UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Office of Research and Development
Washington, D.C. 20460

ETV

ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM
VERIFICATION STATEMENT

TECHNOLOGY TYPE:	**POLYCHLORINATED BIPHENYL (PCB) FIELD ANALYTICAL TECHNIQUES**
APPLICATION:	**MEASUREMENT OF PCBs IN SOILS**
TECHNOLOGY NAME:	**PCB IMMUNOASSAY KIT**
COMPANY:	**HACH COMPANY**
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The U.S. Environmental Protection Agency (EPA) has created a program to facilitate the deployment of innovative technologies through performance verification and information dissemination. The goal of the Environmental Technology Verification (ETV) Program is to further environmental protection by substantially accelerating the acceptance and use of improved and more cost effective technologies. The ETV Program is intended to assist and inform those involved in the design, distribution, permitting, and purchase of environmental technologies. This document summarizes the results of a demonstration of the Hach Company PCB immunoassay kit.

PROGRAM OPERATION

The EPA, in partnership with recognized testing organizations, objectively and systematically evaluates the performance of innovative technologies. Together, with the full participation of the technology developer, they develop plans, conduct tests, collect and analyze data, and report findings. The evaluations are conducted according to a rigorous demonstration plan and established protocols for quality assurance. EPA's National Exposure Research Laboratory, which conducts demonstrations of field characterization and monitoring technologies, with the support of the U.S. Department of Energy's Environmental Management program, selected Oak Ridge National Laboratory (ORNL) as the testing organization for the performance verification of polychlorinated biphenyl (PCB) field analytical techniques.

DEMONSTRATION DESCRIPTION

In July 1997, the performance of six PCB field analytical techniques was determined under field conditions. Each technology was independently evaluated by comparing field analysis results to those obtained using approved reference methods. Performance evaluation (PE) samples were also used to independently assess the accuracy and comparability of each technology.

The demonstration was designed to detect and measure PCBs in soil. The demonstration was conducted at ORNL in Oak Ridge, Tennessee, from July 22 through July 29, 1997. The study was conducted under two environmental conditions. The first site was outdoors with naturally fluctuating temperatures and relative humidity conditions. The second site was inside a controlled environmental chamber, with generally cooler temperature and lower relative humidities. Multiple soil types, collected from sites in Ohio, Kentucky, and Tennessee, were analyzed in this study. The results of the soil analyses

conducted under field conditions by the technology were compared with results from analyses of homogeneous replicate samples conducted by conventional EPA SW-846 methodology in an approved reference laboratory. Details of the demonstration, including a data summary and discussion of results, may be found in the report entitled *Environmental Technology Verification Report: Immunoassay Kit, Hach Company PCB Immunoassay Kit*, EPA/600/R-98/110.

TECHNOLOGY DESCRIPTION

The PCB immunoassay kit utilizes analyte-specific antibodies attached to the inside of plastic tubes to bind and remove PCBs selectively from complex sample matrices. The kit is a semi-quantitative screening method that indicates whether the PCB concentration is above or below the specified threshold values (1 ppm and/or 10 ppm). The kit has most applicability to establishing cleanup guidelines. To initiate the test, the sample (that may contain PCBs) and a reagent containing enzyme conjugate are added to the antibody-coated tubes. An enzyme conjugate consists of an enzyme to which an analyte is attached. Enzyme conjugates and PCBs competitively bind to the antibodies attached to the inside of the tube. Samples with higher levels of PCBs will have more antibody sites occupied by the analyte and fewer occupied by the enzyme conjugate molecules. After incubation, the sample and unbound enzyme conjugate are washed from the tube and color development reagents are added. The concentration of PCBs in a sample is determined by comparing the developed color intensity to that of a PCB standard. The PCB concentration is inversely proportional to the color development, where the lighter the color, the higher the sample PCB concentration.

VERIFICATION OF PERFORMANCE

The following performance characteristics of the PCB immunoassay kit were observed:

Throughput: Throughput was 10 to 13 samples/hour under the outdoor conditions, and 7 to 10 samples/hour under the chamber conditions. These rates included preparation and analysis.

Ease of use: Two operators analyzed samples during the demonstration, but the technology can be run by a single operator. Minimal training (2 hours) is required to operate the PCB immunoassay kit, provided that the user has a basic knowledge of chemistry and lab techniques.

Completeness: The PCB immunoassay kit generated results for all 208 PCB samples for a completeness of 100%.

Blank results: PCBs were detected and reported as 1 to 10 ppm in three of the eight blank soil samples analyzed. Therefore, the percentage of false positive results was 38%. The PCB immunoassay kit reported 2% (4 of 192 samples) false negative results.

Precision: The overall precision, based on the percentage of combined sample sets where all four replicates were reported as the same interval, was 100% for the PE soils and 68% for the environmental soils.

Accuracy: Accuracy was assessed using PE soil samples. Accuracy, defined as the percentage of PCB immunoassay kit results that agreed with the accepted concentrations, was 90%, while the percentage that was biased high or low was 4 and 6%, respectively. All of the biased low results were at concentrations near the 10-ppm threshold value.

Comparability: Comparability, like accuracy, was defined as the percentage of samples that agreed with, was above (i.e., biased high), or was below (i.e., biased low) the reference laboratory results. The percentage of PE and environmental soil samples which agreed with the reference laboratory results was 85%, while the percentage that was biased high or low was 7 and 9%, respectively. In nearly all cases where the test kit result disagreed with the reference laboratory result, the concentration was near one of the kit's threshold values of 0, 1, or 10 ppm.

Regulatory decision-making: One objective of this demonstration was to assess the technology's ability to perform at regulatory decision-making levels for PCBs, specifically 50 ppm for soils. For PE and environmental soil samples in the range of 40 to 60 ppm, 98% of the PCB immunoassay kit results agreed with the reference laboratory in that the test kit reported PCB concentrations as greater than 10 ppm. In contrast, only 2% were biased low, while none of the samples were biased high. As tested, the PCB immunoassay kit's interval ranges would have limited application in determining whether a sample contained > 50 ppm of PCBs, only that the sample contained > 10 ppm of PCBs.

Data quality levels: The performance of the PCB immunoassay kit was characterized as unbiased and precise. In the format that was tested, the kit provided limited information. The kit would be more applicable to cleanup applications, where it could be utilized as a quick test to determine the status of cleanup activities. Hach is working to incorporate testing at additional threshold values.

The results of the demonstration show that the PCB immunoassay kit can provide useful, cost-effective data for environmental problem-solving and decision-making. Undoubtedly, it will be employed in a variety of applications, ranging from serving as a complement to data generated in a fixed analytical laboratory to generating data that will stand alone in the decision-making process. As with any technology selection, the user must determine if this technology is appropriate for the application and the project data quality objectives. For more information on this and other verified technologies, visit the ETV web site at *http://www.epa.gov/etv*.

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