

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF IDAHO

TIMM ADAMS, et al.,)	Case No. CV-03-49-E-BLW
)	
Plaintiffs,)	MEMORANDUM DECISION
)	AND ORDER REGARDING
v.)	MOTION TO EXCLUDE
)	TESTIMONY OF
UNITED STATES OF AMERICA,)	DR. SHANE NEEDHAM
et al.,)	
)	
Defendants.)	
_____)	

INTRODUCTION

The Court has before it the BLM’s motion to exclude Dr. Shane Needham, an expert for the plaintiff. The motion is fully briefed and at issue. For the reasons expressed below, the Court will deny the motion in large part, but will grant one portion of the motion and reserve ruling on another portion. More specifically, the Court will exclude any testimony from Dr. Needham regarding the current industry standards governing pesticide or herbicide analytical labs like the MSU lab, and exclude his opinion that “the procedures and policies used at the analytical lab at MSU exceed the typical standards by comparable labs in the pesticide and herbicide analytical testing industry.” *See Dr. Needham Expert Report* at p. 5. The

Court will reserve ruling on Dr. Needham's testimony that quantifies the "trace" amounts found by MSU, and collects those levels in Table 1 of his expert report. The motion is denied in all other respects.

ANALYSIS

Dr. Needham was retained by plaintiffs to render opinions on the soil sample tests run by Montana State University (MSU). The BLM claims that Dr. Needham is unqualified, and that his opinions are unreliable. The Court will examine each challenge below.

Qualifications

Dr. Needham was retained by plaintiffs to (1) review soil sample testing done by MSU using a procedure known as liquid chromatography/mass spectrometry (LC/MS), and (2) to "give an assessment of the overall procedures used at the [MSU lab] with respect to industry standards." *See Dr. Needham's Expert Report* at p. 5. Dr. Needham is the laboratory director of a contract research firm, which he co-founded in 2000, that specializes in LC/MS, and its more advanced successor, LC/MS/MS. He holds a bachelor of science degree and a Ph.D. in chemistry. He has been working in analytical chemistry since 1991, and performing LC/MS/MS analysis since 1993. He has been involved in developing more than 500 LC/MS/MS methods for the analysis of molecules from various

matrices including the analysis of sulfonylureas from soil – the same analysis at issue in this case. He has published and or presented on LC/MS and/or LC/MS/MS over 80 times.

His background establishes him as an expert on the LC/MS/MS procedure, including the use of that procedure for analyzing sulfonylureas from soil. The Court therefore rejects the BLM’s argument that Dr. Needham is unqualified to evaluate MSU’s use of the LC/MS/MS procedure to test the soil samples from this case.

Even so, the BLM argues, Dr. Needham goes beyond his expertise to testify that MSU followed industry standards. He will so testify – he states in his report that he was retained in part to testify about “industry standards.” *See Dr. Needham Expert Report* at p. 5. Consistent with that, he rendered the following opinion: “[T]he procedures and policies used at the analytical lab at MSU exceed the typical standards by comparable labs in the pesticide and herbicide analytical testing industry.” *Id.*

This opinion, the BLM asserts, must be excluded because Dr. Needham has no experience in the pesticide and herbicide analytical testing industry that would make him an expert on the standards applicable to that industry. It is true that most of Dr. Needham’s experience is in “bioanalytic” laboratories doing pharmaceutical

analysis. When asked in his deposition about industry standards, Dr. Needham answered that “I didn’t feel that this [sic] standards were that important. I looked at the data on a day-to-day basis.” *See Deposition of Dr. Needham, January 28, 2009* at p. 421. When asked if there were any published industry standards for labs comparable to MSU’s lab in the pesticide or herbicide industry, Dr. Needham testified that he was not aware of any and did not rely on any in reaching his opinions. *See Deposition of Dr. Needham, October 6, 2008*, at p. 286. While he once worked in a lab comparable to MSU’s using EPA methods of testing, he left there in 1992 and has not worked in a comparable lab since that time. *Id.* at pp. 82-83.

Dr. Needham’s deposition testimony indicates (1) that he has no expertise in current industry standards for analytical labs in the pesticide or herbicide industry, and (2) that such standards were unimportant to him in any event. Plaintiffs’ briefing confirms this: “Needham did not base his conclusions on the presence or absence of any certifications or external standards, but rather on a review of the actual data produced because of his opinion that only the output of the instrument itself can determine if the sample was accurately analyzed.” *See Plaintiffs’ Brief* at p. 7.

This record shows that Dr. Needham's focus shifted over time. While he was initially retained to testify about industry standards – and he rendered a general opinion thereon, as quoted above – the remainder of his opinions do not rely on industry standards but focus instead on a review of the actual data produced. So it is not surprising that he demonstrates no expertise in the current industry standards governing pesticide or herbicide analytical labs like the MSU lab – those standards were, in his own words, not “important” to him. *See Deposition of Dr. Needham, January 28, 2009* at p. 421.

Given this, the Court finds that Dr. Needham has not demonstrated expertise in the current industry standards governing pesticide or herbicide analytical labs like the MSU lab. He has demonstrated expertise in the LC/MS/MS process, and in the evaluation of MSU's use of that process to test the soil samples in this case.

This means that Dr. Needham is qualified to render most of the opinions contained in his expert report, except for those dealing specifically with industry standards. Thus, the Court will exclude his opinion that “the procedures and policies used at the analytical lab at MSU exceed the typical standards by comparable labs in the pesticide and herbicide analytical testing industry.” *See Dr. Needham Expert Report* at p. 5. The remainder of Dr. Needham's opinions all appear to relate to an evaluation of the LC/MS/MS process and the use of that

process to test soil samples in this case. Dr. Needham is qualified to render opinions on those subjects.

Reliability

The BLM challenges the reliability of Dr. Needham's opinions on the ground that his methodology is flawed. In making these challenges, the BLM relies heavily – at times exclusively – on the opinion of their own expert, Dr. Dallas Wait. To resolve the dispute between Dr. Wait and Dr. Needham, the Court will first explain what they are fighting over – the LC/MS and LC/MS/MS procedures.

The LC/MS procedure is used to detect the presence of a target chemical – known as the analyte – contained in some substance or mixture, such as soil. The procedure runs a known sample of the analyte – here, Sulfometuron-Methyl – through the process to reveal its unique “fingerprint,” known as “retention time.” Once the retention time of the chemical has been identified, samples of the mixture – here, the soil samples – can be tested for the presence of that analyte.

To be more specific, liquid chromatography separates the analyte from a mixture (assuming the analyte is present) while mass spectrometry identifies and quantifies the analyte. When joined, the two techniques are used as an analytical tool to determine the presence of an analyte and, if present, to quantify the amount.

The LC/MS process is complex and not fully described in the briefing. With this sketchy background, the Court will set forth its simplistic understanding of the process.

LC/MS uses a high pressure liquid solution to move the analyte into a column filled with certain material that reacts with the analyte, fragmenting it into two ions (charged particles). Here, the analyte was Sulfometuron-Methyl, and the two ions produced from that chemical were identified as the 150 and 191 ions. Those two ions then move through the column in a certain amount of time, known as the “retention time.” That particular retention time is unique to Sulfometuron-Methyl.

Prior to this litigation, MSU used the LC/MS process to calculate the retention time of Sulfometuron-Methyl so that they could test soil samples from Montana suspected of containing that chemical. In those experiments, MSU found that the retention time of Sulfometuron-Methyl was 12.9 minutes. MSU translates this retention time to a retention factor (K) of between 4 and 5.

When testing soil samples, the LC/MS process looks for and monitors the two ions (the 150 and 190 ions). To conclude that any particular soil sample contained Sulfometuron-Methyl, MSU required that (1) the retention time of the ions produced from the particular soil sample matches that of Sulfometuron-

Methyl; (2) the two ions (150 and 190) must be within 30% of each other; and (3) for reporting of trace amounts below the detection limit, MSU required that the peak for each ion at the proper retention time must be at least 5 times higher than any smaller peaks from other compounds or background “noise.”

Shortly after receiving the first soil sample from the parties in this case, MSU started using an even more sensitive test, known as the LC/MS/MS test. It used an additional mass spectrometer but otherwise employed the same procedures as the prior LC/MS test. According to Heidi Hickes, the Director of the MSU lab, the LC/MS/MS is a substantial advance over the LC/MS test due to its increased accuracy.

MSU was reporting Sulfometuron-Methyl results at 50 ppt and above. The Idaho State Department of Agriculture (ISDA) asked MSU if it could report results lower than 50 ppt. MSU agreed to report that a “trace” was detected if below 50 ppt, but was not willing to report the actual quantity detected if under 50 ppt. In a letter dated June 29, 2001, MSU lab Director Hickes stated that although it “is not laboratory policy to provide information on data outside the validated range of our analytical methods . . . [w]e are willing to make an exception in this case [because] . . . Oust residues . . . had degraded to levels below the range of the validated method . . . [and because MSU had] confidence in the technical expertise and

capability of the laboratory to determine sulfometuron ethyl residues at less than [50 ppt] by LC/MS/MS.” See *Memo of MSU Laboratory Director Hickes (Exhibit 6 to Affidavit of Anderson (docket no. 834))* at p. 1.

When Sulfometuron-Methyl concentration fell below 50 ppt, MSU would simply note that a “trace” of Oust was found, without revealing the actual amount. MSU had a validated level of detection set for its instruments – 50 ppt – and was not willing to report numbers below that level, although it did internally calculate those numbers, and did provide their calculations to Dr. Needham. See *Dr. Needham Deposition of October 6, 2008*, at pp. 90-96. Dr. Needham evaluated MSU’s calculations by looking “at each number that they had” and “see[ing] if that was the same values [sic] I would come up with and same calculations I would use.” *Id.* at pp. 96, 97.

In his expert report, Dr. Needham prepared a table quantifying the Oust concentration levels for those samples where MSU reported only that a “trace” of Oust was found. After completing his calculations, Dr. Needham concluded that

[b]ased on simple statistical calculations by the analysis of “trace” level duplicate samples, it was found the majority of the data is accurate to the 90% confidence level. In analytical chemistry measurements when something is reported accurate with 90% confidence in layman’s terms this means “the chemist is confident that the molecule is detected accurately and reliably.” However, because these “trace” results are below the [lower limit of quantitation], the “traces” are characterized as estimated values even though the values can be reported with a high

degree of confidence.

See Dr. Needham Expert Report at p. 13.

With that background, the Court will turn to the BLM's argument that Dr. Needham's opinions are unreliable because he: (1) used a flawed methodology that failed to consider, among other things, that MSU failed to follow its own Standard Operating Procedures (SOP), and (2) improperly applied quantitative values to the "trace" amounts of Sulfometuron Methyl.

Methodology and SOPs

The BLM argues that Dr. Needham failed to review MSU's standard operating procedures (SOPs) prior to finalizing his report, and failed to consider that MSU did not comply with their own SOPs in conducting the LC/MS/MS testing, which failures render the opinions set forth in his report unreliable.

Dr. Needham did review MSU's SOPs after issuing his expert report but prior to his deposition. When asked at his deposition whether his review of the SOPs changed any of the opinions he rendered in his report, he answered, "[n]ot at all. It actually made it stronger." *See Dr. Needham Deposition* at p. 36.

However, in rendering his opinions, Dr. Needham did not consider the SOPs important. He was asked at his deposition "whether MSU followed its own SOPs in developing its methods for the determination of sulfonylureas in soil? Was that

even – was that important for you to know?” *Id.* at p. 157. He answered, “[n]o. Review of the data was important.” *Id.*

Dr. Needham’s methodology for evaluating the soil sample results produced by MSU’s LC/MS/MS procedure was to examine the data produced by the procedure for each specific sample to determine if the result was accurate.

Whether or not MSU was following its SOPs, Dr. Needham concluded that he could evaluate the accuracy of its results by examining the data produced for each sampling result. He testified that he did not need to review the SOPs

because basically the data that was produced, you could see that the methods and the techniques and the procedures they were using to validate a method were appropriate. You didn’t even need a SOP for it. You could see the procedures they were using was [sic] appropriate for validation of analytical methods.

Id. at p. 153.

The BLM’s expert, Dr. Wait, takes issue with Dr. Needham’s methodology. Dr. Wait concludes that MSU violated its own SOPs, and that those violations rendered the lab results unreliable. For example, Dr. Wait argues that MSU failed to properly calibrate its instruments in accordance with their own SOPs.

Countering that testimony, Dr. Needham asserts that MSU did follow proper calibration standards. *See Dr. Needham Rebuttal Report* at p. 5. This same dispute occurs over retention times, ion fragments, and false positives.

The Court is faced with a battle of experts; the BLM is arguing that Dr. Wait's opinion should trump that of Dr. Needham. Even if one expert could prevail, as a matter of law, based on superior expertise, Dr. Wait does not possess that level of superiority. Indeed, the two experts seem to have complimentary expertise – where one is strong, the other is weak. For example, while Dr. Needham's expertise is especially strong in analyzing LC/MS/MS results, Dr. Wait has far less experience with LC/MS/MS. *See Dr. Wait Deposition* at pp. 32-35. At the same time, Dr. Wait has more experience with environmental testing.

This comparison demonstrates that Dr. Wait's expertise is not so superior to that of Dr. Needham that the Court could rule, as a matter of law, that Dr. Wait's opinion should be adopted over the conflicting opinion of Dr. Needham. This comparison also demonstrates why the central case cited by the BLM – *Bauer v Bayer*, 564 F.Supp.2d 365 (M.D.Pa. 2008) – is inapplicable here. In *Bauer*, the court was faced with a challenge to the plaintiffs' use of the LC/MS/MS procedure to test for the presence of an insecticide in honey bees. The defense expert pointed out significant problems with the lab's handling of the LC/MS/MS procedure. In response, the plaintiffs "have not proffered testimony of a qualified expert to oppose [the defense expert's] review," according to the court. *Id.* at 377. Consequently, the court ignored those test results.

Bauer is inapplicable here because plaintiffs have “proffered testimony of a qualified expert” – Dr. Needham. The BLM asserts, however, that Dr. Needham is taking inconsistent positions, following SOPs in his own lab but ignoring them in MSU’s lab. While a valid subject of cross-examination, this point goes to the weight and not the admissibility of Dr. Needham’s testimony.

The BLM argues next that Dr. Needham used a “mystery” method to evaluate the MSU soil sample results, and that “there is nothing scientific” about his methodology. *See BLM Reply Brief* at p. 4. The BLM asserts that in his report, Dr. Needham merely lists “what MSU was doing, not what steps Needham took to reach his conclusions.” *Id.*

It is true that Dr. Needham’s report is quite general on how he reviewed the data for each MSU soil sample test. But there is no “mystery” about his methodology. He reviewed the data from each MSU soil sample test for accuracy. This data was available to the BLM’s expert, Dr. Wait, as well. Indeed, Dr. Wait testified that he relied on the data: “[T]he data packages that were provided to me should provide all of the information needed for anybody to independently recreate what was done.” *See Dr. Wait Deposition* at p. 87. If the data packages were enough for Dr. Wait to recreate what was done in the MSU lab, they must have allowed Dr. Needham to do the same. The BLM runs into difficulty assailing Dr.

Needham's methodology when its own expert relied on the same methodology.

“Trace” Levels of Oust

The Court has described above how Dr. Needham quantified the levels of Oust in samples where MSU had merely stated that “trace” levels existed. The Court has a number of concerns with this testimony. First, the MSU lab refused to quantify those levels. Second, Dr. Needham does not point to any objective source that supports his opinion that the levels can be quantified even when the lab that did the testing refuses to do so. Third, Dr. Needham states that he has a “high degree of confidence” in his figures, but then deems them “estimated values,” because they are below the [Lowest Level of Quantitation] LLOQ.” *See Dr. Needham Expert Report* at p. 13.

The Court understands that by December of 2001, about 6 months after MSU reported its findings in June of 2001, MSU had performed additional verification tests on its LC/MS/MS procedure and revised its policy to lower the numerical reporting limit to 10 ppt. It is not entirely clear from the record whether any changes to the instruments were necessary to achieve the confidence level required to lower the LLOQ. Obviously, if the LLOQ was lowered in December based on the same instrumentation used in June, with no changes, Dr. Needham's opinion on the trace levels has more reliability than if changes were needed to drop

the LLOQ. The Court simply does not know from this record.

The Court also understands that MSU actually calculated the levels below 50 ppt but was just unwilling to report them formally. MSU provided the data to Dr. Needham that it used to calculate those levels. Thus, Dr. Needham was not conjuring up his own numbers – he was just reviewing MSU’s numbers.

Still, MSU was refusing to report the levels below 50 ppt, apparently because they had not verified the accuracy of their LC/MS/MS method. Given that, and Dr. Needham’s labeling of the levels below 50 ppt as “estimated values,” the Court has concerns about the reliability of these numbers.

To address these concerns, the Court will need to hear testimony outside the presence of the jury on this single issue. Accordingly, the Court reserves ruling on the BLM’s motion to the extent it seeks to exclude Dr. Needham’s testimony that quantifies the “trace” amounts found by MSU, and collects those levels in Table 1 of his expert report.

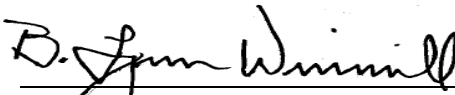
ORDER

In accordance with the terms of the Memorandum Decision set forth above,
NOW THEREFORE IT IS HEREBY ORDERED, that the motion to exclude (Docket No. 747) is GRANTED IN PART, DENIED IN PART AND RESERVED IN PART. It is granted to the extent it seeks generally to exclude any testimony

from Dr. Needham regarding the current industry standards governing pesticide or herbicide analytical labs like the MSU lab, and specifically to exclude his opinion that “the procedures and policies used at the analytical lab at MSU exceed the typical standards by comparable labs in the pesticide and herbicide analytical testing industry.” *See Dr. Needham Expert Report* at p. 5. It is reserved to the extent it seeks to exclude Dr. Needham’s testimony that quantifies the “trace” amounts found by MSU, and collects those levels in Table 1 of his expert report. It is denied in all other respects.



DATED: **April 27, 2009**


Honorable B. Lynn Winmill
Chief U. S. District Judge