UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BEFORE THE ADMINISTRATOR

In the Matter of)	
N.O.C., Inc., T/A Noble Oil Company, Respondent)))	Docket No. II-TSCA-PCB-81-0105
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- Toxic Substances Control Act Rules of Practice Motions to 1. Reopen the Hearing - Where primary basis of motion to reopen the hearing was contention that scientific data on variability (standard deviation) of analyses of PCBs in waste oil matrices first made available subsequent to the conclusion of the hearing cast doubt on the conclusion in the initial decision that level of PCBs in Respondent's oil tank was in excess of regulatory limit of 50 ppm and the only evidence offered in support of the motion was data on interlaboratory variability (the EPA laboratory which made the analysis in question not having participated in the studies which generated the interlaboratory variability data), and under all the circumstances it did not appear likely that such data would change the result, the motion would be denied. Where validity and accuracy of analysis showing PCB concentration in waste oil tank to be in excess of 50 ppm was in issue, matters bearing on whether such analysis was properly conducted which could have been more thoroughly explored at the hearing were cumulative and could not support a motion to reopen the hearing.
- 2. Toxic Substances Control Act Rules of Practice Motions to Reopen the Hearing Where basis of alternative motion to reopen the hearing was contention that Respondent refrained from offering evidence concerning propriety of proposed penalty because of belief that penalty would be considered, if at all, only at a second hearing after liability was first determined and no evidence was offered to show that asserted belief was reasonable, alternative motion would be denied.

Appearances for Respondent:

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Appearances for Complainant:

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Decision Denying Motion to Reopen the Hearing

An initial decision, assessing a penalty against Respondent of \$40,000 for violations of Section 15 of the Toxic Substances Control Act (15 U.S.C. 2614), was issued on December 3, 1982. The decision was served on Respondent by letter from the Regional Hearing Clerk, dated December 13, 1982, and received by Respondent on December 16, 1982. On January 4, 1983, within the 20-day period for filing a motion to reopen the hearing allowed by the Rules of Practice (40 CFR 22.28), counsel moved for an extension of time in which to file such a motion. This motion was granted and under date of January 19, 1983, Respondent filed a motion to reopen the hearing. After requesting and receiving two extensions of time in which to respond, counsel for Complainant's opposition to the motion was received on February 25, 1983. Respondent filed a reply brief under date of March 28, 1983, Complainant was permitted to file a response on April 11, 1983, and Respondent was permitted to and did file a final reply affidavit on May 3, 1983.

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The basic thrust of the motion is that evidence and scientific data bearing on the analytical variability (standard deviation) of analyses of PCBs in waste oil matrices, first made available subsequent to the conclusion of the hearing (February 11, 1982), would preclude a finding that the PCB concentration determined here (76 ppm) was in excess of the then regulatory limit of 50 ppm. In support of the motion, Respondent has attached the affidavit of Mr. William J. Ziegler, a chemist and Laboratory Manager for Stablex-Reutter, Inc., a consulting and testing firm. Mr. Ziegler appeared as an expert witness for Respondent at the hearing and testified, inter alia, that he was then engaged in a research project involving analysis of PCBs in waste oils and that he would be presenting a paper on that subject at the Pittsburgh Conference and Exposition on Analytical Chemistry and Applied Spectroscopy to be held the following month, March of 1982. Assertions in Mr. Ziegler's affidavit are based, in part, on this paper attached thereto.

Alternatively, Respondent contends that the hearing should be reopened to allow evidence on the issue of the civil penalty because it believed that such evidence would be offered, if at all, only at a record hearing after liability had first been determined.

The substance of Mr. Ziegler's affidavit may be summarized as stating that at the time the 50 ppm regulatory limit was established there was no published and well recognized method for testing for PCBs in waste oils at that concentration, that high concentrations of PCBs in transformer fluids could be measured with a high degree of confidence [in the accuracy of the test], but that when waste oils, which present a

considerably more complex matrix than transformer fluids, are analyzed at the [50] ppm level, the precision and accuracy of the method can suffer significantly. It is further asserted that the key to a laboratory quality assurance program is the analysis of spiked and replicate samples and the daily monitoring of accuracy and precision control charts, outside of which the analysis is considered out of control, that the measure of variability of data obtained at the 95 percent confidence level is two standard deviations, that the relation of the mean result obtained to the upper confidence level (UCL) and the threshold value (50 ppm) must be considered to determine if further analysis is warranted and that if the mean result exceeds the threshold value and also the UCL, then there is a considerable probability that the waste is not a hazardous waste. In such a case, further confirmatory and replicate determinations are warranted to substantiate a result in excess of the threshold value. According to Mr. Ziegler, the EPA tests on Sample No. 57970, which determined a PCB concentration of 76 ppm, from Noble Oil Company present exactly this type of situation.

Mr. Ziegler's affidavit states that at the 95 percent confidence $\frac{1}{2}$ limit (level) the interlaboratory variability for Stablex-Reutter for 50 ppm PCB in waste oil is ± 34 ppm, which implies that only a result in

^{1/} Although Mr. Ziegler states that it is the responsibility of every laboratory to monitor the precision and accuracy of its methods to define the degree and accuracy of intralaboratory variability, curiously it is interlaboratory variability that is emphasized here.

excess of 84 ppm can be considered a violation of the 50 ppm limit in the absence of numerous data on spiked and replicate samples, demonstrating a lower variability. If a laboratory does not have a program to monitor intralaboratory variability, or cannot produce data on a method for a given matrix, then data on interlaboratory variability must be considered, even though the precision and accuracy of intralaboratory data should be higher. In this regard, Mr. Ziegler cites two recent studies, "Comparison of Three Extraction Techniques for the Determination of Polychlorinated Biphenyls," Exh II, authored by himself and three others, presented at the mentioned Pittsburgh Conference, and "Data from Round Robin Study on PCBs in Waste Oil," (1982), Exh III, by the National Bureau of Standards. The former study shows that at the 50 ppm enforcement limit, using a 95 percent confidence level (2 x standard deviation) an interlaboratory variability of +67.7 percent exists using a modified EPA Method 608 and Environmental Monitoring and Support Laboratory (EMSL, Cincinnati, Ohio) Methods. This result is asserted to mean that a PCB test result must be greater than 84 ppm before it can be considered a statistically valid violation of the 50 ppm enforcement limit. Laboratories using the Hall Electrolytic Conductivity Detector and the EMSL procedure had a much lower variability than labs using an electron capture (EC) detector. The National Bureau of Standards study involved 19 laboratories and also involved PCBs in waste oil matrices. For samples close to the 50 ppm enforcement limit (41.0, 60.9, 41.0, 60.9, 41.0, 48.0 and 40.0 ppm) a mean standard deviation of 27.4 ppm was obtained. This implies that at the 95 percent confidence level a variability of +54.8 ppm exists at the

50 ppm PCB enforcement limit. Using this data, a sample would have to exceed 105 ppm before it could be considered to be statistically in violation of the 50 ppm limit.

Applying these data to the EPA test on Sample No. 57970 from Noble Oil Company, Mr. Ziegler concludes that the sample result of 76 ppm is neither statistically nor analytically in definitive violation of the 50 ppm PCB limit. He points out that an EC detector was used for the analysis, that EMSL procedure specifies a Hall over an EC detector because of false positive or negative interferences that may result from nonhalogenated materials in waste oils, that it was possible false positive responses were observed in the EPA analysis and to demonstrate that this was not the case, an internal standard and alternate column chromatography should have been performed. He further points out that no internal standard was used by EPA in its analysis so that no positive identification of chromatographic peaks as PCBs can be made, that EPA (EMSL) procedure specifies that at least 10 percent duplicate and 10 percent spiked determinations be performed to ensure that the method is in control and that no such data was provided by EPA to support the reported result on Sample 57970. Because no control charts have been provided to define the intralaboratory variability of the EPA Edison, New Jersey laboratory involved in the test of Sample 57970, Mr. Ziegler asserts that a statement cannot be made as to the variability of the analysis and data on interlaboratory variability and precision must be used. According to Mr. Ziegler, the result of 76 ppm is not statistically in violation of the 50 ppm PCB limit at the 95 percent confidence level using interlaboratory data and EPA requirements in such a situation specify that additional sampling

and analysis is necessary because the UCL is greater than the threshold value.

Opposing the motion, counsel for Complainant has submitted the affidavit of Mr. George M. Karras, the chemist who conducted the test on Sample No. 57970. In accordance with his testimony at the hearing and as found in the initial decision, Mr. Karras used a silica gel cleanup procedure to prepare the sample for the test. This procedure is authorized by EPA (Exh 8) and its purpose is to remove materials which might interfere with the analysis. The test was conducted using Method 608 (44 FR No. 233, December 3, 1979, at 69501-09) beginning with Paragraph 11 (Exh 7).

Mr. Karras states that on January 27, 1982, he analyzed an aliquot of Sample 57970, using the silica gel cleanup procedure and Method 608 beginning with Paragraph 11 as in the original test. The analysis resulted in a determination of 70 ppm PCBs. He further states that at the time of the mentioned analysis on January 27, 1982, he was conducting a laboratory quality assurance program under which he analyzed a sample of waste oil spiked with a known standard of PCBs. He also prepared a quality control chart, covering the period June 1981 through September 1982, to measure intralaboratory variability of the PCB analysis (Exh 2 of affidavit). This indicates that intralaboratory variability in January 1982 was from 74.6 to 127.4 percent at a 99 percent confidence level. Using the lower confidence [variability] level for the January 27, 1982, analysis of Sample 57970 produces a result of 52.44 ppm of PCBs (70.3 ppm x 74.6 percent), which is above the 50 ppm enforcement limit.

Responding specifically to assertions in Mr. Ziegler's affidavit concerning the paper presented at the Pittsburgh Conference showing an

interlaboratory variability of PCBs at the 50 ppm threshold for Stablex-Reutter of +67.7 percent at a 95 percent confidence level, Mr. Karras points out that the EPA Region II laboratory did not participate in the study and that the only appropriate measure of variability for the EPA laboratory is his study on intralaboratory variability previously mentioned. Regarding the NBS study, the EPA Region II laboratory was again not a participant. Mr. Karras states that without having more information as to the conduct of the NBS study he is unable to comment thereon, specifically whether samples of waste oil analyzed were cleaned prior to analysis, what cleanup procedures and gas chromatograph detectors were used, and the training and experience of individuals conducting the analysis. He points out that data accumulated using several cleanup procedures, multiple analytical procedures and performed by individuals with varying degrees of experience can be expected to demonstrate a much higher variability, than in a single laboratory using stringent quality control procedures such as the EPA lab involved here. It is asserted that without such data, the results of the NBS study are not meaningful. He emphasizes that Mr. Ziegler acknowledged that intralaboratory variability data is much preferred to interlaboratory data.

Respondent's brief and an additional affidavit of William J. Ziegler, Laboratory Manager of Stablex-Reutter, Inc., were received on March 31, 1983. Mr. Ziegler points out that no evidence concerning the analysis of Sample No. 57970 performed by Mr. Karras on January 27, 1982, was introduced at the hearing on this matter and that because Method 608 requires that all samples be extracted within seven days and completely

analyzed within 30 days of collection, the January 1982 test may not be regarded as a valid replicate determination (¶ 4). It is asserted that the control chart submitted as Exhibit 2 of Mr. Karras' affidavit covers the period June 28, 1981, through September 25, 1982, and is not applicable to the July 22, 1980 test involved here (¶ 8). Moreover, in the absence of data on the matrix used, the chart is of little value because there is a much lower degree of variability in analysis of a water sample than in a more complex matrix such as a waste oil. The affidavit states that quality assurance data in the form of duplicate determinations, spiked analyses, control charts, internal standards, analysis of field blanks, reagent blanks or alternate column chromatography were not provided to support the July 1980 analysis and that in the absence thereof, interlaboratory variability at the 50 ppm limit must be considered (¶ 5).

Mr. Ziegler states flatly that Mr. Karras has failed to demonstrate that his analysis was in control using the required protocol for PCB analysis set forth in listed EPA publications including Method 608, and EPA-EMSL The Analysis of Polychlorinated Biphenyls in Transformer Fluid and Waste Oils, June 24, 1980. He further states that sections on chromatographic

^{2/} Respondent's Exh 5. ¶ 10.6.2 of the cited procedure provides:

[&]quot;10.6.2 If individual retention time varies by more than 10% over an eight-hour period or does not fall within 10% of an established norm, the system is "out of control." The source of retention data variation must be corrected before acceptable data can be generated."

operating conditions call for the use of an internal standard of p,p'-DDE in every sample and standard for proper identification of PCBs and to prove that the gas chromatograph is functioning properly. He raises doubts as to the value of the control chart in supporting the accuracy of the EPA test, saying that it is not clear whether waste oils were used as the matrices or whether the tests were conducted at the 50 ppm regulatory limit (¶ 8-10). Replicate determinations were allegedly not performed nor were replicate control charts provided for any period of time, pertinent to the initial analysis of Sample 57970, demonstrating the precision of the EPA Region II laboratory in PCB analysis of waste oils (¶ 11 & 13). Laboratory and field replicate data and data on the analyses of fortified samples were not reported as required by ¶ 12.2 of EPA Method 608 (¶ 14).

Mr. Ziegler cites ¶ 7.1 of EPA Method 608 specifying that each time a set of samples is extracted or there is a change in reagents, a method blank should be processed as a safeguard against chronic laboratory contamination, asserts that EPA could not provide data that this was accomplished for either the July 22, 1980 analysis or the January 27, 1982 analysis and asks rhetorically what guarantee is there that such [laboratory] contamination did not occur or that the sample containers were free from contamination (¶ 12). He also cites 44 FR No. 233, December 3, 1979, at 69553 as requiring analysis of a field blank and states that this protocol was not followed by EPA in the case of Sample No. 57970. Absent analysis of a field blank or documentation that sample containers were cleaned as specified in Section 3 of EPA Method

608, there is, according to Mr. Ziegler, no evidence to prove that the container has not been contaminated (¶ 13). Mr. Ziegler complains that the single calibration run by the EPA laboratory is not in accordance with ¶ 6.1 of Method 608 requiring that calibration standards be prepared covering two or more orders of magnitude that will completely bracket the working range of the chromatographic system (¶ 15). The lack of such calibration standards allegedly makes the result (quantitation) obtained on Sample 57970 highly questionable.

Mr. Ziegler maintains that the use of an internal standard of p,p'-DDE is a matter of routine, citing ¶ 11 of the FMSL procedure, and not an option, but must be followed because it is the only way to certify that the gas chromatograph is functioning properly and positively identify the presence of PCBs without bias or error from small deviations in absolute retention times (¶ 16). It is emphasized that identification of PCBs (Aroclor) is based on relative and not absolute retention times, that an internal standard is essential for the very identity of PCBs in a complex matrix such as waste oil and that absent an internal standard, Mr. Karras' opinion that the peaks matched Aroclor 1260 is totally arbitrary. Mr. Ziegler says that the data provided in his study and the NBS study are the first studies on analytical variability of PCB analysis of waste oils at the 50 ppm limit (¶ 17). He asserts that EPA procedures were being used by laboratories, known to be competent in PCB

^{3/} EMSL procedure at the time of the initial test on Sample No. 57970 was a draft "The Analysis of Polychlorinated Biphenyls In Transformer Fluid and Waste Oils," dated June 24, 1980 (note 2 supra), which has now been finalized "The Determination of Polychlorinated Biphenyls in Transformer Fluid and Waste Oils," EPA-600/4-81-045 (Exh 3 to Karras affidavit of February 18, 1983).

analysis, involved in the studies and that unless EPA can demonstrate intralaboratory variability for PCBs at the 50 ppm limit, it is valid to use his data and NBS data to evaluate the statistical significance of results obtained on Sample 57970. In fact, he argues that there is no choice but to use "round robin" data in evaluating evidence in this matter.

Examining chromatograms of tests conducted by the EPA laboratory on January 27, 1982, submitted with Mr. Karras' affidavit of February 18, 1983, Mr. Ziegler alludes to inconsistencies, which he contends raise similar questions as to the July 22, 1980 analysis (\P 18). He notes that the chromatogram (Exh 1 of the Karras affidavit) reflects that a one milliliter sample size was used and that Mr. Karras testified at the hearing that a one milliliter sample size was also used in the July 1980 analysis (¶ 19). He points out that the EMSL procedure (June 24, 1980) specifies that the aliquot must be accurately weighed and states that it is impossible to accurately pipet a one milliliter aliquot of a viscous waste oil. He refers to ¶ 7.2 (7.2.2 of the April '81 procedure) which specifies that the size of the aliquot taken must be determined within +0.001 grams, asserting that failure to do this would add an additional error that could be as high as +20 percent in addition to the normal variability of the test method when performed in a proper manner. According to Mr. Ziegler, this means that if normal variability is +25.4 percent, total variability could be as high as 45.4 percent, which would extend the EPA Region II determination at the 95 percent confidence level to 40 ppm, below the TSCA limit.

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Mr. Ziegler refers to markings on the chromatograms submitted with Mr. Karras' affidavit, which he contends indicate that the calculations shown thereon could be off by a factor of 100 so that the result of 70.3 ppm PCB should be 0.703 ppm (¶ 20). This is because the markings appear to indicate that a one milliliter aliquot of oil was diluted to 100 milliliters, which dilution was not recognized in the calculations.

Responding to these contentions, Complainant, while acknowledging that ¶ 8.3 of Method 608 requires that all samples must be extracted within seven days and completely analyzed within 30 days of collection, contends that Mr. Ziegler misrepresents the purpose of this requirement.

It is asserted that the Method was originally developed for the analysis of wastewater samples, that the purpose of the 30-day requirement is to prevent degradation of the samples and that the re-analysis of Sample 57970 on January 27, 1982, 500 days after it was collected, in no way prejudiced Respondent because if the extended holding period had any effect at all, it was to Noble's advantage in that the concentration of PCBs in the sample was understated (Id. at 8, 9). Mr. Ziegler is of the opinion that degradation of PCBs is unlikely because of their high stability, agrees that extended holding times may understate the level of PCBs, but says that extended holding times may also overstate the level of PCBs, due to volatilization of the lighter hydrocarbon fractions. It is emphasized

^{4/} Response of April 11, 1983, at 7. This argument appears inconsistent with the contention (at 16, infra) that extraction is applicable only to water samples. Paragraph C.2. of the Silica Gel Cleanup Procedure (EPA Exh 8), which is clearly applicable to oil samples, significantly refers to Method 608, 44 FR No. 233, December 3, 1979, 69501-09, in its entirety, rather than just selected portions thereof.

^{5/} Affidavit, dated May 2, 1983, at 2. The Webb and McCall article cited in the EMSL procedure, Quantitative PCB Standards for Electron Capture Gas Chromatography (Journal of Chromatographic Science, Vol. 11, July 1973, at 366), states that chromatograms of PCBs usually show some evidence of degradation or metabolism (Id. at 369). While this is understandable, if, for example, the sample is animal tissue, it is not clear that this applies to waste oils.

that Mr. Karras testified at the hearing that in analyzing Sample No. 57970, he used Method 608 beginning at ¶ 11 (Tr. 178).

The fact that Mr. Karras did not use an internal standard in the analysis of Sample No. 57970 on July 22, 1980 was elicited in crossexamination of Mr. Karras at the hearing (Tr. 196). Disputing Mr. Ziegler's assertion that an internal standard is required on every sample for proper identification of PCBs, Complainant cites ¶ 11.5 of the EMSL procedure (EPA-600/4-81-045, note 3, supra) and contends that an internal standard is required only when the source of Aroclors or PCBs is not apparent. The first sentence of the cited paragraph provides "If the parent Aroclors or source of PCBs is not apparent, calculate the concentration according to the procedure of Webb and McCall." (note 5, supra). The identical statement appears in ¶ 11.4 of the draft procedure. According to Mr. Karras, the Webb and McCall procedure uses an internal standard, but an internal standard was inappropriate in his analysis of Sample No. 57970 on July 22, 1980 and January 27, 1982, because he was able to identify the source of the peaks as Aroclor 1260 (Affidavit at ¶ 7).

Complainant points out that the quotation relied upon by Mr. Ziegler in ¶ 16 of his affidavit relative to analysis of standard mixtures of

^{6/} The Webb and McCall article (note 5, supra) provides that the [GC] peaks are identified by their retention times relative to p,p'-DDE and recommends that this be adopted as a standard method for designating individual PCB GC peaks. Mr. Ziegler testified that p,p'-DDE was a pesticide residue and that "you add that internal standard and you quantify your retention times, which is a measure of identity when the peaks come out on the GC trace. You use the standards as a relative standard to when the materials are coming out and that is how you make your identification of PCB's" (Tr. 289). According to Mr. Ziegler, this was critical in electron capture analysis and additional quality control is necessary to demonstrate that all possible interferences had been removed in the cleanup.

each Aroclor is contained in ¶ 11.4.2 of the draft version of the EMSL procedure, implying that a similar requirement is not contained in the final version. While this is incorrect as ¶ 11.5.2 of EPA 600/4-81-045 contains an identical requirement, Mr. Ziegler's position appears to overlook the alternative to use of p,p'-DDE as an internal standard.

Mr. Ziegler expresses the opinion that he would not leave it to personal judgment as to whether a sample chromatogram sufficiently resembles a standard Aroclor, says that an internal standard is easy to use, that data interpretation without an internal standard is pure opinion, but that data interpretation based on relative retention times is irrefutable scientific fact (Affidavit of May 2, 1983, at 17).

Concerning Mr. Ziegler's statement that the EPA control chart (Exh 2 of Karras affidavit) does not reflect the matrix used, Complainant notes that ¶ 4 of the Karras affidavit clearly states that a sample of waste oil was spiked with a known quantity of PCBs (Response at 10). This, of course, falls short of a declaration that waste oil was the matrix involved in all tests on the chart. The level of PCBs involved in the spike is also not stated. Mr. Ziegler's criticism (¶ 12 of affidavit) that EPA was unable to furnish data substantiating use of a method blank as required by ¶ 7.1 of Method 608 is dismissed as being based on a misrepresentation in that the cited paragraph is applicable

^{7/} Paragraph 11.4.2 of the EMSL draft (¶ 11.5.2 of 60014-81-045) provides in part: "Determine the relative retention time (RRT) of each peak in the standards with respect to p,p'-DDE or assign the RRT shown in the figures [chromatograms of Aroclors, Figures 3, 5 and 6 in the procedure] to the corresponding peak in the standard. (emphasis supplied) Identify the RRT of each PCB in the sample by comparing the sample chromatogram to the standard chromatograms."

to analysis of water samples, and provides in part: "Each time a set of samples is extracted * *." Extraction is assertedly inapplicable to analysis of oil samples which are prepared by dilution with hexane. Answering, Mr. Ziegler declares that the method of preparation of the sample has nothing to do with whether a method blank needs to be analyzed (Affidavit of May 2, 1983, at 5). He cites ¶ 10.5 of EPA/600-4-81-045, providing that each time a set of samples is analyzed or there is a change in reagents, a laboratory reagent blank should be processed as a safeguard against contamination, and alleges that a method blank is always necessary to prove that a laboratory's reagents, glassware and equipment are free from contamination. Regarding Complainant's contention that analysis of a field blank is only necessary in connection with EPA Methods 624 and 625 (44 FR No. 223, December 3, 1979, at 69553), he acknowledges that the cited reference (Appendix III) concerns detailed quality assurance measures for priority pollutant analysis using GC/MS, that Appendix I of the cited reference concerns GC methods for priority pollutant analysis (Methods 601 thru 612) and asserts that the sampling considerations in this section including the importance of a field blank are applicable to Appendix I. He maintains, however, that use of a field blank is critical to prove that contamination has not occurred in the field or that sample bottles used for collection of samples are free from contamination and states that no other technique exists to guarantee contamination free sample containers.

^{8/} See note 4, supra. Extraction can, of course, simply mean withdraw and in this sense it would not seem likely that a one percent oil/hexane sample would be made without withdrawing oil from the initial sample container. Extraction can also imply a chemical process, which appears to be a type of process described in ¶ 9 of Method 608 entitled "Sample Extraction."

Complainant attacks Mr. Ziegler's criticism of the calculations on the chromatogram (Exh 1 to Karras affidavit) as being possibly off by a factor of 100 as illustrating a profound lack of understanding of the procedures used by Mr. Karras in testing the sample (Complainant's Response at 12). It is pointed out that ¶ C.2. "Sample Preparation" of the Silica Gel Cleanup Procedure provides in part "Carefully transfer 1.0 ml of 1% oil sample to the column" and that Mr. Ziegler's apparent assumption that 100 ml of the sample was passed through the column is incorrect. Mr. Ziegler denies any assumption that 100 ml of oil was placed on the silica gel column, saying that this would definitely overload column capacity (Affidavit of May 2, 1983, at 6). He states that a common practice is to place one ml of oil on a column and elute this by adding 100 ml of solvent, the entire eluent being collected. He explains that a common practice is to take the eluent and concentrate it, using Kuderna-Danish glassware, back to the original sample size of one ml, indicating that in the process sensitivity has been increased, and interfering hydrocarbons have been removed. He again refers to markings on the chromatogram of the test conducted January 27, 1982, which clearly state "1 ml sample to 100 ml, F.V. = 1 ml" and emphasizes that "F.V. must stand for final volume." He asserts that if it does stand for final volume there is definitely a factor of 100 error in the calculations. He further

^{9/} Paragraph 12.2 of Method 608 provides that results are to be reported in micrograms per liter without correction for recovery data. It is also noted that ¶ 7.2 FMSL procedure, draft and final version, provides for dilution at the rate of 100:1 for samples [containing PCBs] in the 0 to 100 mg/kg range. Moreover, it is of interest that a completed analysis report, dated July 1980, furnished in a prehearing exchange, but not offered in evidence, reflects the value for Sample 57970 as 76000.0 ug/L PCB-1260. The report indicates that this test was conducted on July 16, 1980, while testimony at the hearing was to the effect that the test relied upon was conducted on July 22, 1980 (Tr. 187, 192-93, 195). It is not clear whether this is an error as to date or a different test.

asserts that if the "in-house" silica gel procedure was followed, there is no need for the markings "F.V. = 1 ml" on the chromatogram and argues that these markings raise legitimate and serious questions as to whether Mr. Karras followed his method in detail.

Mr. Ziegler avers that he was well aware that EPA Method 608 involved wastewater samples, points out that the silica gel cleanup procedure used by Mr. Karras appears to be an in-house and not a published method, and that although this procedure involves waste oils, the chromatographic method used (Method 608) applies to wastewater samples (Affidavit of May 2, 1983 at 2-3). He disclaims any implication that silica gel cleanup of environmental samples is not an approved technique, noting there are several silica gel cleanup techniques in EPA publications. He notes that Method 608 was used notwithstanding availability of the draft EMSL procedure, dated June 24, 1980 (see notes 3 and 4, supra) and that this enables Complainant to "pick and choose," omitting procedures considered inconvenient, while nevertheless, contending approved procedures were followed. He contends that it is clear that appropriate methods and quality assurance protocols were not adhered to in the analysis of Sample 57970.

Alternative Motion

As indicated previously, Respondent has moved in the alternative that the hearing be reopened on the issue of the civil penalty. The basis for this alternative is the contention that Respondent at all times intended that there be a subsequent hearing on the penalty after Respondent's Motion to Reopen the Hearing, dated January 19, 1983, at 14). In a footnote (Id. at 15), Respondent argues that it is entitled to show that no useful purpose would be served by the imposition of a civil penalty because: "(1) Noble provides an important economical alternative to disposal of waste oil by recycling that oil and permitting its reuse by the people of New Jersey and elsewhere; (2) there is no indication or allegation that Noble knew or should have reasonably known in the course of its purchase of waste oil from various dealers throughout the state that PCBs may have been present in the oil; (3) Noble at all times fully cooperated with the EPA even though it had good cause to believe that EPA's sampling and analysis were scientifically invalid; and (4) the imposition of a civil penalty would be a uniquely punitive action without any possible purpose of deterrence." Presumably, evidence bearing on the listed matters would be offered if the motion was granted.

Opposing the alternative motion, Complainant asserts that there is no basis for Respondent's bifurcated hearing theory and points out that the complaint, dated January 24, 1981, informed Respondent that it could request a formal hearing to, inter alia, "contest the appropriateness of the amount of the proposed penalty." It is further pointed out that Rule 22.27(a) of the Rules of Practice (40 CFR Part 22) provides in part that the initial decision shall include a "recommended civil penalty assessment, if appropriate." (Memorandum In Opposition to Respondent's Motion to Reopen the Hearing, dated February 22, 1983, at 22-23).

Additionally, the prehearing correspondence between the ALJ and prior

counsel for Respondent cited at 13-14 of the initial decision, and the Trial Memorandum, dated January 21, 1982, wherein it is argued at 17-18 that the imposition of any penalty would be inappropriate are cited to refute any suggestion that Respondent did not understand that the hearing included the issue of an appropriate penalty, if liability was found (Opposition at 23-24). Complainant also points out that in a similar PCB enforcement proceeding under the Toxic Substances Control Act (Oil Recovery Company, Inc., Docket No. II-TSCA-PCB-81-0106) the hearing of which was held seven months prior to the instant hearing, and wherein counsel for Respondent herein represented respondent in that case, the issue of whether liability and the amount of the penalty would be considered in a single hearing was specifically considered and resolved in the affirmative (Memorandum in Response to Respondent's Reply Brief, dated April 11, 1983, at 15-17).

Discussion

Rule 22.28 of the Rules of Practice (40 CFR Part 22) entitled "Motion to reopen a hearing" provides in pertinent part:

Presiding Officer and filed with the Regional Hearing Clerk."

[&]quot;(a) Filing and content. A motion to reopen a hearing to take further evidence must be made no later than twenty (20) days after service of the initial decision on the parties and shall (1) state the specific ground upon which relief is sought, (2) state briefly the nature and purpose of the evidence to be adduced, (3) show that such evidence is not cumulative, and (4) show good cause why such evidence was not adduced at the hearing. The motion shall be made to the

Complainant says that the quoted rule appears to be patterned after and to serve the same purpose as Rule 59(a), Federal Rules Civil Procedures "New Trials: Amendment of Judgments" (Opposition at 8). It is argued that new trials are not favored and that the grant of a new trial in non-jury cases is limited to situations where there has been a manifest error of law or mistake of fact, citing Wright & Miller, Federal Practice and Procedure, Civil § 2804 (1973). The affidavit of Attorney Alan G. Kelley in support of the motion to reopen acknowledges that the Ziegler data on analytical variability (standard deviation) of PCB analysis was first made available after the hearing in this case and makes it clear that the basic thrust of the motion is that the interests of justice require that the hearing be reopened (Id. at \P 5 & 6). A motion under FRCP Rule 59 upon the ground that the interests of justice require a new trial is at odds with the policy that there be an end to litigation and thus will be granted only in unusual or extreme situations. seem to be especially true of the after occurring events or after acquired data involved here. As counsel points out, however, Mr. Ziegler

^{10/} EPA quotes the following from State of Washington v. United States, 214 F. 2d 33 (9th Cir. 1954):

[&]quot;The policy of Law in having an end to litigation would in most cases prevent the reopening of a case because of afteroccurring events [citation omitted]

But, a general exception exists where substantial justice requires a reopening and when the after-occurring event is of major importance in its impact on the case." 214 F. 2d at 46-47.

This, of course, clearly indicates that an after-occurring event having a major impact on the decision, may be a ground for a new trial in the federal courts.

testified at the hearing that he was evaluating the variability of the 50 ppm TSCA limit and would be presenting a paper on that subject at the Pittsburgh Conference on Analytical Chemistry in March of that year (Tr. 227, 256). Evidence is lacking as to the status of that research at the time of the hearing herein.

Complainant contends that Respondent has failed to identify the specific grounds for its motion, that Mr. Ziegler is making essentially the same points questioning the EPA test procedure in his affidavit as he did in his testimony at the hearing and thus Respondent has failed to show that the evidence proposed to be adduced is not cumulative and lastly, that Respondent has failed to show good cause why the evidence was not adduced at the hearing (Opposition at 13-14). Pointing to the uncertain status of Mr. Ziegler's research paper at the time of the hearing, Complainant asserts that Mr. Ziegler could have testified as to the results of his research or Respondent could have requested an adjournment to enable further testimony after the paper had been completed and presented at the Pittsburgh Conference.

Replying, Respondent argues that the FRCP and cases decided thereunder are inapplicable, that its motion is clearly permitted by the
Rules of Practice, that there is no reason for these rules to be applied
in a rigid, talismanic fashion, that its motion complies with the minimum

11/
requirements of Rule 22.28 and that fundamental fairness requires

^{11/} Although most of the cases cited by Respondent involve rulemaking under the APA, Trujillo v. General Electric Co., 621 F. 2d 1084 (10th Cir., 1980) & Duval Corp. v. Donovan, 650 F. 2d 1051 (9th Cir., 1981) involve adjudication and stand for the proposition that administrative bodies have inherent authority to reconsider their decisions and that an agency's action on a petition for reconsideration is discretionary.

that the hearing be reopened, in that the previously unavailable statistical evidence sought to be introduced has a profound impact on the reliability of the EPA test and upon the threshold question of Respondent's liability for the alleged violation (Reply Brief at 4-10). Respondent also disputes Complainant's contention that the control chart showing intralaboratory variability furnished with the Karras affidavit of February 18, 1983, establishes that the interlaboratory data supplied by Mr. Ziegler is inapplicable (Reply Brief at 11, et seq.). Respondent argues that it should be permitted to cross-examine Mr. Karras as to why this chart, which allegedly was in existence at the time of the hearing, was not produced or referred at the time. It is pointed out that the chart fails to indicate the matrix or the PCB spike level used in the tests and that if, through cross-examination of Mr. Karras, these were shown to be inappropriate, Complainant's argument that it has intralaboratory data, which is preferable to the interlaboratory data proffered by Respondent, must fail (Id. at 13). Respondent further argues that Complainant's submission of a control chart, allegedly made in conjunction with the test on an aliquot of Sample No. 57970 approximately 18 months after the sample was drawn, constitutes belated recognition of the invalidity of the July 1980 analysis and that this invalidity cannot be cured by a test made long after the 30-day period specified by Method

^{12/} One obvious and likely reason is that the test on an aliquot of Sample No. 57970 conducted in January of 1982 was far beyond the 30-day requirement of ¶ 8.3 of Method 608 (note 4, supra, and accompanying text). It is also noted that the final version of the EMSL procedure (¶ 10) requires precision and accuracy data to be maintained after January 1, 1982.

608 (Id. at 14-15). Respondent reiterates its belief that two hearings would occur as a reason for reopening the hearing on the issue of the civil penalty (Id. at 19-20).

Although Respondent may well be correct that administrative agencies are not bound by rigid rules applicable to courts and, consequently, have more discretion in acting upon petitions for reconsideration or motions to reopen the record, it is nevertheless fundamental that motions to reopen the record should not lightly be granted. Here it is obvious that the principal original basis for the motion, i.e., that evidence bearing on the analytical variability (standard deviation) of analyses of PCBs in waste oil matrices, first made available after the conclusion of the hearing, would preclude a finding that the PCB concentration of 76 ppm determined herein was in excess of the regulatory limit of 50 ppm, has been broadened into a full scale attack on the validity of Complainant's conduct of the analysis in question. This is no doubt due, at least in part, to data, a control chart and an analysis of Sample 57970 conducted on January 27, 1982, supplied in opposition to the motion, which were apparently available at the time of the hearing (February 9-11, 1982), but not referenced or offered in evidence. If this data were essential to support the finding of 76 ppm PCBs upon which the finding of violation is based, it is clear that the motion would, of necessity, be granted, because Respondent had no opportunity to question such data through cross-examination or otherwise at the hearing.

^{13/} This is not only because of the expense and inconvenience of hearings, but also because the prevailing party should not be subjected to the risk of having a favorable decision overturned in the absence of substantial reasons.

It is concluded, however, that quality control data and evidence concerning the analysis of Sample 57970 conducted on January 27, 1982, are not essential to support the finding of 76 ppm PCBs. This is because Mr. Karras, the analyst who conducted the July 1980 test, testified that he ran a known standard of PCBs and compared the resulting chromatogram with previous chromatograms to assure that the chromatograph was in good working order (Tr. 196-97). This coupled with the testimony that he used the Silica Gel Cleanup Procedure (Government Exh 8) in preparing the sample and ran the analysis in accordance with ¶ 11 of Method 608 (Government Exh 7) is sufficient to support the validity of the analysis as against other evidence in the record tending to detract therefrom. For the question is not whether detailed testimony or documents in evidence establish, for example, that the sample containers were free of contamination, that cleanup procedures were properly followed and substances which might interfere with the identification of PCBs removed, that the sample aliquots of oil were properly measured or weighed and diluted with the appropriate amount of hexane, which dilution was properly recognized in the calculation of PCB levels or quantities and PCB peaks properly identified, but rather, whether there is sufficient evidence in the record of deficiencies in the foregoing or other respects of the

^{14/} That evidence was detailed in the initial decision and need not be repeated here. Regarding Mr. Ziegler's preference for a Hall electrolytic conductivity detector rather than the GC electron capture detector used here, because the former is halogen specific and will not respond to interferences, Complainant points out that both the draft and final EMSL procedure recognize that other semi-specific detectors such as ECD may be used where sample chromatographic peaks closely match those of the standards and provided proper cleanup procedures are followed.

test as to cast substantial doubt upon the validity of the conclusion that the level of PCBs in Sample 57970, and thus in Tank No. 4, was in excess of 50 ppm. The point being that Mr. Karras could have been cross-examined on all of these matters and the significance of any deficiencies thus revealed supported by the testimony of Respondent's expert, which might have afforded a more substantial basis for Respondent's contention that the test was scientifically inadequate.

As noted earlier, the fact that Mr. Karras did not use an internal standard in the analysis of Sample 57970 in July of 1980 was elicited in cross-examination at the hearing. Although Mr. Ziegler is critical of the failure to utilize an internal standard, contending that this places too much confidence in the personal judgment of the analyst, identifying RRTs of PCBs in the sample by comparing the sample chromatogram to standard chromatograms is sanctioned by the EMSL procedure (note 7, supra, and accompanying text).

The foregoing demonstrates that Respondent's attack on the validity of the analysis of Sample 57970 is largely cumulative of matters which were either specifically raised or by necessary implication inherent in issues considered in the initial decision and cannot support a motion to reopen the record. This includes Mr. Ziegler's complaints that data concerning quality assurance measures have not been furnished, that no evidence of analyses of field and method blanks to assure contamination

^{15/} Whatever may be the proper construction of the 40 CFR 22.28, it would seem to be clear that the rule is not intended to and cannot serve as a vehicle for correcting errors in strategy or oversights of counsel at the hearing. If it was otherwise, the concept of finality would have no meaning.

free sample containers and instruments have been provided, that his concerns about a possible error by a factor of 100 in the calculation of $\frac{16}{}$ PCB levels have not been answered and that the method of sample preparation has not been documented so as to establish that an accurate aliquot of oil was measured or weighed.

Concerning the principal basis of the motion, there is, of course, nothing new or startling about the concept of analytical variability (standard deviation) of analyses of PCBs or other substances for that matter. For example, the Webb and McCall article (note 5, supra) contains data on the relative standard deviation of analyses of various Aroclors, calculated as a percentage of the mean of the results. Similar or identical data is contained in the draft EMSL procedure, dated June 24, 1980, and the final version, EPA-600/4-81-045. Paragraph 13.1 of Method 608 states that EMSL is in the process of conducting an interlaboratory method study to determine the accuracy and precision of this test procedure. Moreover, Mr. Ziegler was questioned on this precise point during the hearing and he replied that the precision of the test depended not only upon how the test was run, but upon the matrix being analyzed (Tr. 259). He indicated that the variability of analyses of PCBs in water samples was less than that of an oil or hydrocarbon sample and that his laboratory liked to keep the relative standard deviation at better (less) than a plus or minus 20 percent difference.

^{16/} This concern results from calculations on the chromatogram of Sample 57970, which was run on January 27, 1982. As noted, supra at 25, this chromatogram is not essential to support the finding of 76 ppm PCBs.

Accordingly, the only new evidence offered in support of the motion is data on interlaboratory variability, which has not been established as applicable to an analysis conducted on July 1980 by a laboratory not participating in the 1982 studies which generated the data. Accordingly, even if this interlaboratory variability data were admitted into evidence, it is unlikely to change the result. Respondent is relying on the interests of justice and fundamental fairness to support the motion, and a requirement that the proferred evidence be likely to change the result seems reasonable.

Respecting the alternative basis of the motion, Respondent has offered no explanation for its asserted belief that the issue of the penalty would be considered at a second hearing only after liability was determined in the first instance. Indeed, in view of the complaint, the rules of practice and the prehearing correspondence cited in the initial decision, it would appear that no reasonable basis for such a belief could exist. Moreover, as Complainant points out, Respondent's silence at the hearing as to any possible second hearing where the issue of penalty would be considered, militates strongly against the existence of

^{17/} As found in the initial decision, duplicate samples from each of the tanks were left with Respondent at the time of the inspection on July 15, 1980. Respondent's silence as to the disposition of these samples and the results of any analyses conducted thereon, could afford the basis for an inference that such evidence would be adverse to Respondent.

such a belief at the time. If the amount of the penalty is unduly burdensome, Respondent would not appear to be totally without remedy.

Conclusion 19,

The motion to reopen the record is denied.

Dated this 16 day of May 1983.

Spencer T. Nissen

Administrative Law Judge

^{18/} Although the Federal Claims Collection Act of 1966 (31 U.S.C. 951-53) provides for a limit on authority of the head of an agency to compromise claims to those that do not exceed \$20,000, it also provides that the Act is not intended to diminish authority to settle or compromise claims and the agency would appear to have inherent authority to enter into an agreement for payment in installments or to otherwise compromise the claim based on economic hardship.

^{19/} Respondent's request for oral argument on the motion is denied.

^{20/} In accordance with 40 CFR 22.28(b), the filing of the motion operated to stay the running of the 20-day appeal period provided by 40 CFR 22.30(a).