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.