UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

THE PROTECTO

Office of Research and Development Washington, D.C. 20460



ENVIRONMENTAL TECHNOLOGY VERIFICATION PROGRAM VERIFICATION STATEMENT

TECHNOLOGY TYPE: POLYCHLORINATED BIPHENYL (PCB) FIELD ANALYTICAL

TECHNIQUES

APPLICATION: MEASUREMENT OF PCBs IN SOILS AND SOLVENT EXTRACTS

TECHNOLOGY NAME: PCB IN SOIL TUBE ASSAY

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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 EnviroLogix Inc. PCB in Soil Tube Assay.

PROGRAM OPERATION

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 (DOE) Environmental Management (EM) program, selected Oak Ridge National Laboratory (ORNL) as the testing organization for the performance verification of polychlorinated biphenyls (PCBs) field analytical techniques.

DEMONSTRATION DESCRIPTION

In July 1997, the performance of six PCB field analytical techniques was determined under field conditions. In September 1998, the performance of EnviroLogix Inc.'s PCB in Soil Tube Assay kit was evaluated similarly. Each technology was independently evaluated by comparing field analysis results with those obtained using approved reference methods. Performance evaluation (PE) samples were also used to assess independently the accuracy and comparability of each technology.

The demonstration was designed to detect and measure PCBs in soil and solvent extracts. For EnviroLogix, the demonstration was conducted at ORNL in Oak Ridge, Tennessee, from September 21 through 25, 1998. 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 temperatures and lower relative humidities. Multiple soil types, collected from sites in Ohio, Kentucky, and Tennessee, were analyzed in this study. Solutions of PCBs were also analyzed to simulate extracted surface wipe samples. The results of the soil and extract analyses conducted under field conditions by the technology were compared with results from analyses of homogenous 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, EnviroLogix Inc., PCB in Soil Tube Assay*, EPA/600/R-98/173.

TECHNOLOGY DESCRIPTION

The EnviroLogix PCB in Soil Tube Assay applies the principles of enzyme linked immunosorbent assay (ELISA) to the determination of PCB. In such an assay, an enzyme has been chemically linked to a PCB molecule or PCB analog to create a labeled PCB reagent. The labeled PCB reagent (called a conjugate) is mixed with an extract of native sample containing the PCB contaminant. A portion of the mixture is applied to a surface (i.e., the inside of a test tube) to which an antibody specific for PCB has been affixed. The native PCB and PCB-enzyme conjugate compete for a limited number of antibody sites. After a period of time, the solution is washed away, and what remains is either PCB-antibody complexes or enzyme-PCB-antibody complexes attached to the test surface. The proportion of the two complexes on the test surface is determined by the amount of native PCB in the original sample. The enzyme present on the test surface is used to catalyze a color change reaction in a solution added to the test surface. Because the amount of enzyme present is inversely proportional to the concentration of native PCB contaminant, the amount of color development is inversely proportional to the concentration of PCB contaminant. The color development is quantified through the use of a hand-held photometer.

The EnviroLogix PCB in Soil Tube Assay is designed for semi-quantitative field screening for PCBs in soil. The kit is supplied with calibrators equivalent to 1 part per million (ppm) and 10 ppm PCB (Aroclor 1254) in soil. These calibrators are used to evaluate threshold levels of 1 and 10 ppm. A threshold level of 50 ppm can also be evaluated using the 10 ppm calibrator by preparing a 1:5 sample extract dilution into methanol. For the extract samples, the threshold levels are 0.4, 4, and $20 \mu g/mL$.

VERIFICATION OF PERFORMANCE

The following performance characteristics of the PCB in Soil Tube Assay were observed:

Throughput: Throughput was 8 samples/hour under outdoor conditions and 7 samples/hour under chamber conditions for one operator. This rate included sample preparation and analysis.

Ease of Use: One operator analyzed samples during the demonstration. Minimal training (4 h) is required to operate the kit, provided the user has a fundamental understanding of basic chemical and field analytical techniques.

Completeness: The PCB in Soil Tube Assay generated results for all 232 PCB samples for a completeness of 100%.

False positive/negative results: All of the blank samples (soils and extracts) were reported as the lowest reporting interval, which included zero; therefore, the percentage of false positive results was 0%. The kit reported no false negative results for extracts, and 4% (7 of 192 samples) for soils.

Precision: The overall precision—based on the percentage of combined sample sets where all four replicates were reported as the same interval—was 56% for the PE soils, 68% for the environmental soils, and 75% for the extracts.

Accuracy: Accuracy was assessed using PE soil and extract samples. Accuracy, defined as the percentage of the PCB in Soil Tube Assay results that agreed with the accepted concentration, was 78% for PE soils and 92% for extracts. In general, the fraction of samples that was biased high was comparable (10% for PE soils and 0% for extracts) to the fraction that was biased low (13% for PE soils and 8% for extracts).

Comparability: Comparability, like accuracy, was defined as the percentage of results that agreed with, was above (i.e., biased high), or was below (i.e., biased low) the reference laboratory result. The percentage of samples that agreed with the reference laboratory results was 82% for all soils (PE and environmental). The fraction of samples that was biased

high was again comparable (12%) to the fraction that was biased low (7%). Extract results could not be compared because no reference laboratory data was generated for these samples.

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, 66% of the PCB in Soil Tube Assay results agreed with the reference laboratory, 32% were biased high, and 2% were biased low. The test kit results for this concentration range were different from what was observed for the entire data set in that the fraction of samples that were biased high was significantly higher (32% versus 12%).

Data quality levels: The performance of the test kit was characterized as unbiased, because most (78%) of the PCB in Soil Tube Assay results agreed with the certified PE values, but imprecise, because nearly half (44%) of the PE replicate results were not reported as the same interval. It should be noted that almost all of the imprecision occurred when the concentration of the sample was near one of the test kit's threshold values (i.e., 1, 10, or 50 ppm).

The results of the demonstration show that the PCB in Soil Tube Assay 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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NOTICE: EPA verifications are based on an evaluation of technology performance under specific, predetermined criteria and the appropriate quality assurance procedures. EPA makes no expressed or implied warranties as to the performance of the technology and does not certify that a technology will always, under circumstances other than those tested, operate at the levels verified. The end user is specified for complying with any and all applicable. Endown State, and Local requirements.

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