

Antimicrobials Division

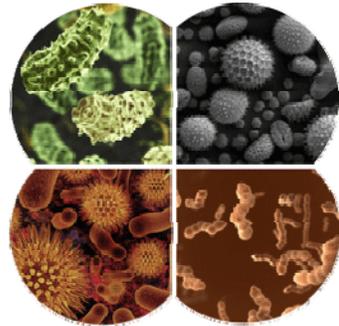
2010 Work Plan



Mold

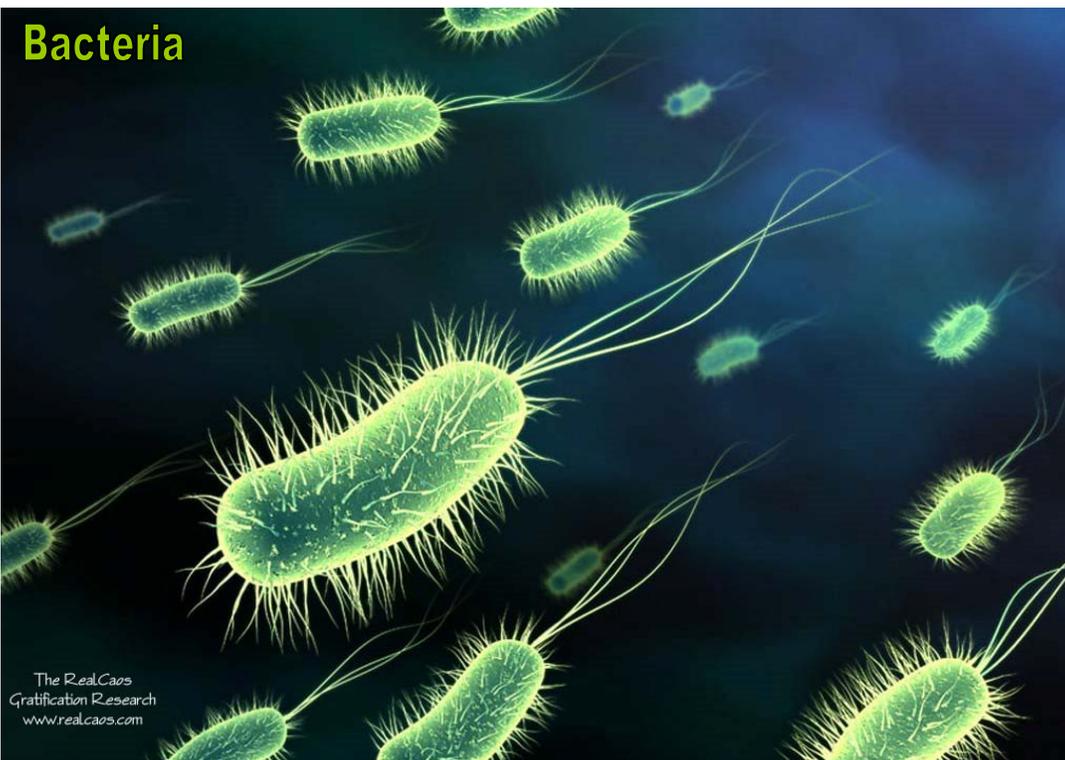


Microbes



Protecting Human
Health & the
Environment

Bacteria



E. coli



FY 2010 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 deadlines.
- AD plans to meet 100% of its FQPA deadlines.
- Register 2 New Chemicals, 24 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 18 Preliminary Work plans; 13 Final Work plans; 1 registration review final decision; 1 reregistration eligibility decision (RED) addendum; 80 Product Reregistration Actions; Continue to support BEAD on UDT issues; and issue 95% of all DCI's approved by OMB within 3 months of the OMB approval date.

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 PRD particularly as it applies to registration review and higher tiered risk assessments.

Meeting production targets, especially for registration actions, are 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 5 new active ingredients with a target of 2 decisions. The target reduction is based upon data deficiencies for 3 pending active ingredients. These actions 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 2010

File Symbol	Chemical	Uses	PRIA Due Date	Registrant	Branch
1258-RGEE	Copper Omadine	MUP for Antifouling Paints	11/30/09	Arch Chemical Company	RMBI
63838-RN	Potassium Hypochlorite 12.5%	Sodium Hypochlorite uses per the RED	4/2/10	Envirotech Chemical Services, Inc.	RMBII
85808-R	N,N'-methylenbis [5-methyloxazolidin]	Oilfield Muds, Fuels, Metalworking fluid preservative	6/4/10	Schulke & Mayr GMBH	RMBI
52484-G	N,N Methylenebismorpholine	Metalworking fluid preservative	4/14/10	The Lubrizol Corp.	RMBI
84610-E	Nanosilver Composite	Polymer, plastics and textile preservative	3/2/11	NanoSilva	RMBI

2. Pesticide Registration – New Uses

AD will complete 24 decisions. AD will work on 29 new use decisions with a target of 24 completions. 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 FY 2010

File Symbol	Chemical	Uses	PRIA Due Date	Registrant	Branch
71654-6	Potassium Peroxymonosulfate	First food use in the presence of farm animals	3/10/10	Virkon	RMBII
1839-155	ADBAC	Indirect Food use	2/19/10	Stepan	RMBI
4582-TE	L-Lactic Acid	Dish Detergent Sanitizer	1/30/10	Colgate-Palmolive	RMBII
68660-RG	Hydrogen Peroxide	Sterilant for food contact surfaces	3/23/10	Solvay Chemicals, Inc.	RMBI
47371-161	ADBAC		5/18/10		RMBI
5383-135	Benzisothiazolin	For use as a food contact surface sanitizer	7/16/10	Troy Chemical Corp.	RMBI

71227-7	Elemental Copper	Materials preservative in water bottle dispensers, ice trays, water bottles	8/21/10	Sinanen Company, LTD	RMBI
39967-49	Tolyfluanid	Roof Coatings Preservative	12/5/09	Lanxess Corp.	RBMI
70087-E	Octadecylmethyl trihydroxysilyl propyl ammonium chloride	Closed Ponds and Swimming Pools/Spas	12/17/09	Coating Systems Laboratories, Inc	RMBI
65402-3	Ethaneperoxoic Acid	Oilfield microbiocide	2/18/10	FMC Corporation	RMBI
84526-6	Hydrogen Peroxide				RMBI
63838-2	Hydrogen Peroxide	Industrial Process water, cooling tower microbiocide	3/12/10	Sanosil USA, LLC	RMBI
86256-R	Octadecanaminium Chloride	Once thru Cooling Towers	5/13/10	EnviroTech	RMBI
75269-G	Didecyl-bis(2-hydroxyethyl) ammonium borate	Lumber treatment	2/7/10	Rutgers Organics BMbH	RMBII
707-307	3(2H)-Isothiazolone, 4,5-dichloro-2-octyl-	To treat wood in aquatic environs	3/15/10	Rohm & Haas Co.	RMBI
464-682	Dimethyl Acetate	Preservative for adhesives, paints, coatings, textiles, leather	3/10/10	The Dow Chemical C.	RMBI
1258-1249	1,2-Benzisothiazol-3(2H)-one, 2-butyl-	Preservative for plastic, metalworking fluids, rubber, and coatings	4/12/10	Arch Chemicals, Inc.	RMBI
84630-E	ADBAC and Silver Nitrate	Preservative on natural and synthetic fibers and textiles	10/8/09	Transtex Technologies	RMBI
72992-RL	Silver Nitrate	Preservative for plastic, metals, rubber, and coatings	12/6/09	Chrysal International BV	RMBI

39967-25	Sodium p-chloro-m-cresolate	Materials Preservative	2/19/10	Lanxess	RMBII
42048-R	L-Lactic Acid	Disinfectant on-board aircraft, potable water storage tanks, aircraft water trucks	12/12/09	Celeste Industries, Corp.	RMBII
82544-R	Silver	Ion Generator Washing Machine	1/9/10	Samsung, Inc.	RMBI
100-1233	Propiconazole	Latex Paint Coatings & Stain, Preservative	3/1/10	Syngenta Crop Protection	RMBII
72920-R	Silver	Ion Generator for water systems	2/14/10	Vorigen, Inc.	RMBI
1624-RGN	Boric Acid	In-can materials preservative	3/25/10	Delta Analytical Corporation	RMBII
5383-89	Carbamic Acid		6/4/10		???
84545-O	Silver		6/14/10	SBiomed, LLC	RMBI
1043-REL	Tetraacetyl ethylenediamine	Hospital disinfect	7/1/10	Steris Corporation	RMBI

3. Other PRIA Actions

Protocols –Complete all internal protocol reviews within the PRIA time lines.
EUPs- Complete all EUP reviews within the PRIA time lines.

4. Emerging Registration Activities

- a. Label consistency and accountability - Fully implement the AD Label Quality Improvement Plan
- b. Continue to assist in OPP-wide efforts to initiate pilots related to the use of “eco-labeling” for pesticide products, including evaluating the appropriateness of the Design for the Environment (DfE) program for pesticide products.
- c. Implementation of alternative methods for eye irritation testing pilot program.
- d. Implementation of the Factual Statement Pilot for Antimicrobials.
- e. Nanotechnology issues continue to be addressed

B. Stewardship of Products on the Market

1. Registration Review

Complete 18 Scoping Assessments (SAs)\Preliminary Work plans (PWPs) 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 PWPs 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

Num.	Name	Publication / Post Date	DD Sig. Date	Science Doc. Sig. Date	DD Briefing	Send to OGC for Review	Team Peer Review	RASSB Peer Review
Quarter 1								
2380	2-Mercaptobenzothiazole	16-Dec-2009	2-Dec-2009	25-Nov-2009	18-Nov-2009	4-Nov-2009	28-Oct-2009	14-Oct-2009
3032	Bromohydroxyacetophenone (BHAP)	16-Dec-2009	2-Dec-2009	25-Nov-2009	18-Nov-2009	4-Nov-2009	22-Oct-2009	14-Oct-2009
3056	Dibromo-3-nitrilopropionamide (DBNPA)	16-Dec-2009	2-Dec-2009	25-Nov-2009	18-Nov-2009	4-Nov-2009	28-Oct-2009	14-Oct-2009
3065	Disodium cyanodithioimidocarbamate (DCDIC)	16-Dec-2009	2-Dec-2009	25-Nov-2009	18-Nov-2009	4-Nov-2009	28-Oct-2009	14-Oct-2009
4061	Lauryl sulfate salts	16-Dec-2009	2-Dec-2009	25-Nov-2009	18-Nov-2009	4-Nov-2009	28-Oct-2009	14-Oct-2009
Quarter 2								
3069	Dowicil 100	24-Mar-2010	10-Mar-2010	3-Mar-2010	24-Feb-2010	10-Feb-2010	3-Feb-2010	20-Jan-2010
3143	Thymol (5-methyl-2-isopropyl-1-phenol)	24-Mar-2010	10-Mar-2010	3-Mar-2010	24-Feb-2010	10-Feb-2010	3-Feb-2010	20-Jan-2010
4027	meta-Cresol (m-Cresol)	24-Mar-2010	10-Mar-2010	3-Mar-2010	24-Feb-2010	10-Feb-2010	3-Feb-2010	20-Jan-2010
5013	Decyl isononyl dimethyl ammonium chloride	24-Mar-2010	10-Mar-2010	3-Mar-2010	24-Feb-2010	10-Feb-2010	3-Feb-2010	20-Jan-2010
5031	1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N'-(1,1-	24-Mar-2010	10-Mar-2010	3-Mar-2010	24-Feb-2010	10-Feb-2010	3-Feb-2010	20-Jan-2010

	dimethylethyl)-6-(methylthio)-							
Quarter 3								
3033	Busan 74*	23-Jun-2010	9-Jun-2010	2-Jun-2010	26-May-2010	12-May-2010	5-May-2010	21-Apr-2010
4022	Chlorine Gas	23-Jun-2010	9-Jun-2010	2-Jun-2010	26-May-2010	12-May-2010	5-May-2010	21-Apr-2010
4098	Xylenol	23-Jun-2010	9-Jun-2010	2-Jun-2010	26-May-2010	12-May-2010	5-May-2010	21-Apr-2010
5012	Dichromic acid, disodium salt, dehydrate	23-Jun-2010	9-Jun-2010	6/2/2010	5/26/2010	5/12/2010	5/5/2010	4/21/2010
Quarter 4								
2645	Terbutylazine	22-Sep-2010	8-Sep-2010	1-Sep-2010	25-Aug-2010	11-Aug-2010	4-Aug-2010	28-Jul-2010
3099	Naphthenate salts	22-Sep-2010	8-Sep-2010	1-Sep-2010	25-Aug-2010	11-Aug-2010	4-Aug-2010	28-Jul-2010
4025	Copper oxides	22-Sep-2010	8-Sep-2010	1-Sep-2010	25-Aug-2010	11-Aug-2010	4-Aug-2010	28-Jul-2010
4026	Copper 8 Quinolinolate	22-Sep-2010	8-Sep-2010	1-Sep-2010	25-Aug-2010	11-Aug-2010	4-Aug-2010	28-Jul-2010

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

Num.	Name	Publication / Post Date	DD Sig. Date	Send to OGC for Review	Team Peer Review
Quarter 1					
4082	Silver compounds	2-Dec-2009	25-Nov-2009	10-Nov-2009	4-Nov-2009
5029	2-(Decylthio)ethanamine Hydrochloride (DTEA)	2-Dec-2009	25-Nov-2009	10-Nov-2009	4-Nov-2009
Quarter 2					
0044	OBPA (10, 10'-Oxybisphenoxarsine)	24-Mar-2010	10-Mar-2010	24-Feb-2010	17-Feb-2010
3149	Tris(HOCH ₂ -) Nitromethane	24-Mar-2010	10-Mar-2010	24-Feb-2010	17-Feb-2010
4072	Peroxy Compounds	24-Mar-2010	10-Mar-2010	24-Feb-2010	17-Feb-2010
Quarter 3					
2380	2-Mercaptobenzothiazole	23-Jun-2010	9-Jun-2010	26-May-2009	19-May-2010
3032	Bromohydroxyacetophenone (BHAP)	23-Jun-2010	9-Jun-2010	26-May-2009	19-May-2010
3056	Dibromo-3-nitropropionamide (DBNPA)	23-Jun-2010	9-Jun-2010	26-May-2009	19-May-2010
3065	Disodium cyanodithioimidocarbamate	23-Jun-2010	9-Jun-2010	26-May-2009	19-May-2010
Quarter 4					
3069	Dowicil 100	22-Sep-2010	8-Sep-2010	25-Aug-2010	18-Aug-2010

4061	Lauryl sulfate salts	22-Sep-2010	8-Sep-2010	25-Aug-2010	18-Aug-2010
5013	Decyl isononyl dimethyl ammonium chloride	22-Sep-2010	8-Sep-2010	25-Aug-2010	18-Aug-2010
5031	1,3,5-Triazine-2,4-diamine, N-cyclopropyl-N'-(1,1-dimethylethyl)-6-(methylthio)-	22-Sep-2010	8-Sep-2010	25-Aug-2010	18-Aug-2010

1. RED Addendum

The Antimicrobials Division will fulfill its promise to complete a reregistration eligibility decision addendum for the antimicrobial uses of Copper Compounds (Case 4025, 2026).

2. Product Reregistration

Complete 80 Product Reregistration Actions

These product registration actions represent the Division's contribution to the overall OPP product registration performance goals. These actions may include product reregistrations, amendments, suspensions and/or cancellations. Progress meetings are held monthly with the Deputy Office Director.

3. Data Call-Ins

Request OMB Clearance for 20 generic data call-in (GDCI) and product specific Data Call-Ins (PDCI) packages related to reregistration and 20 GDCI packages in support of registration review – Total requests = 40

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

II. Enhancement of Science Policy and Framework

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

1. Continue to identify and establish joint review related initiatives.
2. Continue 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)
7. Facilitate implementation of the validated quantitative test for hard surface disinfectants once approved by the TFB.
8. In consultation with stakeholders, draft a comprehensive strategy to transition from use of the existing qualitative test methods for antimicrobial efficacy to the newly validated quantitative methods.

B. Work with other Federal Agencies

1. Continue working with Federal and state government agencies on mold remediation and address other environmental issues.
2. 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)
3. Work with the Consumer Products Safety Commission (CPSC) to revitalize public awareness of wood products treated with chromated copper arsenate (CCA) and other pesticides.
4. Working with CDPR to coordinate efforts/ potentially share work on coppers ecological assessment for wood treatment and antifouling use patterns.
5. Continue work with Public Health Action Plan to Combat Antimicrobial Resistance Interagency Task Force (NIH, CDC, FDA, and EPA) to address emerging threats of antimicrobial resistance.

6. Continue to support the CDC's Emerging Infectious Disease conferences which bring together public health professionals to encourage the exchange of scientific and public health information on global emerging infectious disease issue.
7. Continue working with the Food and Drug Administration and the Consumer Product Safety Commission on hazard and risk issues with Triclosan.

C. Work with Other EPA 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. Work with OW on making final determination related to ammonia petitions.
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. Coordinate with Office of Water regarding TREX modeling for coopers.
6. Coordinate with Office of Water regarding emerging drinking water treatment technologies.
7. Work with the Office of Enforcement and Compliance Assurance, Regional Staff, and other federal/state agencies to revitalize public awareness of wood products treated with chromated copper arsenate (CCA) and other pesticides.
8. With support from ORD and OPPT, hold a consultative SAP meeting on key science issues affecting risk assessments for nanosilver pesticide products.
9. To the extent possible identify currently registered products that contain nanoscale constituents and establish a policy to address hazard and exposure concerns associated with their continued registration and use.

D. Other Program Efforts (Within OPP)

1. Work with BEAD and commercial microbiology testing laboratories to improve test methods for towelette products.
2. Continue working with BEAD and the Antimicrobial Efficacy Working Group on improvements to the Use Dilution Method.
3. Participate in the steering committee that will manage the development and validation of methods for hard surface disinfectants used against biofilm.
4. Implement product reregistration MOU with PRD to forward divisional and office-wide product reregistration goals.
5. 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.
6. Work with FEAD and OGC to finalize responses to public comments on the proposed 158W Antimicrobial Test Rule.
7. Issue revised draft PR Notice on False or Misleading Pesticide Product Brand Names. Review public comments received in FY10, and issue a final PR Notice in FY11.
8. Issue revised fact sheet on “Determining If a Cleaning Product is a Pesticide under FIFRA” in FY 10. Coordinate with other OPP and EPA offices.

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 antimicrobial 810 efficacy guidelines for public comment. Review public comments received and finalize guidelines in FY11.
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. Complete the LEAN Review of the ATP and develop an implementation plan.
5. Expand the use of Structural Activity Relationship (SAR) evaluations in human health and ecological risk assessments.
6. Provide guidance to the regulated community on label claims related to H1N1.
7. Complete the majority of all general ECR's within the established OECA timeframes.
8. Continue to integrate enforcement case reviews (ECRs) from the ATP program into the general ECR tracking program.
9. Participate in OPP workgroup to develop options for implementing Globally Harmonized Systems for OPP labels and provide recommendations and options for implementation in OPP.
10. Continue coordination with other offices in EPA for comments on mold guidance PR-Notice. Issue draft PR Notice on Mold-Related Products. Review public comments received in FY10, and issue a final PR Notice in FY11.
11. Issue FR 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.
12. 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.

13. AD will continue the QA/QC Program for Labels. This Program includes a 10% review of antimicrobial labeling related to both registration and reregistration. Once a week, random labels will be chosen for review prior to the labeling being approved.
14. Post on the web guidance on how to submit alternate fragrance by notification.
15. Post on the web guidance on data and labeling required to register a product for use on artificial turf.
16. Develop guidance regarding mold and mildew stain removal claims.
17. Publish the mold PR Notice for public comment
18. Work with HED on reviewing pet incidents.
19. Maintain strong partnerships with infection control prevention groups (APIC, ASHES, SHEA, AHA, and others) to assist with education efforts on the safe and effective use of antimicrobial pesticides.
20. Showcase the antimicrobials program at the annual meeting of the American Society for Microbiology.
21. Publish the prions 810 efficacy guidelines for public comment. Review public comments received and finalize guidelines in FY11.

III. Homeland Security Efforts

1. List Registered Anthrax-Related Products. When products have been registered with a claim to inactivate *B. anthracis* spores (anthrax-related), post those products on OPP's or AD's web site.
2. Issue Final Efficacy Testing Guidelines pertaining to an Anthrax-related Claim. Draft guidance is expected to be issued for public comment in FY 2010 as a part of the 810 efficacy guidelines for sterilants. AD will review publicly submitted comments, make appropriate revisions to the guidelines, and publish the final 810 guidelines in FY2011.

3. Implement the EPA-USDA Interagency Agreement (IA): “Laboratory Studies to Determine the Efficacy of Selected Decontamination Products against FAD Agents.” Complete work on the basic and advanced plans scheduled for FY2010. Since this project is not be funded in 2011, perform studies only until FY10 funds are gone.
4. Assist in developing and/or reviewing key HS documents/projects from other federal agencies and EPA offices. AD will review and comment on all HS-related documents and projects related to decontamination and remediation involving antimicrobial pesticides.
5. Coordinate on avian flu and pandemic flu procedures and issues pertaining to antimicrobial products that are registered for avian influenza viruses and for human influenza viruses.
6. Develop and issue a Notice of Proposed Rulemaking (NPRM) for Prions that addresses EPA’s position that a prion is a pest in FY2011. Review public comments received in response to the NPRM and begin to develop the final rule for issuance in FY2011-12.
7. Assist BEAD in developing efficacy test methods, as needed, for antimicrobial products intended for use against biological warfare agents or significant emerging pathogens.

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 1st 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 EPA’s Correspondence Management System (CMS).
6. *Web-Distributed Labeling* – Continue working with OPP staff and external stakeholders to further explore the possibility of distributing pesticide labeling via the internet.
7. *ATP Tracking Database* – Support ITRMD efforts to develop and pilot the ATP tracking system.

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:

Ensure 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. Historically, 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.

Conduct a LEAN Review of the ATP to improve program efficiency and reduce costs.

Provide time review of novel and new label claims such as exposure reduction and other claims for antimicrobial products.

C. Resource Management

Gateway to Market	
Goals for FY2010	Workplan Title
Complete 4 new active ingredient decisions in accordance w/ FIFRA and FQPA safety standards while meeting FQPA and PRIA deadlines	Registration: New Active Ingredients
Complete 30 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 request for Experimental use permit possibly as early as the 1 st Quarter FY09	Other Registration Activities- Make EUP Determinations

Gateway to Market	
Item	Total
Total FTEs	29
Total Travel \$	\$25K
Total Extramural \$	\$569,876K
Total Intramural \$	\$5.2K

Stewardship of Products on the Market	
Goals for FY2010	Workplan Title
Complete 18 Scoping assessments (SAs)\Preliminary Work Plans (PWPs)	Registration Review
Complete 13 Final Work Plans (FWPs)	Registration Review
Complete 1 RED Addendum Documents\Memoranda	Post RED Implementations
Complete 80 product reregistrations	Product Reregistration
Send 40 requests to OMB for Clearance <ul style="list-style-type: none"> • 20 DCIs and PDCIs for all completed REDs • 20 GDCI for support of Registration Review 	Data Call-Ins
Continue to 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

Stewardship of Products on the Market	
Item	Total
Total FTEs	20.8
Total Travel \$	\$25K
Total Extramural \$	\$718,238K
Total Extramural/Homeland Security \$	\$700K
Total Intramural \$	\$5.2K

Enhancement of OPP's Science and Policy Framework	
Goals for FY2010	Workplan Title
<ul style="list-style-type: none"> • Continue discussions between AD and Canada, Mexico to develop guidance on NAFTA label and joint review initiatives; • Continue working with OECD on finalizing and implementing harmonized test guidelines for hard surface disinfectants and treated materials; • Continue working with OECD on finalizing guidance document for efficacy testing of swimming pool and spa products; • Expand the use of Structural Activity Relationship process; 	Work with OECD and NAFTA
<ul style="list-style-type: none"> • Continue working with Federal and State Government agencies on mold remediation activities. 	Work with Other Federal Agencies
<ul style="list-style-type: none"> • Continue collaborating with commercial efficacy testing laboratories to develop improvements to antimicrobial efficacy test methods • Issue the updated air, water, and material textile product performance guidelines for antimicrobial pesticides for public comment 	Other Initiatives

Enhancement of OPP's Science and Policy Framework	
Item	Total
Total FTE	9.2
Total Travel \$	\$17,757K
Total Extramural \$	\$25K
Total Extramural for Technical NOWSEE Homeland Security	\$65K
Total Intramural \$	\$5.241K

Overall Programmatic Management to Allow Us to Better Deliver On Our Vision	
Goals for FY2010	Workplan Title
<ul style="list-style-type: none"> • Document Management – Work with OPP Scanning Group • Records Management • Information Management/Technology • Web Content Management • Electronic Labeling an Data Submission • GovTrip • PeoplePlus/TAIS • Correspondence Tracking • Quality Assurance/Quality Control • Contracts • Budget • Human Resource 	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

Overall Programmatic Management to Allow Us to Better Deliver On Our Vision	
Item	Total
Total FTE	59
Total Travel \$	\$67,757
Total Extramural \$	\$1,378,114
Total Intramural \$	\$15,641
Total Homeland Security \$	\$350,000
Total Training/Registration\$	\$32,614

Current Antimicrobials FTE Resources

(Table excludes DD, DDD 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				0.10	4.10
Homeland Security/Special Projects	1.0					1.0
Ombudsman/Communications and Special Projects	2.0					2.0
Post-RED Follow-up			1.0	2.0	1.0	4.0
Product Reregistration		0.1	2.0		1.0	3.10
Registration		8.8	3.0	6.0	6.0	23.8
Registration Review			4.0	6.5		10.5
Senior Scientists	2.0			1.0	.25	3.25
OECD/NAFTA				0.25	.25	.50
Special Projects (Policy & interpretative guidance development)		2.1		0.25	2.40	4.75
Stay-In-School & SCEP Students	1.0	1.0				2.0
TOTALS	10.0	12.0	10.0	16.0	11.0	59