# Microbiological Testing Programs by USDA

**Rosemary Mucklow**

Good Morning. Thank you Dr. Koohamaraie. The government promised that it would send someone to help me on this daunting subject, and I am delighted that the person selected comes from the slightly more neutral ground of the Agricultural Research Service. They could have done worse!

Let's get a couple of things abundantly clear at the outset today. I am not a scientist! I did miserably at science in my school years. I did take Microbiology 1A in 1969, and the three college units that I received were somehow counted towards my degree in accounting. I even got an A for the class, but that was more likely because I organized the class, and my good friend Dr. George York from U.C. Davis drove 80 miles to San Francisco every week to give the course. Industry and inspection people attended the same course together, and it was all about basic micro testing to prepare for alternatives to conducting a mid-shift wash and sanitizing clean up in ready-to-eat (RTE) departments.

So if I'm not a scientist, why am I here? Candidly, I'm a political scientist, and I've learned that microbiology and pathogen testing have a whole lot more to do with politics than they do with science, when the USDA gets involved and the rubber meets the road. Since I'm sufficiently well-surrounded by real scientists in this gathering, in addition to the distinguished Dr. Koohmaraie, I'm beginning to feel a little bit like an invader from outer space in this elite gathering.

I'm going to assume Dr. Dikeman invited me here today to speak, and to be challenged if you will, about the political science of microbiological testing by the government in the meat industry, and to some lesser extent in the poultry industry and even the rest of the food industry. The ground rules of pathogen testing as utilized by the government seem to be changing and evolving even as we speak.

The industry has recognized for many years that it is good business and it pays to make meat safe for people to eat. The liability of the alternative is simply not a viable option, especially in today's society of lawsuits. The long-term viability of companies depends on producing a safe, wholesome product. Consumers will return to buy again if they don't get sick. Just over 20 years ago, one of the first big scares about unsafe meat because of invisible pathogens was roast beef. Distinguished microbiologists at ABC Research responded to the USDA's rule requiring that all cooked beef would henceforth be well-done by developing time/temperature/humidity related schedules that would assure not only that we could still have rare roast beef but that it could also be safe.

By the early 1990s, Dr. Russell Cross, as Administrator of FSIS, recognized that there were serious gaps in USDA's knowledge base on the prevalence of microorganisms. Then Secretary Madigan announced the program to "determine the food safety profile of beef" in March 1992, and it was followed by similar baseline testing programs for raw poultry and pork. Dr. Cross said "the data … will provide a microbiological 'picture' of raw beef today … (telling) us whether certain bacteria of public health concern are present on raw beef and, if present, the levels of these bacteria. The data will serve as a point of reference, a gauge, for evaluating the public health impact of tomorrow's ideas for improving inspection."

Promises were made that the identity of the plants from which samples were collected would forever be kept confidential. This commitment by USDA ensured cooperation by the industry that the sampling and testing scheme, the most ambitious ever undertaken, was designed on the principle of testing to find, not testing to punish! I don't need to tell this audience that there are a lot of tricks in the trade for sampling to help insure better chances of getting negative results. Too bad that the testing to find not to punish promise made in 1992 was broken by subsequent administrations. Chalk that broken promise up to political science. The first question for reciprocation is then: ***Is it OK for the government to break confidentiality commitments?***

One of the baseline studies focused on ground beef, and it figured heavily in later events. I find it interesting that, while the sampling for steers/heifers, cows/bulls, and market hogs each extended for a full 12 months, thus incorporating all seasons, those for raw ground beef, ground chicken and ground turkey were for eight, six, and six months respectively. The *de facto* case in ground beef is that 80% of the samples were collected in a 3-month period: October, November and December 1993**.** The second question for reciprocation: ***In a country as large as the United States, with huge seasonal***

*R. Mucklow*
*Executive Director*
*National Meat Association*
*1970 Broadway Ste 825*
*Oakland, CA 94612*
*rosemary@nmaonline.org*

*Proceedings of the 54th Reciprocal Meat Conference (2001)*

***and geographic differences by region, I would suggest to you that such a limited time frame undermines the scientific validity of the baseline data findings used subsequently to develop a regulatory national performance standard.***

In October 1994, then Administrator of FSIS, Michael Taylor, cleverly constructed an interpretation of product adulteration under the statute that ground beef was adulterated if it was found to contain *E. coli* O157:H7. The cleverness extended to the enforcement of this interpretation, which was based substantially on a test to punish concept. USDA itself would do random testing at grinders and in the marketplace beyond its normal jurisdiction, but still within the enforcement arm of the statute and it would "punish" those whose product tested positive by demanding them to make a voluntary recall. However, Mr. Taylor suggested without any subtlety that the random USDA testing would encourage more industry testing. Please keep in mind that plants that tested had to report a positive finding of *E.coli* O157:H7 bacteria, if found, since it was an adulterant in the product and thus must, by law, be reported to USDA. Since it takes at least 3 to 5 days for a laboratory to report a confirmed positive, and raw ground beef does not enjoy a long shelf life, especially at retail, most ground beef is likely to be consumed by the time laboratory results are known. The question for reciprocation here is***: In retrospect with the benefit of 20/20 vision, would there have been a better way to improve the safety of ground beef than this test to punish program?***

In February 1995, Taylor announced the proposed mega-reg, and I remember well the discussion about some of its salient features at NMA's convention in San Francisco. It was visionary stuff, despite his lack of knowledge about the industry he was in charge of regulating! He proposed the use of *Salmonella* as a target pathogen to be sampled by the company, and entered in a moving sum verification chart. The data would be provided to FSIS. In essence, this was a process control approach, using a pathogen rather than an indicator microorganism. The question here, and I almost hesitate to ask it since there are probably many of you that have participated in exquisite research discussion around this subject, is: ***What level of prevalence and uniformity of distribution for a microorganism should exist in a population in order to be able to consistently measure process control?***

You all may remember that the proposal was debated for about nine months, culminating in six days of meetings in Washington in September 1995. It took until the following July to give birth to the Pathogen Reduction, HACCP Rule, and it was remarkable in some of its salient features with respect to microbiological testing. First, there was generic *E. coli* testing for carcasses, rather than the *Salmonella* targeted testing proposal. Second, there was something relatively unknown to the meat and poultry industry: performance standards for *Salmonella*. We're not here to debate the legalities, and the gun-shy meat industry was not ready in 1996 or 1997 to initiate litigation against the unknown behemoth of performance standards, but this was a whole new concept that was not raised in the proposed rule. The standard for ground beef was established, lo and behold, based on the 1993-94 baseline study, and translated into a public health protection rule that said that you could have five or fewer positive *Salmonella* samples in a 53-sample set of raw ground beef and get a passing grade. Six (or more) meant you failed the sample set. The question for reciprocation here is: ***Should not USDA have conducted a risk analysis to determine that 5 out of 53 does not pose a health concern but 6 out of 53 does pose such a concern? Or, alternatively, that 26 out of 53 for ground turkey doesn't pose a health risk, but 27 does? Isn't this what science is all about?***

The federal government has enormous resources at its disposal. Even the United States Department of Agriculture has huge resources. USDA's Chief Economist is a career civil servant and his office provided to then Acting Under Secretary Mike Taylor, in March 1996, comments about the cost-benefits of the proposed mega-reg and an evaluation of the rule and its impact as related to risk analysis from the Office of Risk Assessment Cost Benefit Analysis. Chief Economist Collins commented in particular on the micro sampling plan, noting that it needs to be risk-based, that is, a function of the frequency with which pathogens occur on different species or products. There is limited data about the frequency of a specific pathogen on different species or products. Certainly, the base line data tried to get to this point, and maybe that was in the minds of policy makers when they determined that 5 out of 53 samples on raw ground beef was as acceptable as 26 out of 53 on ground chicken or 29 out of 53 on ground turkey. However, there was no scientific rationale postulated for such huge differences. The question here for reciprocation is: ***Is there a scientific rationale to support a huge variation for pathogen performance standards in various raw meat and poultry products that are subjected to a subsequent heat processing step before consumption?***

There has been Washington, DC talk that a legislative amendment to the federal meat inspection act could "fix" the Texas litigation issue, by in effect, making the action that FSIS took in the Supreme Beef case lawful. Currently, that case is at the 5th Circuit Court of Appeals, which is expected to rule later this year. An effort to do just that failed on the floor of the United States Senate by one vote last year. While the views of the people assembled here may be relatively unimportant to the Club of One Hundred, I'd like to know how you all feel about Senatorial Science.

There's a lot more that we could discuss. I hope that the questions I have raised will stimulate our discussion here today, and that we can all leave here enriched in the subject of the politics of microbiological testing.

Thanks.