Dairy Food Safety Researcher

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However, the history of how the tests came to be is telling in the reluctance of the political and regulatory sectors to give up the recently devised testing system.

In recounting the history, Cullor hit upon several key facts that seem to indicate that science, fairness and reason was overruled by political and public relations ploys.

The key reason the tests were developed was to provide a tool that would allow the regulatory structure within the dairy industry to screen raw milk for antibiotic residues, as part of a goal of having no traces of man-made antibiotics in milk.

Whether or not that should be the goal has been and continues to be debated. Nevertheless, with tests in hand, the industry began in January to use new tests to screen for any trace of antibiotic residues.

According to Cullor, since mid-1994 there have been antibiotic residue assays used in practice that have never been "scientifically field tested" nor received NMC Inc. Research Committee recommended validation protocol.

These same tests, Cullor said, are "accepted" by the Center of Veterinary Medicine/Food and Drug Administration, "performance tested" by the Association of Official Analytical Chemists, and "recommended" by the National Conference On Interstate Milk Shipments (NCIMS).

According to Cullor, these tests are used for tanker milk, for trace back on bulk tank milk, and routinely used on individual animal milk samples, although they have not been field tested on tanker loads, on bulk tank milk, and never received the NMC Inc. validation protocol.

"During late 1990, the Government Accounting Office (the GAO is an agency of and answerable to the U.S. House of Representatives) reported that, in their opinion, the Food and Drug Administration did not possess the appropriate technologies to assure consumers that the nation's milk supply was free of antibiotic residues.

"In responding to this report, the FDA pulled together a mechanism to cerfity such assays."

According to Cullor, the assays (or tests) which were developed were done through an "interpretive memorandum issued by the FDA (milk branch)" that summarized the laboratory evaluations of the proposed beta-lactam antibiotic residue tests.

According to Cullor, this method of testing tests is a protocol that calls "for the evaluation of manufacturer's label claims by using spiked milk samples with the parent compound of the antibiotic under study."

In simpler terms, this means that the Center For Veterinary Medicine/FDA accepted tests devised by test manufacturers and tested them by seeing if they would react to milk purposefully spiked with the parent chemicals in antibiotics (not the residues).

They repeated this elementary procedure from 30 to 60 times per test being evaluated, and at different dose levels in the milk.

That's it.

According to Cullor, no field research was done and no tests were done to determine the number of false positive reactions to other substances.

In other words, the tests were never checked to see what else would cause a positive reaction. Cullor said that in his laboratory's study using these same tests the cow's natural antibodies could cause a positive reaction for drug residues.

As a chemical antibiotic breaks down in the cow's system, portions of the chemical called residues linger. They are called "violative" because they inhibit growth.

The residue tests were never evaluated as residue tests, according to Cullor. "They had to do something in a hurry and this is what they did. And for me to say, 'Now you need to start all over,' is not popular."

His suggestion for the industry and government to either adopt his recommendation of sharing responsibility so that milk producers stop being financially hurt and put out of business on the basis of un-scientifically proven tests, or start all over and conduct the tests on these residue tests that good science dictates.

"What they did was fine. It was a good start," he said of the FDA tests. "But you ought to go into the field and see how it works in the real world. That's what bothers me."

He said that, "... from a scientific point of view, (what needs to be done) is to really put together a protocol to validate these tests that includes field trials."

He said that, as a scientist, he would "... call time out and go back and fix (the testing procedures) according to scientific principles."

However, because of the political and business ramifications, Cullor said he doesn't think that abandoning the tests is possible. That's why he suggested a system for using the current tests as screens only, backed up by precise third-party validation tests.

Currently, validation of the tests is to have the same lab repeat the same residue test on the same milk sample. That ensures that the residue test is consistent, not correct.

"If you really believe the tests are good, fine, keep it as a screening test and then send it to a third party. Let the processing plant pay for it (if the screening test was a false positive and the milk was dumped)."

He said that he has heard quoted prices for conducting a precise residue test ranging from $200 to $400 per sample.

But that compares to the thousands of dollars an individual producer can lose based on the current residue tests. To the individual, a loss of that can mean the end of the dairy farm.

"Instead of a little freckled-face guy in California yelling and screaming," Cullor said about his call for changes in residue testing procedures, if processors were to find out how expensive it is to pay for the false positives, then a group with strong political clout might be able to form that could get something done to correct the situation.

"If tests perform then fine," he said about his suggestion for processors using backup testing and reimbursing the producer for wrongfully dumped milk, etc.

"It spreads risk, responsibillty, helps producers, and the consumer, it stills keep them protected.

"But we can keep that vital resource, the dairy producer. They can maintain their ability to support their families and support the rest of the country that consumes their dairy products.

"If you don't do that, the insurance industry is already concerned," he said.

That statement was reinforced during the meeting in a talk by Robert Moser, a representative for Nationwide Insurance Co.

In his presentation, Moser said, "Toward the end of January, I noticed a number of losses coming through with milk identified as a problem and the description of the loss indicating the cuase of the (as) antibiotics in the milk.

"Our past history shows we would have eight to 10 of these types of claims during a year. In January, we had more than this number in about three weeks."

He said he had all claims sent to him instead of going to an adjuster. Then he started making direct calls on the farmers making the claims. (The insurance policy covered these losses) And Moser started calculating the insurance company's losses because of the large number of milk dumpings.

"With most of the trucks being two compartment trucks, this means that we would have to dump around 20,000 pounds and we looked at an average loss of around $2,500.

"With this year's estimate of 100 claims, very quickly our anticipated loss appears to be $250,000 this year.

"This is in contrast to 10 claims in 1994 for a total loss of approximately $25,000."

He said that while in the past a farmer might tell him that he treated a cow and her milk accidently got in the tank, "When I started contacting farmers this January and February, the story changed drastically. Most of the farmers said that they had not treated any of the animals recently and had no idea of what the problems were.

"Some of the farmers even went so far as buying locks for their barns

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