developing standard operating procedures for outbreak response which include regulating the distribution, storage, use and disposal of disinfectants.

Pesticide procedures element k: Provision for training of users and applicators.

RDM/A AI activities will include adequate safe use training on handling, use and disposal of disinfectants as a component in broader training on HPAI outbreak response and containment. Development Alternatives Inc. has implemented training in HPAI Commodities, including proper use of PPEs and disinfectant, in Vietnam and Laos. FAO will implement training in other countries and provide follow-up to the DAI training in Vietnam and Laos, in coordination with host country governments.

Pesticide procedures element l: Provision made for monitoring the use and effectiveness of this pesticide.

To monitor and evaluate the use and effectiveness of Virkon™ and other disinfectants, FAO and other HPAI partners that might use or fund the purchase of disinfectants and supplies for spraying will comply with the following:

- Store disinfectants should be under lock and key, out of the reach of children.
- Produce simple 'safe disinfectant use' training materials, quick reference guides, posters and flyers.
- Procure simple protective clothing (gloves, masks, boots, etc.) for ministry staff and others that mix and apply disinfectants.
- Ensure that staff are trained on how to mix, apply and dispose of disinfectants.
- As additional disinfectant choices become available, annually update the list of registered products and evaluate them following the 12 Pesticide Procedures (a. through l.) found in Regulation 216.3.

An action plan matrix with assignment of roles/responsibility, deadlines, and sign-off by Chief of Party or responsible authority is being developed to monitor the implementation of actions outlined in this PERSUAP.