

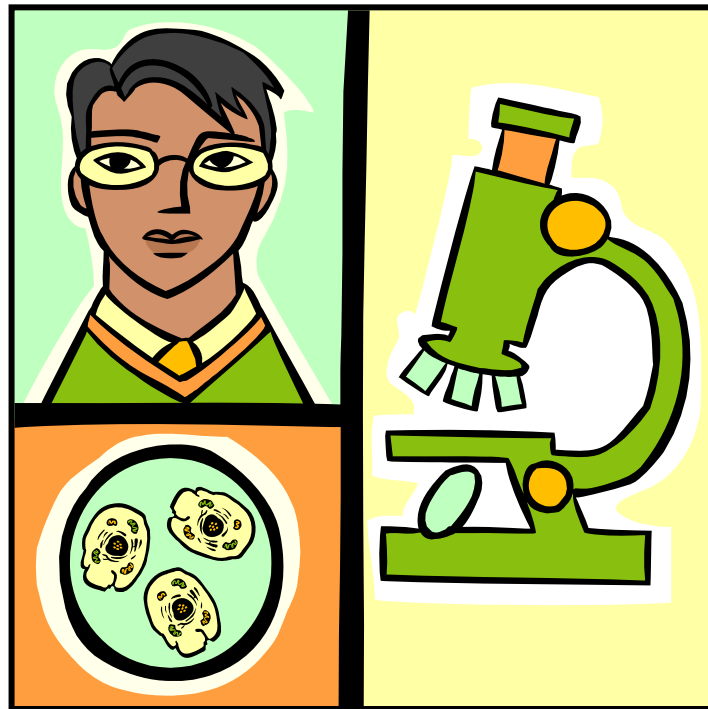


February 17, 2009

Antimicrobials Division  
2009 Workplan  
U.S. Environmental Protection Agency

# Antimicrobials Division

## Work Plan For Fiscal Year 2009



# **FY2009 Work Plan Antimicrobials Division Office of Pesticide Programs**

## **Vision Statement**

The Office of Pesticide Programs' Antimicrobials Division will ensure the protection of human health and the environment as it uses the best science and regulatory efficiencies in its registration and re-evaluation of chemicals used as pesticides against microbiological pests.

## **The Antimicrobials Division will support OPP's mission by:**

- AD plans to meet 100% of its PRIA & FQPA deadlines.
- Register 3 New Chemicals, 27 New Uses, 65 Old FT actions, 65 Old NFT actions, 800 AMD FT actions, 100 AMD NFT actions, and process 500 Notifications.
- AD will complete 15 Preliminary Workplans; 12 Final Workplans; 5 RED Addendum Documents; complete 3 registration reviews for final decision; 80 Product Reregistration Actions; Support BEAD on workshop to resolve UDT issues with OMB; and issue 15 DCI's once approved by OMB. Request 30 DCI's from OMB.

## **I. Being an effective gateway to the market and an effective steward of pesticides already on the market.**

### **A. Gateway to the market (Registration)**

AD acknowledges that it will only be able to achieve these performance objectives with support from HED, BEAD, EFED, RD, FEAD, and SRRD particularly as it applies to registration review and higher tiered risk assessments.

Meeting production targets, especially for registration actions, is somewhat dependent on the availability and quality of the data to support the chemical, product and/or use and assumes no renegotiations occur. Data deficiencies can result in the establishment of new time lines.

#### **1. Pesticide Registration - New Active Ingredients**

AD will work on 3 new active ingredient submissions. These decisions will provide new chemistries to the antimicrobial marketplace and will be made in accordance with the safety standards of FIFRA and FQPA and in the timeframes set forth under FQPA and PRIA.

### New Active Ingredient Candidates for FY 2009

Chemical	Uses	PRIA Due Date	Registrant	Branch	Comments
Copper omadine	antifoulant	1/28/09	Arch Chemicals, Inc.	RMBI	Renegotiated
Cetyl pyridinium chloride	Materials preservative	3/6/09	Vertellus Health & Speicality Products, LLC.	RMBI	Renegotiated
Tetramethylol acetylenediurea	Industrial preservative	4/15/09	Thor GMBH	RMBI	May need additional renegotiation

## 2. Pesticide Registration – New Uses

**AD will complete 28 decisions.** These decisions will provide new use opportunities to the antimicrobial marketplace and will be made in accordance with the safety standards of FIFRA and FQPA and in the timeframes set forth under FQPA and PRIA.

### New Use Candidates for FY2009

Chemical	Uses	PRIA Due Date	Registrant	Branch	Comments
Zinc pyrithione	Textile	7/15/09	Arch Chemicals, Inc.	RMB1	Renegotiated
Triethylene glycol	Air sanitizer	12/09/08	Prolitec, Inc.	RMBI	On Target
Alkyl* dimethyl benzyl ammonium chloride *(50%C14, 40%C12, 10%C16)	HVAC	11/24/08	Aeris Technologies Ltd	RMBI	On Target
Silver	Food contact sanitizer	3/09/09	ETI H2O, Inc	RMBI	Renegotiated
Ethaneperoxoic acid Hydrogen peroxide	Aseptic packaging change	2/10/10	FMC	RMB1	On Target
Hydrogen peroxide Peroxyacetic acid	Laundry (higher rate)	3/16/09	Ecolab	RMB1	On Target
Alkyl* dimethyl benzyl ammonium chloride 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	Materials preservative	1/24/09	Mason Chemical Company	RMB1	On Target
Tolyfluanid	Roof coating	3/3/09	Lanxess	RMB1	On Target
Alkyl* dimethyl benzyl ammonium chloride *(60%C14, 30%C16, 5%C18, 5%C12) Alkyl* dimethyl ethylbenzyl ammonium chloride *(68%C12, 32%C14)	Preservative uses	3/24/09	Mason Chemical Company	RMB1	On Target

Alkyl dimethyl benzyl ammonium chloride	Application rate increase	2/28/09	Brinton Products, LTD.	RMB1	On Target
Alkyl* dimethyl benzyl ammonium chloride 1-Decanaminium, N-decyl-N,N-dimethyl-, chloride 1-Decanaminium, N,N-dimethyl-N-octyl-, chloride	Materials preservative wallboard	1/26/09	Mionix Corporation	RMB1	On Target
2,6-Dimethyl-m-dioxan-4-ol acetate	Preservative uses	5/6/09	Dow	RMB1	On Target
Silver chloride	Preservative uses	6/12/09	Clariant Coporation	RMB1	On Target
Alkyl* dimethyl benzyl ammonium chloride	Food contact sanitizer	5/16/09	Stephan	RMB1	On Target
Zinc sulfate monohydrate	Swimming pools	4/10/09	Arch Chemicals, Inc.	RMB1	On Target
Hydrogen peroxide Ethaneperoxoic acid	Commercial, industrial, institutional use	4/24/09	Clean Earth Technologies, LLC	RMB1	Renegotiated
Hydrogen peroxide	Aseptic packaging	8/20/09	Solvay	RMB1	On Target
Dowicil™ 75 Preservative	Add Mineral Slurries	10/08	Dow	RMB2	Complete (withdrawn)
Bromine Chloride	Food Contact Sanitizer	11/08	Albemarle	RMB2	Complete (registered)
Thymol	Food contact sanitizer	1/09	Toxcel	RMB2	Renegotiated
Cu-HDO	Aquatic Use	4/09	Toxcel	RMB2	Renegotiated
49403-GT 4 chloro-3,5-xyleneol	Material Preservative	4/09	Clariant	RMB2	On Target
Carbamic Acid	New use-Leather	4/09	Dow	RMB2	On Target
Cupric Oxide/Poly-B	Increase Retention Rate in wood	4/09	Rutgers Organic	RMB2	On Target
1258-RGGR Calcium Hypochlorite	Swimming Pool Uses	4/09	Arch	RMB2	On Target
83691-G Sodium Hypochlorite	Toothbrush	5/09	D. B. Square	RMB2	On Target
Triadimefon 39967-AO	Wood & Material Preservative	7/09	LanXess Corp.	RMB2	On Target
Bromine	Drinking Water	8/09	Halo Source	RMB2	On Target

### 3. Other PRIA Actions

Protocols – Develop criteria for tier 1 & tier 2 protocol reviews. Complete all internal protocol reviews within the PRIA time lines. Post existing protocols to AD’s website.

#### 4. Other Registration Activities

##### a. Make Barrier Determinations

The Agency is currently considering “barrier exemption” requests and intends to complete them in FY09. There are no PRIA or FQPA due dates associated with these actions.

#### B. Stewardship of Products on the Market

##### 1. Registration Review

Complete 14 Scoping Assessments (SAs)\Preliminary Work plans (PWP) and 13 Final Work Plans (FWPs).

These registration review actions represent the Division’s contribution to the overall OPP registration review performance goals. Completion of PWP is achieved when the Notice of Availability (NOA) is published in the Federal Register and the associated public docket is opened. The interim milestones presented below will be used to track progress:

#### Preliminary Work Plan Process Milestones

Chemical	Draft SAs to RMB2	Draft PWP	Peer Review Panel	Revised SAs and PWP	Brief DD	Final SAs and PWP	Open Docket
<b>Quarter 1</b>							
Citric Acid, and salts	10/31/08	11/7/08	11/13/08	12/1/08	12/8/08	12/15/08	Complete
Mineral Acids	10/31/08	11/7/08	11/13/08	12/1/08	12/8/08	12/15/08	Complete
Ethanolamine, 2-	10/31/08	11/7/08	11/13/08	12/1/08	12/8/08	12/15/08	Complete
3H-1,2-Dithiol-3-one, 4,5-dichloro	10/31/08	11/7/08	11/13/08	12/1/08	12/8/08	12/15/08	Complete
<b>Quarter 2</b>							
Inorganic Halides	1/30/09	2/6/09	2/12/09	2/27/09	3/5/09	3/12/09	3/25/09
Bromine Chloride	1/30/09	2/6/09	2/12/09	2/27/09	3/5/09	3/12/09	3/25/09
Zinc Salts	1/30/09	2/6/09	2/12/09	2/27/09	3/5/09	3/12/09	3/25/09
Bromine	1/30/09	2/6/09	2/12/09	2/27/09	3/5/09	3/12/09	3/25/09
p-Chloro-m-xyleneol	1/30/09	2/6/09	2/12/09	2/27/09	3/5/09	3/12/09	3/25/09
<b>Quarter 3</b>							
Silver Compounds	4/30/09	5/7/09	5/14/09	5/28/09	6/4/09	6/11/09	6/24/09

2-(Decylthio)ethanamine Hydrochloride	4/30/09	5/7/09	5/14/09	5/28/09	6/4/09	6/11/09	6/24/09
2,4-Imidazolidinedione, 3-bromo-1-chloro-5,5-dimethyl	4/30/09	5/7/09	5/14/09	5/28/09	6/4/09	6/11/09	6/24/09
<b>Quarter 4</b>							
Tris(HOCH <sub>2</sub> -) Nitromethane	7/30/09	8/6/09	8/13/09	8/27/09	9/3/09	9/10/09	9/23/09
OBPA	7/30/09	8/6/09	8/13/09	8/27/09	9/3/09	9/10/09	9/23/09
Peroxy Compounds	7/30/09	8/6/09	8/13/09	8/27/09	9/3/09	9/10/09	9/23/09

Final registration review work plans are considered complete upon signature by Division Director and posting to the existing docket. The following interim milestones will be used to track progress:

### Final Work Plan Process Milestones

Chemical	Response to Comments	Draft FWP	Final FWP	FWP Docketed
<b>Quarter 1</b>				
Oxazolidine-E	11/3/08	11/24/08	12/15/08	Complete
Caprylic Acid	11/3/08	11/24/08	12/15/08	Complete
<b>Quarter 2</b>				
Biobor	2/11/09	3/4/09	3/20/09	3/25/08
Nuosept 145	2/11/09	3/4/09	3/20/09	3/25/08
<b>Quarter 3</b>				
Citric Acid, and salts	5/13/09	6/3/09	6/19/09	6/24/09
Mineral Acids	5/13/09	6/3/09	6/19/09	6/24/09
HMAE	5/13/09	6/3/09	6/19/09	6/24/09
3H-1,2-Dithiol-3-one, 4,5-dichloro	5/13/09	6/3/09	6/19/09	6/24/09
<b>Quarter 4</b>				
Inorganic Halides	8/19/09	9/2/09	9/25/09	9/30/09
Bromine Chloride	8/19/09	9/2/09	9/25/09	9/30/09
Bromine	8/19/09	9/2/09	9/25/09	9/30/09
p-Chloro-m-xyleneol	8/19/09	9/2/09	9/25/09	9/30/09
Zinc Salts	8/19/09	9/2/09	9/25/09	9/30/09

## Post-RED Implementation

### Complete 5 RED Addendum Documents\Memoranda.

The reregistration decisions listed below will be amended as a result of new data becoming available or other comments received on the RED decision. These actions will also begin the implementation process for Product Reregistration in some cases. Not all of the interim milestones will apply depending on the nature of the action.

### Post-RED Implementation Process Milestones

Chemical	Risk Assessment to RMB2	Stakeholder Interaction Closes	Revised Risk Assessment	Draft Addendum/Memo	Brief DD	Final Addendum/Memo
<b>Quarter 2</b>						
Phenols and Salts	12/20/08	1/29/09	2/17/09	3/3/09	3/17/09	3/24/09
Iodine	12/20/08	1/29/09	2/17/09	3/3/09	3/17/09	3/24/09
<b>Quarter 3</b>						
DGH	12/30/08	2/27/09	5/13/09	6/4/09	6/18/09	6/25/09
<b>Quarter 4</b>						
Zinc Pyrethione	5/15/09	7/1/09	7/31/09	8/21/09	9/3/09	9/16/09
Dimethyldithiocarbamate salts	5/15/09	7/1/09	7/31/09	8/21/09	9/3/09	9/16/09

## 2. Product Reregistration

### Complete 80 Product Reregistration Actions

These product reregistration actions represent the Division's contribution to the overall OPP product reregistration performance goals. These actions may include product reregistrations, amendments, suspensions and/or cancellations. This goal accounts for over 58% of the anticipated number of pending products beginning FY2009. Progress meetings are held monthly with the Deputy Office Director.

## 3. Data Call-Ins

Request OMB Clearance for 15 generic data call-in (GDCI) and product specific Data Call-Ins (PDCI) packages related to reregistration and 15 GDCI packages in support of registration review – Total requests = 30

Issue 30 DCIs upon approval including some which were submitted to OMB in FY'08.



This entire activity does rely in part on the timeliness of OMB's review and approval which presents a significant uncertainty to planning.

## II. Homeland Security (Biodefense and Food/Agriculture Defense)

Homeland Security Presidential Directive (HSPD)-9 ("Defense of United States Food and Agriculture") describes the President's national policy to prevent, detect, respond to and recover from terrorist attacks, major disasters, and other emergencies for U.S. agricultural and food production systems. Among other things, HSPD-9 states, "The Secretaries of Homeland Security, Agriculture, and Health and Human Services, the Administrator of the Environmental Protection Agency, and the heads of other appropriate Federal departments and agencies, in consultation with the Director of the Office of Science and Technology Policy, will accelerate and expand development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases." AD (with support from BEAD) will assist USDA with research to determine the efficacy of disinfectants against highly pathogenic Foreign Animal Diseases (FAD) by entering into a five year Interagency Agreement (IA) with USDA and providing funding, management, and technical input for this project. The IA is entitled, "Disinfectant Efficacy Testing for Foreign Animal Disease (FAD) Agents." This research program is intended to fill a major data gap that exists for efficacy data for disinfectants used to inactivate FADs that pose the greatest potential threat to agricultural animal populations and the U.S. economy.

Homeland Security Presidential Directive (HSPD)-10 ("Biodefense for the 21<sup>st</sup> Century") describes the President's national policy to prevent, detect, respond to and recover from an attack with biological weapons. Biodefense includes the testing and approval of chemical decontaminants ("antimicrobials") for use in neutralizing or reducing biological pathogens. Because no antimicrobials are currently registered for inactivating *Bacillus anthracis* spores and most biological warfare agents and because there is a need to fill this gap, AD's activities will focus on (1) assisting BEAD in developing efficacy test methods for antimicrobial products intended to be used against biological warfare agents or significant, emerging pathogens, (2) issuing draft efficacy guidelines (Section 810.2100) for sterilants and sporicidal decontaminants intended to inactivate anthrax spores, (3) reviewing and making registration decisions on applications for registration of products intended to inactivate *Bacillus anthracis* spores, and (4) coordinating appropriate homeland security issues with the Office of Emergency Management (OEM) and the Office of Homeland Security (OHS).

Another homeland security-related effort concerns defining prions as "pests" under FIFRA so that products intended to be used against prions are required to be registered as antimicrobial pesticides. Prions are the putative causative agent for "transmissible spongiform encephalopathies" (TSE) such as "mad cow" disease in cattle, scrapie in sheep, and Creutzfeldt-Jakob disease in humans. In September 2003, OPPTS decided that prions are pests. In September 2007, the AA/OPPTS signed an Early Guidance memo directing OPP to develop a Notice of Proposed Rulemaking (NPRM) that will propose to incorporate that decision into EPA's regulations (i.e., 40 CFR 152.5). This rulemaking is being tracked in RAPIDS and SCOUT. The NPRM is currently planned to be presented to the FIFRA Scientific Advisory Panel in April 2009 and signed by the AA/OPPTS in March 2010.

### **III. Enhancement of OPP's Science and Policy Framework**

#### **A. AD is working with OECD and NAFTA on global data harmonization efforts such as:**

1. Update final draft guidance for NAFTA labels for hard surface disinfectants as necessary and continue to identify and establish joint review related initiatives.
2. Continue as the Project Manager Co-Chair overseeing the OECD validation testing of a new quantitative hard surface disinfectant test method. Continue to work with BEAD on method improvements for the quantitative test.
3. Continue working with OECD to finalize the Guidance Document on the Evaluation of the Efficacy of Antimicrobial Treated Articles with Claims for External Effects. Support efforts to advance guidance document to full OECD Test Guideline Validation.
4. Continue working with OECD to finalize the Draft OECD Guidance Document for Establishing the Efficacy of Biocides Used in Swimming Pools and Spas. Participate on an *ad hoc* group (other participants: Australia, Ireland, Spain, the UK) to explore developing guidelines, at a minimum, for pools and spas.
5. Support development of proposed OECD Test Guidelines and Guidance documents (e.g., proposed OECD antifoulant release rate methodology). (Ongoing effort)
6. Support development of proposed OECD harmonization efforts or projects that may arise (e.g., possible project re: harmonization of human and/or environmental exposure/risk assessments for ballast water uses). (Ongoing effort)

#### **B. Work with other Federal Agencies**

1. Continue working with Federal and state government agencies on mold remediation and address other environmental issues.
2. *Clostridium difficile*: Work with CDC, FDA, academia, and the BEAD Microbiology Laboratory to identify a target strain and sporulation medium for achieving high titers of spores to be used in testing products against *Clostridium difficile* spores. Issue interim guidelines for conducting testing to support *Clostridium difficile* label claims.
3. Working with the U. S. Coast Guard (USCG), develop policy and technical procedures related to ballast water (BW) management, both domestically and internationally. Provide technical expertise to the USCG who has the lead on regulation of ballast water uses in U. S. (Ongoing effort)

#### **C. Work with Other Program Offices (Outside of OPP)**

1. Working with OPPT, develop guidance and/or a framework for Structure Activity Relationship (SAR) analyses and environmental modeling. (Ongoing effort)

2. Coordinate a stakeholder process exploring the re-use, recycling and/or disposal of treated wood products at the end of their service life (e.g. railroad ties and utility poles). This activity will involve extensive interactions with OPPT and OSWER. The results of this process will be captured as a Post-RED Implementation activity.
3. Ammonia Petition –Continue meetings with OW to discuss use of ammonia in the disinfection of drinking water. Make a final determination on the Petition.
4. Monitor and support OPPT/ORD development of Agency-wide cancer and non-cancer toxicological endpoints for formaldehyde. Once the endpoints have been finalized OPP may need to revisit its previous decisions on formaldehyde and formaldehyde-releasing chemicals.
5. Will coordinate Post-RED Implementation activities for Iodine with the Office of Water. OW expressed interest in the risk assessment and risk management decisions for Iodine during the comment period and OPP is exploring ways to address their concerns in a possible addendum to the RED.

#### **D. Other Program Efforts (Within OPP)**

1. Work with BEAD and commercial microbiology testing laboratories to improve test methods for towelette products.
2. Participate in the steering committee that will manage the development and validation of methods for hard surface uses against biofilm.
3. Work with BEAD and industry to conduct a workshop to investigate procedural enhancements to the AOAC Use-Dilution Method. Publish FR Notice announcing AOAC Use-Dilution Method Workshop (FY'09)

#### **E. Pesticide Environmental Stewardship Program (PESP)**

1. Coordinate activities such as the HVAC PR notice with the Antimicrobials Sector in the PESP program. The National Air Duct Cleaners Association (NADCA) are charter PESP partners.
2. Continue to coordinate key label/science issues with the American Public Health Laboratories (APHL).
3. Working with the IPM Institute of North America which is pilot testing an antimicrobial evaluation tool for their IPM Star program (a written school assessment tool), widely used in schools across the U.S. (partnering with Sherry Glick, BPPD Schools Sector Lead).

#### **F. Additional Initiatives**

1. Publish the 810 efficacy guidelines specifically for sterilant, disinfectant, and sanitizer products for public comment.

2. Continue the update of the 810 efficacy guidelines for air, water, and textile materials.
3. Evaluate the possibility of adopting the American Dental Association/American National Standards Institute (ADA/ANSI) guidelines and test methods for antimicrobial pesticide uses in dental unit waterlines.
4. Present HVAC PR Notice by 12/9/08 to SFIREG; Issue HVAC PR Notice in final form by 6/18/09.
5. Hold 158W workshop on 11/6/08. Proposed Rule for 158W was published on October 3, 2008.
6. Obtain OD agreement on revised ATP program plan. Implement new testing and communications strategies.
7. Expand the use of Structural Activity Relationship (SAR) evaluations in human health and ecological risk assessments.
8. Update OECA on which companies marketing ion generators expressed interest in registering their product. Companies that did not already submitted the required documentation may be subject to enforcement action.
9. Continue to provide input on pandemic influenza preparedness plans. Develop a list of registered products with human Influenza label claims.
10. Complete the majority of all general ECR's within the established OECA timeframes.
11. Continue to integrate enforcement compliance requests (ECRs) from the ATP program into the general ECR tracking program.
12. Support development of a framework to register new pesticide active ingredients that utilize nanotechnology. This framework should consider scientific uncertainties, policy, and regulatory implications. The work will be accomplished through an intra-office workgroup and in coordination and consultation with other EPA offices, other Federal agencies, other countries and stakeholders.
13. Continue to assist in OPP-wide efforts to evaluate use of "eco-labeling" for pesticide products, including evaluating the appropriateness of the DfE program for pesticide products. Initial recommendations from the PPDC Workgroup on Comparative Safety Statements will be made to full PPDC in October 2008.
14. Working with American Chemistry Council (ACC) to assess environmental exposure (using new modeling approach) from uses of copper (Cu) which includes copper-impregnated roof shingles and copper-treated wood structures (e.g., decks, fences). Critical to finalizing the environmental risk portion of copper RED (due for completion in FY09).

15. Participate in OPP workgroup to develop options for implementing Globally Harmonized Systems for OPP labels and provide recommendations and options for implementation in OPP.
16. Continue coordination with other offices in EPA for comments on mold guidance PR-Notice. The guidance will be submitted to OMB for the significant guidance determination in FY09.
17. Draft second FR Notice notice further clarifying that the Agency has determined certain devices are pesticides and therefore are subject to FIFRA regulations. Notice will establish timeline and process for obtaining registration.
18. The Antimicrobial Exposure Assessment Task Force II (AEATF II) is in the process of submitting exposure study protocols for generating generic exposure data on a broad range of use patterns and associated application methods to support registration and re-registration by its member companies. AD will review the protocols and prepare associated materials for presentation and submission to the Human Subjects Review Board (HSRB). After the studies are completed, AD will review the results and prepare associated materials for a follow-up presentation to the HSRB. It is anticipated that AD will attend the HSRB meetings twice a year, presenting one or two AEATF protocols or studies each time.
19. Fuel Ethanol Production – Publish a guidance document for antimicrobial use in the ethanol fermentation process on our web site. Get final concurrence from FDA.
20. In an effort to improve upon the consistency of antimicrobial labeling, AD will implement a QA/QC Program for Labels. This Program includes a 10% review of antimicrobial labeling related to both registration and reregistration. The review will take place every Thursday and before the final label has been approved.

#### **IV. OPP's Overall Programmatic Management to Allow Us to Better Deliver on Our Vision**

##### **A. Information Management/Information Technology**

1. *PRISM* – Review requirements and work with ITRMD and the other divisions to effectively implement PRISM as a solution strategy / application to unify and replace current systems including OPPIN and related Lotus Notes databases. The following areas will be the major focus for AD during the requirements and 1<sup>st</sup> phase implementation of PRISM:
  - a. *Document Management* – Continue to work on the OPP Scanning Workgroup to consolidate scanning efforts office-wide and to develop a structure and format for housing all our electronic documents and records which will be supported by the agency approved software – Documentum (The OPP Enterprise Document Management System).
  - b. *Electronic Labeling & Data Submission* – Continue to encourage registrants to submit information electronically as well as develop strategies for improving how we handle and process these submissions quickly and efficiently.

- c. e-Submission – Work with ITRMD to develop a workflow and process for handling electronic submission in OPP specifically registration and reregistration processes and workflow for AD.
2. *Web Content Management / Public Documents* – Continue to create HTML and PDF documents for antimicrobial information being released to the public by posting on EPA’s website under the direction of ITRMD’s Web Team in conformance with all EPA standards and guidelines. This includes the transition to the new Federal Register templates, Federal Docket Management System (FDMS), and use of Regulations.gov for release of public information.
3. *GovTrip* – Continue to process travel for Division employees and using GovTrip as the online booking agent.
4. *PeoplePlus/TAIS* – Time and Attendance Management will be supported by the timekeeper and administrative staff for all divisional employees using the PeoplePlus system.
5. *Correspondence Tracking* – Continue tracking divisional correspondence not tracked through other databases using the AD Correspondence Tracking System developed in Lotus Notes and Chronological Files maintained by administrative assistants. For over a year, AD has tracked AX, AL, and OPPTS correspondence via the Agency’s Correspondence Management System (CMS), and will continue its efforts to support these systems.

## **B. Results/Measures:**

AD continues to collaborate with other Divisions to evaluate its human health indicators and measures with regards to EPA and OPP's efficiency. Following are some measures and data sources the Division will continue to evaluate and monitor:

### **1. Confirm the Efficacy of Hospital Disinfectants**

The Antimicrobial Testing Program (ATP) was initiated in response to findings presented by the Government Accounting Office (GAO) which indicated that the EPA lacked assurance that antimicrobial products registered by the Agency were efficacious. EPA has focused its efforts on evaluating registered products that are most crucial to infection control (sterilants, tuberculocides, and hospital-level disinfectants). ATP Implementation provides increased assurance antimicrobial products used in hospital settings are efficacious potentially reducing the incidence of nosocomial infections.

AD will review industry provided and other related data that may demonstrate antimicrobial product effectiveness in reducing disease and infection outbreaks. Initial finding and data sources should be presented by stakeholders by Spring 2009.

### **2. Homeland Security Readiness -- Decontamination**

Anthrax/Decontamination Product Listing -- Once one or more products have been registered with a claim to inactivate B. anthracis spores (anthrax-related), post a list of those products on AD's web site. It is possible that one product may be registered in FY2009.

AD is developing draft guidance on efficacy testing required to support an anthrax-related claim. This draft guidance is expected to be made available for public comment in FY 2009 as an amendment to the 810 efficacy guidelines.

The EPA-USDA Interagency Agreement (IA) outlines three tasks to be completed in FY2009: (1) develop a Quality Assurance Project Plan (QAPP), (2) conduct a literature search for efficacy studies involving foreign animal disease agents, and (3) develop and select standardized laboratory techniques to measure the efficacy of decontamination products. These tasks will provide the foundation for efficacy testing to be conducted in subsequent one-year segments that will continue under the IA.

### C. Resource Management

Gateway to Market	
Goals for FY2009	Workplan Title
Complete 3 new active ingredient decisions in accordance w/ FIFRA and FQPA safety standards while meeting FQPA and PRIA deadlines	Registration: New Active Ingredients
Complete 27 new use decisions in accordance w/FIFRA and FQPA while meeting FQPA and PRIA deadlines	Registration: New Uses
Develop criteria for tier 1 & tier 2 protocol reviews	Other PRIA Actions
Complete barrier exemption requests possibly as early as 1 <sup>st</sup> Quarter FY09	Other Registration Activities-Make Barrier Determinations
Complete request for Experimental use permit possibly as early as the 1 <sup>st</sup> Quarter FY09	Other Registration Activities-Make EUP Determinations

Gateway to Market	
Item	Total
Total FTEs	32
Total Travel \$	\$20K
Total Extramural \$	\$837.5K
Total Intramural \$	\$2K

Stewardship of Products on the Market	
Goals for FY2009	Workplan Title
Complete 14 Scoping assessments (SAs)\Preliminary Work Plans (PWP)	Registration Review
Complete 13 Final Work Plans (FWPs)	Registration Review
Complete 5 RED Addendum Documents\Memoranda	Post RED Implementations
Complete 80 product reregistrations	Product Reregistration
Send 30 requests to OMB for Clearance <ul style="list-style-type: none"> <li>• 15 DCIs and PDCIs for all completed REDs</li> <li>• 15 GDCI for support of Registration Review</li> </ul>	Data Call-Ins



<b>Stewardship of Products on the Market</b>	
Mail 15 DCIs upon approval including ones requested in FY08	Data Call-Ins
Assist BEAD in developing efficacy test methods for antimicrobial products intended for use against biological warfare agents or significant emerging pathogens	Homeland Security and Biodefense

<b>Stewardship of Products on the Market</b>	
<b>Item</b>	<b>Total</b>
Total FTEs	22
Total Travel \$	\$20K
Total Extramural \$	\$200K
Total Extramural/Homeland Security \$	\$350K
Total Intramural \$	\$16K

<b>Enhancement of OPP's Science and Policy Framework</b>	
<b>Goals for FY2009</b>	<b>Workplan Title</b>
<ul style="list-style-type: none"> <li>• Continue discussions between AD and Canada, Mexico to develop guidance on NAFTA label and joint review initiatives;</li> <li>• Continue working with OECD on developing harmonized test guidelines for hard surface disinfectants and treated materials;</li> <li>• Continue working with OECD on finalizing guidance document for efficacy testing of swimming pool and spa products;</li> <li>• Expand the use of Structural Activity Relationship process;</li> </ul>	Work with OECD and NAFTA
<ul style="list-style-type: none"> <li>• Continue working with Federal and State Government agencies on mold remediation activities.</li> </ul>	Work with Other Federal Agencies
<ul style="list-style-type: none"> <li>• Continue collaborating with commercial efficacy testing laboratories to develop improvements to antimicrobial efficacy test methods</li> <li>• Continue the update of the air, water, and material textile product performance guidelines for antimicrobial pesticides</li> <li>• Communicate HVAC PR Notice issues and activities.</li> </ul>	Other Initiatives

<b>Enhancement of OPP's Science and Policy Framework</b>	
<b>Item</b>	<b>Total</b>
Total FTE	12
Total Travel \$	\$30K
Total Extramural \$	\$25K
Total Extramural for Technical NOWSEE Homeland Security	\$65K
Total Intramural \$	\$2.2K

<b>Overall Programmatic Management to Allow Us to Better Deliver On Our Vision</b>	
<b>Goals for FY2009</b>	<b>Workplan Title</b>
<ul style="list-style-type: none"> <li>• Document Management – Work with OPP Scanning Group</li> <li>• Records Management</li> <li>• Information Management/Technology</li> <li>• Web Content Management</li> <li>• Electronic Labeling and Data Submission</li> <li>• GovTrip</li> <li>• PeoplePlus/TAIS</li> <li>• Correspondence Tracking</li> <li>• Quality Assurance/Quality Control</li> <li>• Contracts</li> <li>• Budget</li> <li>• Human Resource</li> </ul>	Information Management/Information Technology
Continue collaboration with other Divisions to collectively develop human health indicators and measures with regards to EPA and OPP's efficiency	Results/Measures

<b>Overall Programmatic Management to Allow Us to Better Deliver On Our Vision</b>	
<b>Item</b>	<b>Total</b>
Total FTE	6
Total Travel \$	\$10K
Total Extramural \$	\$25K
Total Intramural \$	\$2.2K

## Current Antimicrobials FTE Resources

(Table excludes DD, ADD, and BC's)

Activity	IO FTEs	RMBI FTEs	RMBII FTEs	RASSB FTEs	PSB FTEs	TOTAL FTEs
Administrative (Budget, Human Resources, Facilities, Contract Management and IT)	4.5				0.10	<b>4.6</b>
Homeland Security	1.0				0.25	<b>1.25</b>
Ombudsman/Communications		2.0				<b>2.0</b>
Post-RED Follow-up			2.5	2.0	1.0	<b>5.5</b>
Product Reregistration		0.1	2.0		1.0	<b>3.1</b>
Registration		7.8	7.0	8.0	6.5	<b>29.3</b>
Registration Review			5.5	6.5		<b>12.0</b>
Senior Scientists	2.5				0.15	<b>2.65</b>
OECD/NAFTA	1.0			0.25		<b>1.25</b>
Special Projects (Policy & interpretative guidance development)	4	2.1		0.25	1.0	<b>7.35</b>
Stay-In-School Students (2)	1.0		1.0			<b>2.0</b>
Leave Without Pay		1				<b>1</b>
<b>TOTALS</b>	<b>14.0</b>	<b>13.0</b>	<b>18.0</b>	<b>17.0</b>	<b>10.0</b>	<b>72.0</b>