OFFICE OF INSPECTOR GENERAL

Catalyst for Improving the Environment

Public Liaison Report

EPA Did Not Properly Process a Hospital Disinfectant and Sanitizer Registration

Report No. 2007-P-00018

March 29, 2007

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Abbreviations

EPA	U.S. Environmental Protection Agency
GAO	Government Accountability Office
OIG	Office of Inspector General
OPP	Office of Pesticides Program
OPP-AD	Office of Pesticides Program-Antimicrobials Division
PRIA	Pesticides Registration Improvement Act
PSB	Product Science Branch
RMB II	Regulatory Management Branch II

U.S. Environmental Protection Agency
Office of Inspector General

2007-P-00018
March 29, 2007

At a Glance

Catalyst for Improving the Environment

Why We Did This Review

We did this review in response to a hotline complaint alleging that a pesticide product was improperly registered by the U.S. Environmental Protection Agency (EPA) in 2004, over staff concerns and without the required fee. We sought to determine whether the product contained a new active ingredient, which would have lengthened the approval process and required EPA to bill the registrant a $50,000 registration fee. We also looked at whether EPA resolved staff concerns and science review deficiencies prior to registration.

Background

The product reviewed is a disinfectant and sanitizer designed to kill bacteria and viruses on hard, non-porous, inanimate surfaces, primarily in hospital patient care areas. The product has failed EPA efficacy tests and EPA has asked the manufacturer to voluntarily withdraw the product. We do not include the name of the product or manufacturer in this report due to possible enforcement action.

For further information, Contact our Office of Congressional and Public Liaison at (202) 566-2391.

To view the full report, click on the following link:
www.epa.gov/oig/reports/2007/20070329-2007-P-00018.pdf

EPA Did Not Properly Process a Hospital Disinfectant and Sanitizer Registration

What We Found

EPA's Office of Pesticides Program-Antimicrobials Division (OPP-AD) did not properly process registration for an antimicrobial pesticide that was the subject of our review. Specifically:

- OPP-AD did not properly recognize that the antimicrobial pesticide product contained a new active ingredient. As a result, OPP-AD did not collect the registration fee for products with new active ingredients. For this particular product, the fee would have been $50,000.
- OPP-AD branch management did not address all staff concerns regarding product registration. Staff consistently indicated a former manager exerted verbal pressure for them to approve the product reviewed. This contributed to a working environment of distrust, fear, and confusion that current OPP-AD managers must work hard to overcome.
- OPP-AD branch management did not resolve all science reviewers' concerns regarding the product.

The deficiencies generally occurred due to a lack of procedures. Throughout our review, a lack of documentation made it difficult for us to identify the rationale for decisions made. Post-registration testing, at the Director's request, found problems regarding the effectiveness of the product. This led to EPA enforcement officials asking the registrant to voluntarily withdraw the product from the marketplace.

What We Recommend

We recommend that the Director, Office of Pesticides Program, establish procedures to determine the accuracy of active ingredient status and to assign responsibilities, document and resolve discrepancies between staff concerns and management decisions, and document the resolution of data deficiencies. We also recommend surveying staff to determine if they still have concerns about their work environment and, if so, take steps to resolve their issues. In addition, we recommend performing a detailed root cause analysis of products similar to the one that failed to identify why a significant number of antimicrobial products are not effective. The Agency generally agreed with our conclusions and recommendations and is taking action to correct the issues identified in our report.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
INSPECTOR GENERAL

March 29, 2007

MEMORANDUM

SUBJECT: EPA Did Not Properly Process a Hospital Disinfectant and Sanitizer Registration
Report No. 2007-P-00018

FROM: Eileen McMahon
Assistant Inspector General for Congressional and Public Liaison

TO: Jim Gulliford, Assistant Administrator for
Office of Prevention, Pesticides, and Toxic Substances

This is our report on our review of the issues surrounding the registration of a hospital disinfectant and sanitizer that resulted from an Office of Inspector General (OIG) Hotline complaint. The report contains findings and recommendations that describe needed improvements the OIG has identified and corrective actions the OIG recommends. This report represents the opinion of the OIG and the findings contained in this report do not necessarily represent the final U.S. Environmental Protection Agency (EPA) position. Final determinations on matters in this report will be made by EPA managers in accordance with established resolution procedures.

The findings in this report are not binding in any enforcement proceedings brought by EPA or the Department of Justice under the Federal Insecticide, Fungicide, and Rodenticide Act to recover costs.

The estimated cost of this report – calculated by multiplying the project's staff days by the applicable daily full cost billing rates in effect at the time is $300,881.

Action Required

In accordance with EPA Manual 2750, you are required to provide this office with a written response within 90 days of the final report date. You should include a corrective action plan for agreed upon actions, including milestone dates. We have no objections to the further release of this report to the public. This report will be available at http://www.epa.gov/oig.

If you or your staff have any questions, please contact me at 202-566-2391; or Paul McKechnie, Product Line Director for Public Liaison, at 617-918-1471 or mckechnie.paul@epa.gov.

Table of Contents

Chapters

Appendices

Chapter 1
Introduction

Purpose

On May 5, 2005, the U.S. Environmental Protection Agency (EPA) Office of Inspector General (OIG) received an anonymous hotline complaint. The complaint alleged improprieties within EPA's Office of Pesticides Program-Antimicrobials Division (OPP-AD) in the registration of an antimicrobial pesticide for use as a hospital disinfectant and sanitizer. In particular, the complainant alleged that the product contained a new active ingredient but was not registered as such, resulting in EPA not billing the registrant for the $50,000 registration fee. The complainant also alleged EPA registered the product over the objections of staff, and that a former branch chief coerced staff into approving the registration.

Our overall objective was to determine whether EPA appropriately registered the hospital disinfectant and sanitizer product in question. Based on concerns raised in the hotline complaint, we sought to answer the following questions:

1. Did the product contain a new active ingredient and, if so, was the application processed as though it did?

2. Did staff express concerns about the product registration and, if so, what steps did EPA managers take to resolve their concerns? What pressure, if any, did EPA managers exert on staff to approve the registration?

3. Were science review deficiencies resolved? Were the active ingredients listed on the label complete and accurate?

We do not disclose the name of the product or the product's manufacturer in this report due to possible enforcement action.

Background

Institutions, such as hospitals, and individuals spend about $1 billion each year on antimicrobial products. More than 5,000 such products, containing about 275 active ingredients, are currently registered with EPA and sold in the marketplace. Nearly 60 percent of antimicrobial products registered, such as the one reviewed, are intended for use in hospitals and other health care environments.

In 2004, EPA conditionally registered an antimicrobial pesticide manufactured by a privately held company. The pesticide was to be used primarily as a hospital

disinfectant and sanitizer. The registrant submitted its application to EPA on March 22, 2004. EPA conditionally approved the product on October 21, 2004. This approval allowed the registrant to market the product and enter into negotiations with distributors. A chronology of events is in Appendix A.

The registrant claimed the product was a broad spectrum, ready-to-use public health disinfectant, cleaner, and food contact sanitizer. "Broad spectrum" refers to a product that is efficacious against both gram-positive and gram-negative bacteria. "Ready-to use" means the product does not need to be diluted or mixed. The company said the product is primarily intended for general use in hospitals on hard, nonporous, inanimate objects and surfaces. This would include non-critical medical devices, surgical tables, and anesthesia machines in patient care areas. The product reviewed was in liquid form.

EPA conducts post registration testing only of active ingredients of some products with hospital and tuberculocidal claims. The registrant-reported composition of the inert ingredient component of the product was not confirmed because EPA does not verify the composition of ingredients listed as inert. Thus, EPA tests confirmed only the presence and percentage of active ingredients in the product, not the composition of inert ingredients.

OPP-AD, within EPA's Office of Prevention, Pesticides, and Toxic Substances, is responsible for all regulatory activities associated with antimicrobial pesticides. This includes product registrations. Within OPP-AD:

- The **Product Science Branch (PSB)** conducts acute toxicology, efficacy, and product chemistry data reviews of antimicrobial pesticides, and identifies any data deficiencies that should be resolved by the Regulatory Management Branches prior to registration approval.
- The **Regulatory Management Branch I** is responsible for registering some antimicrobial products, outreach and communication efforts, and requesting post registration product testing.
- The **Regulatory Management Branch II (RMB II)** is also responsible for registering antimicrobial products, including ones with the active ingredients in the subject product, as well as re-registration. It approves or denies approval for all original products and can override others' objections to the registration.

Scope and Methodology

We performed our review in accordance with *Government Auditing Standards*, issued by the Comptroller General of the United States. We conducted the review from August 8, 2005, to September 28, 2006. We performed most of our work at OPP-AD in Washington, DC. We also visited the OPP Microbiology and

Analytical Chemistry Laboratory Offices, Environmental Science Center, Fort Meade, Maryland.

For all three objectives, we reviewed the product's official records (the "jacket") from the 2004 registration application to the present, and reviewed other pertinent documents. We also reviewed applicable laws, regulations, policy, and guidance. We obtained information primarily from OPP and EPA's Intranet site. We interviewed OPP-AD staff members from RMB II and PSB who were involved in the registration. We interviewed EPA Fort Meade laboratory scientists to discuss the scientific evaluation of the product health claims and product chemistry analysis. We observed a demonstration of how the laboratory evaluated the product health claims. Throughout the review we met with OPP-AD managers to discuss the status of our work and obtain feedback.

For Objective 2, we interviewed the current and former OPP-AD associate director, its current director, RMB II and PSB branch chiefs, the former RMB II branch chief, and the OPP ombudsman. For Objective 3, we analyzed scientific data, and reviewed PSB's assessment of the data from scientific studies to determine whether the conclusions drawn by the registrant or its contract laboratories were scientifically sound.

We interviewed the Office of Enforcement and Compliance Assurance official who reviewed the Fort Meade laboratory test results and referred the case to the appropriate EPA region for enforcement action. We also contacted the regional enforcement case officer to obtain the current status of the case.

Our review of management controls and compliance was limited to those related to the registration process for the subject product. However, written internal controls were inadequate due to a general lack of written procedures. We obtained Office of Prevention, Pesticides, and Toxic Substances Fiscal Years 2004 and 2005 Federal Managers' Financial Integrity Act assurance letters. These letters did not identify any old or new management control weaknesses or management challenges. However, OPP-AD officials were unaware of their role in the preparation of the assurance letters. They could not provide us with their branch or divisional level input toward the final assurance letters. Thus, we could not draw any conclusions regarding the absence of reported weaknesses in the assurance letters.

Prior Audit Coverage

In 1990, the Government Accountability Office (GAO) issued a report, *EPA Lacks Assurance Disinfectants Work (GAO/RCED-90-139).* The report noted that EPA lacked sufficient internal controls to ensure the quality and integrity of the disinfectant efficacy data that registrants submitted. It also noted registrants submitted selective data to EPA, and EPA lacked an enforcement strategy to ensure that marketed disinfectants worked as claimed. According to EPA officials, they have generally implemented GAO's recommendations. We did not verify EPA's claims because it was not within the objectives of our review.

Chapter 2
Lack of Procedures Led to Registration Not Being Processed Properly

OPP-AD did not properly process registration for the antimicrobial pesticide that was the subject of our review, and failed to recognize a new active ingredient in a hospital disinfectant and sanitizer product. Also, OPP-AD did not address concerns regarding the effectiveness of the product. Specifically:

- OPP-AD did not properly recognize that the product contained a new active ingredient. As a result, EPA did not bill the registrant the fee for products with a new active ingredient. For this particular product, the fee would have been $50,000.
- Former OPP-AD branch managers did not address all staff concerns regarding product registration. Several staff consistently indicated that a former manager exerted verbal pressure for them to approve the product, contributing to a working environment of distrust and confusion.
- OPP-AD branch managers did not resolve all science reviewers' concerns regarding product approval.

The deficiencies generally occurred due to a failure to identify a new active ingredient and a general lack of procedures regarding handling registrations. Throughout our review, a lack of documentation made it difficult for us to identify the rationale for decisions made. Post-registration testing demonstrated problems regarding the effectiveness of the product. At EPA's request, the registrant voluntarily withdrew the product from the marketplace.

Misclassifying Active Ingredient Status May Have Resulted in Lost Fees

OPP-AD staff and managers indicated they did not assess or collect the registration fee required for products containing a new active ingredient. Based on the applicable fee schedule and other factors, the fee would have been $50,000. OPP-AD did not recognize that the product contained a new active ingredient.

New Active Ingredient Not Designated as Such

The current RMB II branch chief believed that the active ingredient "X" in the product was not treated as a new active ingredient because the ingredient had been identified as an active ingredient in a previously registered product. However, that product's registration was canceled and thus no longer registered.

OPP-AD's current management team agrees that this product should have been processed as containing a new active ingredient. The current RMB II branch chief said he initially believed once a chemical was an active ingredient in a registered product it cannot again become a new active ingredient, even if the prior product's registration is canceled. However, he agreed that based on additional OPP clarification, the product should have been considered as having a new active ingredient. Other OPP-AD managers agreed. In an email, the current branch chief also noted that in hindsight it would appear that this should have been treated as a new active ingredient procedurally given that there were no currently registered products with active ingredient "X" listed as an active ingredient when the application was received.

Further, there were inadequate procedures to determine when a product with an active ingredient has been canceled. Without adequate procedures, confusion resulted. The OPP-AD division director said that the PSB chemist should have identified that there was a new active ingredient through his review of the Product Code related to the canceled registration. However, the director also said that product coding in the database does not distinguish between current and canceled registrations. Consequently, staff may not have been aware the prior product was canceled. The PSB chemist indicated he should have caught the classification mistake. RMB II staff believed the former RMB II manager was responsible for the mistake because that person had agreed during the pre-registration meeting to register the product without a new active ingredient designation.

In addition to costing the registrant the $50,000 fee, the designation of a new active ingredient could have taken up to 1.5 years to register. OPP-AD staff noted that most products are registered in less than a year.

Key Decision Documents Not Available

The official record did not contain key decision documents. The record contained no documentation regarding the new active ingredient determination. It did not contain a record of key meetings, such as the pre-registration meeting. It did not contain documentation of how and why the former RMB II manager overrode staff objections about the way the product was registered. As a result, staff and managers had differing recollections of how the product was registered without a new active ingredient designation.

OPP-AD's written guidance notes that within 30 days after the pre-application meeting, OPP-AD is to provide a set of minutes. The minutes are to describe the matters discussed, any commitments made, and any conclusions reached. Staff involved in the meeting should concur with the contents of the meeting record prior to its issuance to the company. Both the OPP-AD associate director and PSB team leader said it is important to record and keep an EPA-approved copy of the pre-registration meeting in the official file, referred to as the "jacket." However, both acknowledged this is not consistently followed. The OPP-AD

associate director noted that if such records were kept, the misunderstandings and controversies regarding the pre-registration meeting discussion and the registrant agent's claim regarding this product could have been avoided.

Pre-registration meetings should not be used to make decisions such as the acceptability of test data. The purpose is clearly to ensure that all forms, data, and other relevant information needed for a new registration are contained in the package. Application package content is a primary function of these meetings. In his response to our draft, the OPP director noted that pre-application meeting guidance is posted on its Website and that application content is a primary focus of those meetings.

Because the jacket did not contain all documentation critical to the registration decision, we relied on staff and managers to describe the circumstances surrounding the misclassification of the product. As OPP's director noted in the response to our draft report, the jacket is not intended to contain all documents related to the registration, such as the actual laboratory studies.

OPP-AD Did Not Appear to Address Staff Concerns

OPP-AD managers did not have written procedures to determine whether there were staff concerns regarding a product registration approval, or to address or document those concerns. OPP-AD managers and staff could not describe how staff concerns should be resolved, nor provide detailed procedures on the resolution process. As a result, staff and management had differing opinions about duties and responsibilities. Staff made verbal statements indicating their manager exerted verbal pressure to approve registration of the product reviewed. However, due to the lack of documentation, neither we nor staff could find evidence that this occurred. While we do not intend to imply that this one case is indicative of the division in general, it is a serious and continuing concern among staff and should be addressed by OPP-AD management. OPP commented that it does have established procedures to resolve staff concerns and will again disseminate them to all staff and managers.

Staff told us the product was registered against their verbal objections regarding the new active ingredient issue and unresolved science deficiencies. Although their concerns were not documented, they unanimously and consistently told us they had informed the former RMB II branch chief about these matters.

The primary RMB II product reviewer for active ingredient "X" said he told the former RMB II chief that he believed the product contained a new active ingredient and that the product chemistry report deficiencies should be resolved prior to approval. He said he felt so strongly that he refused to sign the registration approval form. Rather than addressing his objections, the branch chief instructed another staff member to prepare and approve the registration form. Although the product took 3 months longer than the division's 4-month

goal, the product reviewer said he believed the former RMB II branch chief and OPP-AD divisional director pressured him to approve the product because they had promised the registrant a "quick" registration. The former branch chief acknowledged that the new active ingredient registration takes much longer than the registration of a product with "old active." However, the division director and former branch chief denied these allegations and said they did not recall the staff raising concerns.

The RMB II product manager who approved the registration also stated she had product chemistry concerns. However, she said she was new at the time and did not feel she should hold up the product's approval. Further, she noted she was a microbiologist, while the branch chief was a chemist and the unresolved issues were primarily chemistry-related. However, she said employees reluctantly performed tasks because they "did not want to be in trouble." She said she and other staff approved the registration "because the branch chief told them to do it."

A third product reviewer said she was glad her involvement with the registration of this product was minimal. She said that the registrant's agent was putting an "extreme amount of pressure on the staff" to get the product approved "within the promised timeframe." This product reviewer declined to be involved with the registration or sign the approval letter. She was able to convince the former branch chief to not give her further responsibilities related to this product, noting she feared approving the product "would come back to haunt her."

We discussed the staff concerns issue with the current OPP-AD associate director and RMB II branch chief. The associate director told us that OPP-AD began evaluating the division's working environment in May 2006. The associate director also said the Division initiated team building exercises. Both the associate director and branch chief expressed their willingness to continue taking measures to prevent reoccurrence of similar situations in the future.

Not All Science Review Deficiencies Resolved

OPP-AD procedures did not require PSB scientists to conduct product reviews and analyses that would help them determine whether registrants' conclusions were scientifically sound. Although OPP stated that critical analysis is the essence of a PSB reviewer's job, the PSB scientists did not agree. Questionable data and conclusions also went unnoticed during supervisory reviews. OPP noted that, because this was a routine package, managers would likely not get involved in the product science review. We agree that manager involvement in routine cases may not be necessary. However, in this case, a brief management review may have provided the vehicle for staff to have their concerns heard.

Some of these data clearly questioned the efficacy of the product (the product's ability to produce the desired effect). PSB scientists and their team leader told us their job did not require them to critically analyze data or question the data.

OPP's response noted that when the registrant resubmitted sanitizer claim test results that concluded the product was efficacious, the sanitizer claim had to be accepted. Others raised questions about product chemistry and its storage stability. Because neither the registrant's filing nor its jacket at OPP-AD contained all required data, we could not definitively determine why the process failed.

Although staff raised concerns about certain deficiencies in the registrant-submitted data, they failed to recognize other noticeable inconsistencies that were indicators of potential problems. Procedures do not require that the PSB manager and team leader ensure that staff critically review registrants' data. In some cases, the unidentified inconsistencies were more significant than the concerns the PSB staff raised. For example, data submitted by the registrant for its sanitizer claim showed that the contact time needed to pass the sanitizing test was longer than contact time necessary to pass the tuberculocidal test – the opposite of what you would expect because the tuberculosis bacteria are more difficult to kill than most other species of bacteria.

Also, the registrant submitted required data from efficacy and toxicity studies, but did not submit all required product chemistry data. Because the subject product was produced by an integrated system, the registrant was required to submit all product chemistry data, including data on water solubility, vapor pressure, and octanol/water coefficient. Certain chemical and physical characteristics of the product (e.g., color, odor, physical state) are needed for EPA to respond to emergency requests for identification of unlabeled pesticides involved in accidents and spills or implicated in poisoning episodes. Data on stability, oxidation/reduction potential, flammability, explodability, storage stability, corrosion characteristics, and dielectric breakdown voltage are used for hazard assessment.

Initial product chemistry reviews, conducted by the PSB chemist, found some data unacceptable because the data did not meet regulations or EPA guidelines, or were not addressed in the application submission. Prior to registration, the registrant clarified certain issues raised, and requested waivers for others. However, the jacket did not contain all records of decisions reached regarding waiver requests, nor could OPP-AD staff or management provide copies of the waiver approvals. Management believed these unresolved deficiencies did not affect OPP-AD's ability to make a decision about registering the product. Nonetheless, documentation on the final disposition of the waiver requests is needed to support decisions and provide for transparency.

During post-registration testing, the Fort Meade laboratory does not typically, nor in this case was it asked to, analyze a sample of the product reviewed to determine all its specific ingredients. Therefore, we could not determine whether the inert ingredients listed on the label were complete and accurate.

Distributor Products Were Subsequently Registered

In January 2006, EPA laboratory tests determined that the product was ineffective against *Staphylococcus aureus* and *Pseudomonas aeruginosa* and, therefore, EPA could not substantiate its health claims. OPP-AD's PSB prepared the required official memo to the EPA Office of Enforcement and Compliance Assurance for taking enforcement action to have the product withdrawn from the marketplace. However, in April 2006, 10 weeks after the product was determined ineffective and 7 weeks after OPP-AD's PSB prepared the official memo, another OPP division – the Information Technology and Resources Management Division – approved the registration of three products manufactured by the same company with the same ingredients but distributed under different names by a different company.

EPA asked the registrant to voluntarily withdraw the original and all distributor products from the marketplace. After being informed by EPA of the failing laboratory evaluations, the registrant asked the distributor product company to stop distributing the products.

Upon receiving the distributor product registration application, EPA does not currently check the status of the original product for any pending adverse actions. The OPP-AD manager agreed that the problem was the timing of the various actions. He also acknowledged that those who register distributor products had no way of knowing that there was an imminent action and would not know there was a pending action unless they routinely checked with the Office of Enforcement and Compliance Assurance. He stated that improving the distributor product registration process could help prevent distributing products that are not effective.

Post-Registration Efficacy Test Results Show Problems

OPP-AD accepts registrants' submitted label claims that are supported by appropriate data and does not conduct its own pre-registration efficacy testing. Further, OPP-AD does not currently have the statutory authority to conduct pre-registration testing itself. Post-registration hospital disinfectant and antimicrobial test results available to us showed a 40-percent failure rate for tuberculocidal product tests (25 failures out of 62 tests). It also showed a 29.5-percent failure rate for hospital disinfectant tests (76 failures out of 259 tests). EPA does not have a mechanism to track and determine the root cause of such failures.

In a 1990 GAO report, *EPA Lacks Assurance Disinfectants Work* (GAO/RCED-90-139), GAO noted that EPA lacked sufficient internal controls to ensure the quality and integrity of the disinfectant efficacy data that registrants submitted.

The current OPP-AD associate director acknowledged that this is a key issue and improvements are still needed in this area. We believe that fully implementing our recommendations should help reduce the rate of post-registration efficacy failures.

Conclusions

OPP-AD did not have written, detailed procedures to guide the antimicrobial pesticide registration process. Because staff and managers did not correctly identify whether the product reviewed contained a new active ingredient, EPA did not bill the registrant the $50,000 registration fee. Also, staff and managers are unclear about how to resolve staff concerns about registration deficiencies. Product science branch reviewers disagreed with their managers about their duties and, as a result, did not critically review and analyze key product data. The registrant's jacket did not contain key decision documents. OPP-AD's lack of procedures resulted in confusion among the staff and different perceptions regarding responsibilities between the staff and management. Uncertainty about responsibilities and authority created an environment of distrust and confusion within OPP-AD. Current management believes this environment has improved and management is committed to resolving any remaining issues.

Recommendations

We recommend that the Director, Office of Pesticide Programs:

2-1 Establish procedures to:

- Correctly identify the status of each active ingredient to ensure that an ingredient previously recognized as active is not part of a product for which registration was subsequently canceled.

- Assign responsibilities and authority to identify new active ingredients and prepare detailed workflow instructions to process registration applications.

- Determine the necessity of meeting with registrants and their agents, and document the purpose and outcome of all such meetings.

- Resolve and document discrepancies between staff concerns and management decisions related to product registration.

- Encourage all staff to critically review registrant-submitted data to ensure data are scientifically sound and raise appropriate concerns about the product's chemical composition, toxicity, and efficacy.

- Ensure that the approval or disapproval of waivers and resolution of all data deficiencies are documented in the jacket.

- Prevent distributor product registrations when the original product is under consideration for enforcement action. Require staff to timely share failing post-registration test results with appropriate divisions responsible for reviewing distributor product registration applications and granting approval.

- Document the resolution of all data deficiencies.

- Determine and assess registrant fees.

2-2 Determine whether OPP-AD employees still have concerns about their working environment and, if so, work to resolve staff issues. In the interim, continue divisional and/or branch team building exercises that would include clarification of roles and responsibilities and management expectations.

2-3 Perform a detailed root cause analysis of antimicrobial pesticides similar to the subject product that failed post-registration testing, and identify appropriate actions to minimize the registration of failing products. Such steps could include developing a pre-registration, sample check program, or similar effort that would provide the added assurance.

Agency Comments and OIG Evaluation

EPA generally agreed with our conclusions and recommendations and stated that in many cases it has begun taking, or completed, actions to correct issues that we identified. EPA made detailed comments on our draft report and, where appropriate, we made revisions. EPA's complete response is in Appendix B. We redacted one line in EPA's response because it may contain Confidential Business Information.

OPP agreed that the product should have been processed as a new active ingredient and the registrant should have been billed a registration fee. It has taken steps to more consistently document pre-registration meeting results, posted pre-application meeting guidance on its Website, and noted that it makes every effort to ensure its files properly document Agency decisions.

OPP agreed to remind staff about procedures to address staff concerns about registration issues. OPP did not agree that the one registration we reviewed was indicative of larger management issues. We do not intend to imply that this one registration should be viewed as an indictment of the entire Antimicrobials Division. We do note that other staff and managers were unsure about how to resolve scientific differences and did not share the same opinion about their duties and responsibilities. OPP's willingness to refresh staff understanding about their duties and how to resolve differences should help alleviate confusion.

Science reviewers consistently told us that, in part because they are not present during testing, they did not believe they were in a position to question a registrant's pre-registration test results. Science reviewers stated that if the registrant submits all required data and that data supports the product claims, it is not up to EPA science reviewers to question the validity of the data. We disagree and noted several examples that should have caused EPA reviewers to question the efficacy of the product that was the subject of this review. For example, reviewing the data the registrant submitted, we found the tuberculocidal contact time relative to the sanitizing contact time to be inconsistent with expectations. We believe OPP staff should have questioned the registrant about these contact time claims and/or required the registrant to conduct more tests before registering the product.

We removed the recommendation to collect the registration fee because OPP noted that it does not have legal authority to collect back registration fees. We added language to recommendation 2-1 for OPP-AD to add procedures for accurately identifying and assessing registrant fees.

We do believe that there is merit in analyzing staff attitudes and the general working environment. Although OPP correctly notes that this was one incident, involving a manager who no longer works for EPA, current staff told us they were reluctant to raise concerns and are confused about their duties and responsibilities. We believe it is important that current Antimicrobials Division leadership demonstrates its willingness to move forward from the past and work with staff to correct any confusion and mistrust that staff may harbor.

We clarified our statement on page 10 regarding pre-registration testing requirements. We noted that OPP does not conduct in house pre-registration tests. We added language to recommendation 2-4 encouraging OPP to pursue a sample check program, or similar effort, in an attempt to improve product efficacy test results.

Status of Recommendations and Potential Monetary Benefits

RECOMMENDATIONS						POTENTIAL MONETARY BENEFITS (in $000s)	
Rec. No.	Page No.	Subject	Status[1]	Action Official	Planned Completion Date	Claimed Amount	Agreed To Amount
2-1	11	Establish procedures to: • Correctly identify the status of each active ingredient to ensure that an ingredient previously recognized as active is not part of a product for which registration was subsequently canceled. • Assign responsibilities and authority to identify new active ingredients and prepare detailed workflow instructions to process registration applications. • Determine the necessity of meeting with registrants and their agents, and document the purpose and outcome of all such meetings. • Resolve and document discrepancies between staff concerns and management decisions related to product registration. • Encourage all staff to critically review registrant-submitted data to ensure data are scientifically sound and raise appropriate concerns about the product's chemical composition, toxicity, and efficacy. • Ensure that the approval or disapproval of waivers and resolution of all data deficiencies are documented in the jacket. • Prevent distributor product registrations when the original product is under consideration for enforcement action. Require staff to timely share failing post-registration test results with appropriate divisions responsible for reviewing distributor product registration applications and granting approval. • Document the resolution of all data deficiencies. • Determine and assess registrant fees.		Director, Office of Pesticides Program		$50,000	
2-2	12	Determine whether OPP-AD employees still have concerns about their working environment and, if so, work to resolve staff issues. In the interim, continue divisional and/or branch team building exercises that would include clarification of roles and responsibilities and management expectations.		Director, Office of Pesticides Program			
2-3	12	Perform a detailed root cause analysis of antimicrobial pesticides similar to the subject product that failed post-registration testing, and identify appropriate actions to minimize the registration of failing products. Such steps could include developing a pre-registration, sample check program, or similar effort that would provide the added assurance.		Director, Office of Pesticides Program			

[1] O = recommendation is open with agreed-to corrective actions pending;
C = recommendation is closed with all agreed-to actions completed;
U = recommendation is undecided with resolution efforts in progress

Appendix A

Chronology of Product Registration

Date	Action
January 2004	**New Law Signed:** The Pesticide Registration Improvement Act was signed by the President, providing more specifics on implementing the Federal Insecticide, Fungicide, and Rodenticide Act. The President's approval triggered a 60-day implementation period for EPA prior to the March 23, 2004, implementation, under which EPA took a number of steps to implement the new Act.
February 19, 2004	**Pre-Registration Meeting Held:** The registrant's agent met with former RMB II branch chief and other OPP-AD staff to propose registering product.
March 17, 2004	**Federal Register Notice Issued:** EPA published Federal Register notice related to fees and timeframes. According to fee schedule, registrant would have been billed a $50,000 fee if product had a new active ingredient.
March 22, 2004	**Application Submitted to Agency:** The registrant submitted application. The registrant's package claimed OPP-AD agreed the product qualified for a 120-day review and active ingredient "X" would not be considered a new active ingredient.
March 23, 2004	**New Law Effective:** The Pesticide Registration Improvement Act goes into effect.
June 23, 2004	**OPP-AD Letter Sent to Registrant's Agent:** The letter indicates that the registrant's application was deficient, noting acute toxicity data were incomplete.
July 7, 2004	**Agency Product Chemistry Review Performed:** Reviews found the concentration of listed actives on the registrant's confidential statement of formula consistent with the label and that all ingredients in the formulation were acceptable for use.
July 15, 2004	**Additional Data Submitted Via Email:** The registrant's agent submitted additional efficacy data for sanitizing claims requested by an OPP-AD scientist.
July 20, 2004	**OPP-AD Letter Sent to Registrant's Agent:** EPA informed the registrant that the application was further deficient because efficacy and product chemistry data did not support the product's use. The letter also suggested label revisions.
July 2004	**Some Requirements Waived:** PSB staff told us that they waived some data requirements for flammability, explodability, and dielectric voltage breakdown, but denied waivers for data requirements of stability, melting point, boiling point, dissociation constant, ocanol/water partition coefficient, water solubility, and vapor pressure. We were unable to verify staff statements because the files did not contain documentation of their decisions.
July 21, 2004	**Additional Data Submitted:** The registrant submitted additional efficacy data.
August 11, 2004	**Agent Response Submitted:** The registrant's agent responded to EPA's July 20 letter addressing deficiencies, and stated the letter appeared to contradict agreements in the February 19 pre-registration meeting.
October 21, 2004	**Conditional Registration Granted:** OPP-AD granted conditional registration.

Date	Action
December 28, 2004	**Amendment Accepted:** OPP-AD accepted an amendment to the registration with conditions – (1) submitting storage stability study by March 31, 2006, and (2) submitting eye and dermal acute toxicity studies.
January 13, 2005, and January 18, 2005	**Old Active Validation Requested:** The registrant's agent requested confirmation that the active ingredient – active ingredient "X" – was not considered a new active ingredient. The request resulted from "a few States" asserting that the ingredient is a new active ingredient.
January 24, 2005	**Letter to OPP-AD Submitted:** The registrant's agent submitted toxicity studies/amendments required by the December 28, 2004, letter.
January 2005	**Branch Chief Leaves EPA:** The RMB II branch chief at that time left EPA to work for a private company.
June 23, 2005	**Letter Regarding New Active Ingredient Sent:** OPP-AD sent letter to registrant's agent in response to request for confirmation that active ingredient "X" was not a new active ingredient. OPP-AD replied that it had concerns with the accuracy of the listed ingredient declared on the product label.
June 27, 2005	**Amendments Conditionally Accepted:** OPP-AD conditionally accepted amendments based on January 24, 2005, toxicity data.
July 28, 2005	**Amendment Application Received:** The registrant added a new organism and new enforcement analytical method to the label.
September 2005	**Samples Collected:** OPP-AD requested that EPA's Fort Meade laboratory collect samples for efficacy and chemical formulation analysis tests.
January - April 2006	**Laboratory Results Provided:** EPA received laboratory results from Fort Meade.
February 16, 2006	**Enforcement Memo Prepared:** PSB prepared an enforcement referral memo to EPA Office of Enforcement and Compliance Assurance.
April 6, 2006	**Distributor Product Registrations Approved:** Another OPP division granted conditional registration to three distributor products from another company. These products contain the same active and inert ingredients as the product reviewed, but are marketed by another company under different trade names. OPP approves distributor product registration without any evaluation of the status of the original product.
July 5, 2006	**Enforcement Memo Transmitted:** PSB sent the February 16, 2006, memo to the EPA Office of Enforcement and Compliance Assurance, which was received by that office on July 10.
July 31, 2006	**Voluntary Withdrawal Requested:** EPA Region 9 sent a letter to the registrant requesting voluntary withdrawal of the product in our review.
August 7, 2006	**Show Cause Letter Issued:** EPA Region 9 sent a "show cause" letter to the registrant.
August 28, 2006	**Laboratory Data Requested by Registrant:** The registrant's attorney responded to EPA's August 7 "show cause" letter requesting laboratory results. The letter stated the registrant remains committed to working cooperatively with EPA staff to resolve the matter. The letter stated the company is not distributing the product for commercial purposes so EPA did not need to issue a Stop, Sale, Use or Removal Order.

Appendix B

Agency Response to OIG Draft Report

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: OPPTS Comments on the Draft Public Liaison Report:
EPA Did Not Properly Process Hospital Disinfectant and Sanitizer Registration

FROM: James J. Jones, Director
Office of Pesticide Programs

TO: Paul D. McKechnie
Director for Public Liaison
Office of the Inspector General

This memorandum responds to your request for review and comment on the draft report prepared by the Office of the Inspector General which evaluates a Hotline compliant that the Office of Pesticide Programs, Antimicrobials Division did not properly process a registration application for a hospital disinfectant and sanitizer product.

In reviewing the document, it is clear that your staff have done an exceptional job of understanding our registration program under the Federal Insecticide, Fungicide and Rodenticide Act and its most recent amendment, the Pesticide Registration Improvement Act (PRIA) which was enacted in 2003. While no one looks forward to being under the scrutiny of an IG investigation, your staff conducted themselves with a high degree of professionalism and sensitivity that I believe contributed to the overall effectiveness of the investigative process.

In general my staff agree with the findings but are concerned that an isolated incident is being used largely to indict an entire Division. I share this concern and encourage your staff to strongly consider this issue as they finalize the report. Detailed comments are provided below.

Finding #1

- OPP agrees that the subject application should have been processed as a new active ingredient.

- The correct fee amount at the time of this application for this action would have been $50,000. This was the fee associated with a new active ingredient falling into the A42 fee category, which covers non-food, indoor use as described in FIFRA Section 2(mm).

- It would be more accurate to say that a fee of $50K would have been billed or assessed to the registrant. PRIA includes a provision for small business waivers of fees. The registrant in this case would likely have applied for such a waiver, which would have then been evaluated by the Agency. It is likely the company would have met the waiver criteria.

- PRIA did not change the definition of a new active ingredient. OPP provided additional clarification on the website as to how to interpret the fee categories listed in PRIA. It was at that time that the additional phrase "currently registered products" was added to articulate OPP's long-standing policy on new active ingredients.

- Page 5, Paragraph 2: This discussion could be simplified to make the point that the current management team agrees that the product should have been handled and processed as a new active ingredient.

- An A42 has a 540 day completion requirement under FIFRA Section 3(h), so it is more accurate to say that had the chemical been designated as a new active ingredient, it could have taken up to 540 days to complete the action. It should also be noted that given the nature of (redacted), and what is understood about that chemical, it is unlikely that a large database would have been required, which would also have shortened the potential review time needed.

- Page 5, Paragraph 5: Reference to "managers" is inappropriate since, based on our understanding of the investigation, only one manager was involved in that decision, the former Chief of RMB2 (Regulatory Management Branch 2).

- Guidance on pre-application meetings has been posted on the Agency website at http://www.epa.gov/oppad001/preapplmeet010.htm for a number of years. The purpose is to ensure that all forms, data, and other relevant information needed for a new registration are discussed. Application content is a primary focus of these meetings.

- OPP agrees that the implementation of Division guidance regarding the documentation of pre-registration meetings must be applied consistently. AD has taken steps to place renewed emphasis on this policy by re-issuing the policy and having follow-on discussions with staff in Branch and PRIA meetings about the importance of timely documentation of pre-registration meetings.

- OPP makes every effort to ensure that all product jackets contain documents critical to the registration of the product. It appears that documentation of the resolution of some key issues around this application was not developed or was not included in the file jacket (e.g., waiver determinations). Jackets do not normally include the actual studies themselves or, in many cases, reviews of studies since there are other document management systems in place to store those types of records. The jacket system is not designed to house all documents pertaining to a particular registration.

Finding #2

- There are established procedures within OPP to address the concerns of staff that hold a dissenting opinion on a give matter. Current AD management is aware of these procedures which describe how staff concerns should be resolved. Staff should also be aware of this policy since it was disseminated throughout OPP. Nevertheless, we will again provide staff with the policy.

- This finding is based on conflicting recollections of the events surrounding this registration action amounting to a "he said, she said" situation. The lack of documentation of the concerns raised in the interviews greatly weakens the assertion that OPP-AD management did not appear to address staff concerns. Further, the finding is exceedingly broad. Even if the information provided during the interview process is considered valid, this would have to be considered an isolated incident involving one manager who no longer is employed by the Agency. Therefore, the finding, if retained, should be very specific to pertaining to an isolated event in the past. Further, inference should not be made that there is a "working environment of distrust, fear and confusion". The report is silent on the condition of the current working environment in both the Branch and the Division, which would be more pertinent when considering recommendations.

- In terms of the statement regarding a "quick" registration it should be noted that the normal time frame for the type of action that this was classified as is 120 days. However, the action took almost 7 months to complete.

Finding # 3

- The role of science reviewers in OPP is to provide an independent, critical analysis of registrant submitted data in determining whether to register a product and how to label such a product to protect human health and the environment. This is the essence of these positions; therefore, the information presented on Page 7, Paragraph 5, appears to have been taken out of context.

- The PSB Team Leaders are responsible for final review and approval of all data that are submitted to the Branch. Therefore, it is not customary or necessary for the PSB Branch Chief to engage in the final review process. However, the Branch Chief is involved in the review process when it involves a new technology or submission that requires

management oversight. Since this was a routine application, the PSB Branch Chief did not review the data or conclusions made by the science staff.

- Efficacy concerns over sanitizer claims were sent to the company indicating that all sanitizer claims had to be removed. The registrant later submitted efficacy data to satisfy the sanitizer claim for which an acceptable review is in the product registration file.

- In reference to the chemistry and efficacy data submitted to support the application, mention is made of OPP staff failing to "recognize other notable inconsistencies that were indicators of potential problems". OPP has not received the analysis that was used by the IG to come to this conclusion, so it is not possible to comment on the accuracy of this statement.

Recommendations:

OPP agrees with bullets 1 - 8.

2-2

PRIA does not include provisions for charging a registrant a fee after a registration action has been completed. OPP is not aware of any process or procedure for legally billing a registrant in a case like this. Therefore, OPP does not believe it has the legal authority to implement this recommendation. Further, the term "collect" is not appropriate. OPP issues an invoice to registrants, who either pay the fee or request a waiver. Therefore, the appropriate language would be to "Issue an invoice…." Based on our limited knowledge of the company, we believe that, if a large fee were invoiced to this company, it is likely that they would seek and receive a fee wavier. Also, the correct fee amount at the time of this application for this action would have been $50,000. This was the fee associated with a new active ingredient falling into the A42 fee category which covers non-food use, indoor uses as described in FIFRA Section 2(mm).

2-3

OPP disagrees with this recommendation. The finding that relates to this recommendation is based on conflicting recollections of the events surrounding this registration action amounting to a "he said, she said" situation. The lack of documentation of the concerns raised in the interviews greatly weakens the assertion that OPP-AD management did not appear to address staff concerns. Further, the finding is exceedingly broad. Even if the information provided during the interview process were considered valid, this would have to be considered an isolated incident involving one manager who no longer is employed by the Agency. Therefore, the finding, if retained, should very specifically pertain to an isolated event in the past, and the inference should not be made that there is a "working environment of distrust, fear and confusion". The report is silent on the condition of the current working environment both in the Branch and the Division which would be more pertinent when considering recommendations.

2-4

OPP-AD is gathering data towards understanding the possible causes for antimicrobial products passing the efficacy requirements at the time of initial registration, but failing the same requirement during the post registration testing program. Based on the database, we will evaluate the active ingredients used to formulate the products, possible anomalies in the manner in which the products were tested for registration versus post-registration testing, and other issues that have been brought to AD's attention regarding the test methods. In addition, due to the documented problems with repeatability and reproducibility within the qualitative Use-Dilution test methods, AD is working in conjunction with the Organization for Economic Cooperation and Development (OECD) to validate and adopt a quantitative test method for hard surface disinfectants.

2-5

On page 9, the report states "OPP-AD does not currently have the statutory authority to require pre-registration testing." This statement is not accurate. OPP does require the applicant for registration to conduct pre-registration testing, and our evaluations are based, in part, on the resulting data. However, OPP-AD plans to investigate the feasibility of a sample check program for select hospital disinfectants. This may reduce the number of products that ultimately fail the post-registration surveillance. OPP-AD believes the remaining recommendations from the GAO's 1990 report, *EPA Lacks Assurance Disinfectants Work* (GAO/RCED-90-139) have been implemented, as outlined in the July 6, 2006, memo (see attachment).

Attachment

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 7, 2006

MEMORANDUM

Subject: GAO Report Recommendations
GAO/RCED-90-139

From: **S/**Michele E. Wingfield, Chief
Product Science Branch
Antimicrobials Division (7510C)

To: Tapati Bhattacharyya, Project Manager
Office of Congressional and Public Liaison (OCPL) (3AI00)

The Antimicrobials Division, Office of Pesticide Programs, provides the following response to your request for an update on the recommendations made by the Government Accounting Office (GAO) in their 1990 report entitled, "Disinfectants, EPA Lacks Assurance They Work." Please feel free to contact me if you have any additional questions.

Recommendation # 1:

To increase the degree of certainty that disinfectant efficacy test methods and standards are valid, we recommend that the Administrator, EPA, develop a detailed plan, including cost estimates and milestones, to resolve the controversies surrounding existing methods and standards. The plan should include a research strategy that addresses problems with the alleged variability in test methods, adequacy of lab tests to simulate actual use, and the validity of performance standards, as discussed in this chapter.

Response: Test Methodology Development

The Agency has had a guidance strategy in place since 1987 outlining the need for investigation of the test methods used to support efficacy claims of antimicrobial products. In 1990 and 1991,

the Agency awarded three cooperative agreements for research and development of test methods to address sporicidal, tuberculocidal, and virucidal testing. The research for these three cooperative agreements was completed in the late 1990s. Of the three, the sporicidal test method was further developed into a "universal" method that could evaluate the efficacy of spores, mycobacterium, vegetative bacteria, fungi, and viruses. This new method has a quantitative performance (based on log reduction) rather than the previous qualitative (presence/absence) standard that is used for the existing AOAC test methods. As a part of international harmonization efforts, in 2002, the Agency hosted an Organization for Economic Cooperation and Development (OECD) workshop to begin discussions on harmonizing test methods for public health antimicrobial products. Following the workshop, a steering committee has been working towards developing a test method specifically for hard surface disinfectants. If approved, the data generated from this method would be acceptable in all OECD member countries. The Antimicrobials Division has representation on the steering committee and the Biological and Economic Analysis Division's Microbiology Laboratory will participate in the validation of the new method. The method proposed for international validation is based upon the "universal" method funded by EPA.

Further, we recommend that the Administrator, EPA, convene the FIFRA Scientific Advisory Panel to assist in developing the plan and overseeing the research strategy direction and management.

Response: Use of the FIFRA Scientific Advisory Panel to Review Test Methodology

A microbiology sub-panel of the FIFRA Scientific Advisory Panel was established in FY 91. Members were chosen from academia and the Centers for Disease Control and Prevention. EPA has utilized the expertise of the SAP sub-panel for guidance and review of the test methodology research cooperative agreements and for review of an EPA policy for the acceptance of protocols and/or method modifications which deviated from the standard accepted methods. The Agency continues to use a SAP External Review panel for evaluating new methods for antimicrobial pesticides. In recent years, the panel has provided recommendations for a variety of novel technologies, including but not limited to, biofilm protocols, fruit and vegetable washes, antimicrobials used for pathogen reduction in water in food processing plants, dental unit waterline applications and bacteriophages.

Recommendation # 2:

In addition, we recommend that the Administrator, EPA, develop and publish a policy that establishes specific criteria for evaluating the validity of new disinfectant efficacy test methods and modifications to methods, including criteria for determining when independent laboratory data, such as data from a collaborative study, are needed to demonstrate the validity of proposed methods and modifications.

Response: Policy for Evaluating New Efficacy Test Methods and Method Modifications

In 1991, a workgroup was established to develop an EPA policy detailing the criteria and process which should be used to accept new protocols and modifications to standard methods. By the

end of the second quarter FY91, the workgroup had drafted a document entitled, "Systematic Process and Criteria to Assess the Validity of EPA/Registrant/Commercial Laboratory Proposed Test Methods and Modifications." The document was presented to the SAP microbiology sub-panel in May 1991. The SAP approved the document, stressing the importance for scientific review of new test methods, protocols and modifications to standard methods. In addition, the Agency has posted on the Antimicrobials website, guidance to applicants outlining the review process for new test protocols.

Recommendation # 3:

To improve EPA controls over the quality and integrity of registrant-submitted data, we recommend that the Administrator, EPA, implement a pre-registration-testing program to verify selected disinfectant efficacy data. The Administrator could target pre-registration tests on those claims that are of the greatest public health significance and/or products with suspected efficacy problems.

Response: Pre-registration Testing of Sterilants – Post-registration Testing of Sterilants, Tuberculocides, and Hospital Disinfectants

Since they are the most critical to infection control, EPA initiated pre-registration testing of all new sterilant claims. This testing was conducted by the Indiana State Chemist Laboratory located at Purdue University. Since the August 3, 1996 Food Quality Protection Act amendments to FIFRA, removed liquid chemical sterilants from the definition of a pesticide (these products are now regulated by the Food and Drug Administration) this pre-registration program is no longer in place.

The Agency also initiated a Post-registration Antimicrobial Testing Program to evaluate the claims for sterilants, tuberculocides, and hospital disinfectants. Again, since sterilant products are the most critical to infection control, these products were tested first. More than half of the registered liquid chemical sterilants were removed from the marketplace by enforcement actions because of failures in the testing program or through voluntary cancellation by the affected registrants. With the assistance of state laboratory support from North Carolina, Ohio, and Michigan, and the establishment of the Office of Pesticide Programs Microbiology Laboratory, efficacy testing of tuberculocides and hospital disinfectants in ongoing. Approximately one third of these products are failing efficacy testing, resulting in enforcement actions (cancellations, fines), removal of label claims, and reformulation of products to bring them into regulatory compliance.

To improve the effectiveness of the data review, lab inspection, and data audit programs, we recommend that the Administrator, EPA:

Direct the Laboratory Data Integrity Assurance Division to identify all laboratories that have performed efficacy studies submitted to EPA to support disinfectant registrations and meet the division's goal of inspecting these labs at least every 2 years (at a minimum, direct LDIAD to use the Office of Pesticide Programs Pesticide Document Management System, which contains the best available information for identifying the labs);

Response: The Office of Compliance Monitoring conducted a manual review of efficacy studies submitted to the Agency of identify performing laboratories. Routine procedures have been implemented to identify new laboratories at the time of study submission.

Direct LDIAD to establish a check sample program as part of the lab inspection program to better assess the ability of labs to perform disinfectant efficacy tests;

Response: EPA did not establish a check sample program because the resources required for such a program would be substantial, and the information provided would not be very useful. Instead, the Agency assures the quality of data through inspections of laboratories performing antimicrobial efficacy testing.

Direct the Office of Compliance Monitoring to review its internal controls for ensuring that inspections/audits are processed on time; and

Response: OCM implemented new procedures for conducting antimicrobial lab audits and Good Laboratory Practice inspections. In addition, a GLP Inspection Review Committee was established to review/process inspection reports in a timely manner.

Direct the Office of Pesticide Programs and the Office of Compliance Monitoring to develop and implement specific guidance for data reviewers, lab inspectors, and data auditors to follow; further, direct these offices to develop, publish for comment, and implement detailed policies and guidelines to decide what registration and/or enforcement action to take on the basis of findings from lab inspections and data audits.

A Reference Guide/Training Manual for Conducting Efficacy Reviews is available for all efficacy reviewers in addition to the Standard Evaluation Procedures guidance. Criteria for rejecting studies have been established. Standard efficacy reporting templates, to be used by the regulated community when submitting efficacy studies, have been posted on the Antimicrobials Division's website. As stated above, OCM has established procedures for lab inspectors and data auditors to follow when conducting inspections.

Recommendation # 4:

We recommend that the Administrator, EPA, develop, publish for comment, and implement an enforcement strategy to ensure that the marketed disinfectants work as claimed. This strategy should specify (1) the mechanisms and procedures for identifying potentially ineffective disinfectants; (2) the procedures for investigating and verifying complaints about potentially ineffective disinfectants, including, where necessary, the use of independent laboratory testing; and (3) the criteria and procedures for initiating registration and/or enforcement action against disinfectants found to be ineffective.

Response: The Office of Enforcement and Compliance Assurance and the Office of Pesticide Programs has developed and implemented the Antimicrobial Testing Program (ATP), a national program strategy which included a regulatory and enforcement strategy. This program

addresses, among other things, the three GAO specifications (namely, procedures for identifying potentially ineffective disinfectants, inspection/investigation procedures, and criteria for initiating actions.)

In light of federal budget constraints, we also recommend that the Administrator explore options for pooling resources from the states, user groups, and industry to implement a national disinfectant efficacy enforcement strategy.

Response: During the sterilant phase of the testing program, the Agency entered into an Interagency Agreement with FDA and cooperative agreements with the Mississippi State and Indiana State Chemist to conduct efficacy testing for sterilant products. EPA currently has cooperative agreements in place with state laboratories from North Carolina, Ohio, and Michigan and in the past, Florida, to assist with testing tuberculocidal and hospital disinfectants. EPA also has a state-of-the art research microbiology laboratory that, among other activities, conducts efficacy testing for the ATP. In addition to efficacy testing, formulation chemistry analysis is conducted on all products in the ATP.

Recommendation # 5:

We recommend that the Administrator, EPA, develop a detailed cost/benefit analysis of alternatives for operating a laboratory facility to research and test the efficacy of disinfectants, including the option of charging fees to register disinfectants to help finance such a facility, and submit the results of its analysis to the Congress so that the Congress may weigh the advantages and disadvantages of various alternatives.

Response: In 1996, the Office of Pesticide Programs Microbiology Laboratory was opened at the Environmental Science Center on the grounds of Ft. Meade, Maryland. This state-of-the-art facility also houses the EPA's Analytical Chemistry Laboratory. In addition to testing tuberculocides and hospital disinfectants for the ATP, the OPP Microbiology Laboratory has conducted test methodology research on sporicides and disinfectants, and aided the Antimicrobials Division in reviewing protocols for new label claims.

In March 2003, the Pesticide Regulatory Improvement Act established fees for the registration of pesticides, including antimicrobial products. While these fees were not used to finance the research laboratory they are used, in part, to fund external review of data for regulatory decisions.

Appendix C

Distribution

Office of the Administrator
Assistant Administrator, Office of Prevention, Pesticides & Toxic Substances
Agency Followup Official
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