LISTERIA RISKS IN READY-TO-EAT MEATS CAN BE CONTROLLED USING A TRUE HACCP APPROACH

Submitted on May 8, 2001

at the Scientific Conference

**USDA Public Meetings on the FSIS Proposed Rule,
"Performance Standards for the Production of Processed
Meat and Poultry Products"**

Submitted by:

**Dr. James L. Marsden
Dr. Randall K. Phebus
Dr. H. Thippareddi**

EXECUTIVE SUMMARY

This manuscript is submitted by the Meat Safety Research Group at Kansas State University, member of the USDA Food Safety Consortium and the National Alliance for Food Safety. It brings forth our observations relative to the effectiveness of the current production and regulatory system for ensuring the safety of ready-to-eat (RTE) meat and poultry products, and provides our view of the design of future production systems based on stringent, scientifically validated and verified HACCP concepts. KSU research data validating various antimicrobial intervention systems are discussed to support the overriding concept that RTE product manufacturing must incorporate a true pathogen "kill step" (critical control point; CCP) at the finished product stage to ultimately ensure product safety. In addition to this CCP, several supporting programs and technologies are discussed as additional requirements for ensuring continuous pathogen control of specific product types (i.e. sliced luncheon meats). These programs and technologies have been highly developed in other manufacturing and service industries, and can logically be implemented in the RTE meat and poultry manufacturing sectors.

BACKGROUND

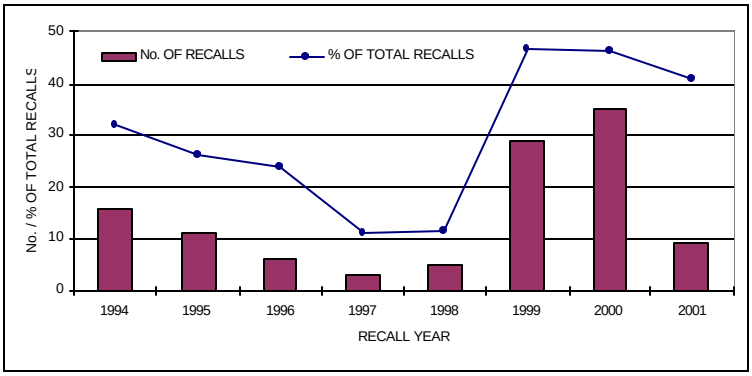
Listeria monocytogenes' association with foodborne disease dates back to a 1981 outbreak in Nova Scotia, Canada involving 41 patients who consumed contaminated coleslaw. In 1985, the pathogen was associated with a large disease outbreak due to contaminated Mexican-style soft cheese. As is often the case with *L. monocytogenes*, a high mortality rate was observed with this outbreak (142 cases and 48 deaths). Reported cases of listeriosis are infrequent; however, it is generally believed that the true rate of disease is substantially higher. Over 75 percent of listeriosis cases reported in 1989-90 were maternal and neonatal infections (Rocourt, 1990; Rocourt and Brosch, 1992). *L. monocytogenes* is the fifth most common cause of bacterial meningitis in the United States and is the third most common cause of bacterial neonatal meningitis in the United Kingdom (Synnot *et. al.*, 1994; Farber and Peterkin, 2000). The CDC reported in 1999 that *L. monocytogenes* had the second highest case fatality rate (20%) and the highest hospitalization rate (90%) of all pathogens that it tracked. Listeriosis cases, particularly those associated with mortality, are characterized by victims being very young, elderly, or immuno-compromised (i.e. chemotherapy, AIDS, diabetes, and organ transplant patients). Americans are falling under one or more of these demographic classifications at a rapid rate. Obviously, the severe disease characteristics associated with certain strains of *L. monocytogenes*, along with the organism's documented association with RTE meat and poultry products *(readers are referred to the recently released draft L. monocytogenes risk assessment document jointly issued by the FDA and USDA)*, legitimize the increased level of regulatory and scientific scrutiny currently being directed towards control of this foodborne pathogen.

After making the definitive association between *L. monocytogenes* contamination of food products and human disease in the early 1980s (including RTE meat products in 1989), a significant reduction (approximately 50%) in the incidence of listeriosis occurred in the 1990s, mostly due to regulatory agency activities and significantly enhanced efforts by industry to control contamination of the processing environment. However, further reductions have not occurred. This may be attributed to greater reliance of families on processed, convenient foods that are minimally processed (especially at the home). Further, manufacturers may have reached a threshold level of success for controlling *Listeria* spp. and *L. monocytogenes* in the processing environment merely using traditional cleaning and sanitation approaches.

Although RTE meat and poultry products do not necessarily represent the riskiest of products on the market relative to *L. monocytogenes*, the frequency and volume of consumption of hot dogs, sausages, luncheon meats, and deli-type products must make their safety a very high level of priority. Studies have demonstrated a high frequency of *L. monocytogenes* contamination of retail frankfurters and luncheon meats in the US. Marsden (1994) indicated that 1.4% (294/20,296 samples) of processed meats harbored *L. monocytogenes*. Retail frankfurters (20 brands) were tested by Wang and Muriana (1994) and found to be contaminated at a rate of 7.5% (six brands found positive). It appears that cooked and RTE poultry products may demonstrate even higher frequencies and levels of contamination (Farber and Peterkin, 2000). The populations of *L. monocytogenes* in processed meat products are low, with 80-90% of samples containing <10-100 CFU/g. Higher populations have been documented in RTE products, including products associated with some outbreaks (Rocourt and Cossart, 1997).

Due to the regulatory attention that RTE meat and poultry products receive due to a "zero tolerance" standard for the presence of *L. monocytogenes*, a significant number of recalls have plagued the industry leading to millions of dollars lost and loss of brand equity. The USDA Food Safety and Inspection Service has conducted a national random testing program since 1987 for RTE meat and poultry products, collecting approximately 7000 samples annually. Products found to harbor the pathogen are considered adulterated under the Federal Meat Inspection Act and the Poultry Products Inspection Act. Figure 1 shows the number and percentage of all meat and poultry recalls attributed to *L. monocytogenes* from 1994-present.

Fig. 1 Meat and poultry recalls due to *L. monocytogenes* (1994-present).



As illustrated in Fig. 1, the occurrence of meat and poultry-related recalls has increased dramatically since the implementation of the USDA Pathogen Reduction; HACCP final rule. In 1999 and 2000, 29 and 35 recalls were initiated, respectively, representing approximately 46% of all meat and poultry recalls those years. This trend is continuing in 2001, with nine *L. monocytogenes* related recalls occurring to date (41% of total 2001 meat and poultry recalls). This vastly increased frequency of recalls is at least partially a consequence of the USDA policy to sample and test RTE products after company pre-shipment record review, as mandated by HACCP, has been completed and the product is eligible for shipment. Additionally, production lots are now defined as from clean-up to clean-up which results in very large volumes of products involved. Prior to the final rule, companies were allowed to hold lots of tested product until advised of negative *L. monocytogenes* results by USDA. Companies also were allowed to define small production units (i.e. 2 hours) as a lot.

The above recall figures correspond to tremendous cost to processors in terms of product, legal fees, and brand equity. Additionally, the programs conducted by each processor to prevent *L. monocytogenes* contamination of products, detect its presence if necessary, and train employees are very costly. As illustrated by three very large *Listeria* related recalls in 1998 (Bilmar Foods/Sara Lee; 35 million pounds), 1999 (Thorn Apple Valley; 35 million pounds, bankrupts the company), and 2001 (Bar-S Foods; 14.6 million pounds), ***the current technological status of the RTE meat and poultry processing industry is inadequate to ensure delivery of L. monocytogenes-free products***.

CURRENT INDUSTRY APPROACH TO *L. monocytogenes* CONTROL

Manufacturers of RTE meat and poultry products obviously fear the consequences of *L. monocytogenes* in their products, and most have gone to great lengths (and expense) to assure the safety of their products. Their approach has largely been an attempt to eliminate the pathogen from the production environment through comprehensive cleaning and sanitizing, separation of raw material and processed product areas, employee control in production areas (employee hygiene and movement), and environmental microbiological testing of non-contact food surfaces. Some processors have explored the use of antimicrobial food additives and/or processing aids, however, their widespread use has not occurred. Most of these approved chemicals do not provide the level of microbial reductions desired, or they are only bacteriostatic in nature (still an important feature in *L. monocytogenes* control).

The effectiveness of the above mentioned industry activities for controlling *L. monocytogenes* in RTE products is inadequate, as documented by the frequency of *Listeria* detection in RTE meats (scientific surveys, recalls, and CDC data). There is a tremendous variability in the scientific capabilities, financial resources, and willingness of different companies to operate at a high level of control. However, even companies that implement and operate the best *L. monocytogenes* control programs are at significant risk of a product contamination ("adulteration") event. Problems that these authors have noted during extensive collaboration with processors include, but are not limited to:

- No incorporation of a validated antimicrobial intervention technology after post-process re-exposure of products to the processing environment (during casing/cook-in bag removal, slicing and repackaging);
- Incomplete separation of raw materials/products and post-process product environments (numerous points where biosecurity breaches occur);
- Inadequate control of personnel and production activities in critical, post-process zones;
- Numerous non-critical processing activities occurring in critical processing zones (boxing, palletizing, labeling, employee/equipment movement);
- Operation of "cleanroom" processing areas that do not effectively control all sources of potential *L. monocytogenes* contamination, and that are not validated/verified adequately (i.e. does not use HEPA filtered air or positive pressurization, inadequately prevents human contact with exposed product);
- Use of cleaners and sanitizers that are not highly effective at removing biofilms, penetrating organic build-up, or applied in a scientifically designed manner (i.e. accounting for water hardness, application temperature effect, synergistic or sequencing effects of chemicals, available contact time, and proper rotation);
- Incomplete coverage of equipment and other surfaces with cleaners and sanitizers during sanitation activities;
- Utilization of processing equipment that is not easily cleanable and sanitizable (i.e. exposed grease joints, electronic controls, non-sealed gear boxes);
- Inadequate control of chilling and cold storage (warehouses, transportation, retail marketing) allowing outgrowth of *L. monocytogenes* during extended product shelf life;

SUGGESTIONS TO RTE MEAT & POULTRY PROCESSORS FOR THE FUTURE

It is extremely important for processors to continue diligent efforts to control *L. monocytogenes* in the production environment, however, they must begin using more advanced approaches and technologies to reach a level of biosecurity that will continuously prevent product contamination. The *status quo* approach to environmental control and cleaning and sanitizing will not assure product safety. It is likely that companies will require the technical assistance of outside companies or consultants who specialize in high-level microbiological control of critical manufacturing environments, such as those common in the pharmaceutical, biotechnology, health care and electronics industries. Operation and maintenance of a true Class 10,000 cleanroom (this is probably the level needed in RTE meat product manufacturing) is much more involved than operation of "cleanrooms" currently described by the industry. Use of "isolation technologies" and mini-controlled environments should be used in certain situations to protect exposed products after the cook step. Again, expert technical assistance is likely necessary to implement such control measures, but such approaches could greatly reduce the level of risk for finished product exposure to *L. monocytogenes*. Third party verification of the effectiveness of these systems is a likely benefit to processors who want to reduce liability and increase buyer confidence.

"Chemicals (cleaners, sanitizers and disinfectants) are chemicals" say several quality assurance and HACCP directors at processing facilities where these authors have worked. This is untrue. Chemicals perform very differently based on numerous product, water, surface, temperature, and rotational characteristics. It is highly obvious that many processors do not reap the full benefit of pathogen (or spoilage flora) control from the dollars they spend on cleaning and sanitizing activities. Also, many processors do not employ chemicals that have been specifically validated against *L. monocytogenes* (particularly in biofilms). Processors should seek out chemical suppliers who can offer validated products and who are willing, and technically capable, of providing expert guidance in

their application. Additionally, processors should work with suppliers of disinfection technologies used in other industries to adapt and apply these products to the meat and poultry industry.

Above all other recommendations, RTE meat and poultry manufacturers must incorporate a validated post-process intervention technology into their production systems. No level of environmental sanitation will achieve the ultimate goal of *Listeria*-free RTE meat products. Validated technologies are now available commercially to meet this recommendation. Such technologies as the Stork RMS-Protecon steam-based system for packaged (unsliced) products, Alcide's Sanova™ process (acidified sodium chlorite) for pre-packaging application, Flow Technology's high pressure system for packaged products, and certain hot water application systems for packaged products are now available. Several other technologies are under investigation, including chemical sprays (cetyl peridinium chloride and peracetic acid) and ionizing radiation. Processors will need to verify that any one, or a combination, of these technologies meet their pathogen reduction requirements and result in organoleptically acceptable products. Even if subtle product changes occur in certain products, the public health benefits of providing a "pasteurized" product should outweigh these effects. *It should be noted that consumers detected different product characteristics when milk was thermally pasteurized, however, they adapted to and accepted these changes in light of the health threats associated with consumption of raw milk.*

In summary, RTE meat and poultry product processing operations of the future must be founded on scientifically validated HACCP principles, especially the utilization of a final product antimicrobial "kill step". The entire operation, from raw material receipt to at least wholesale distribution, must be established and verified as a continuous, integrated system where a continual risk control occurs. The industry, and the USDA, must approach the production and marketing of RTE meat and poultry products with a new mindset. This approach must resemble more closely the production of Grade A pasteurized milk, pasteurized eggs, and pasteurized fruit juices.

KSU RESEARCH TO VALIDATE ANTIMICROBIAL TECHNOLOGIES FOR RTE PRODUCTS

Kansas State University has been working with technology providers and processors to validate various intervention strategies that could be used as post-process critical control points for the manufacture of RTE meat and poultry products. This section of the manuscript discusses general findings from this research. Readers interested in more detailed findings can contact our research group (using the information provided at the end of the document) and any non-proprietary findings will be made available. Much of this work is in various stages of peer review and journal publication. The following discussion is based on systems that KSU has evaluated/validated and is not intended to suggest that other intervention systems are not efficacious.

Stork RMS-Protecon Steam-Based System

The extent of heat application to a product for microbiological control depends on the goal; whether to cook or partially cook the product throughout to inactivate internalized microorganisms, or merely to reheat the product surface sufficiently to kill any external contamination. For non-sliced RTE meat and poultry products, the need exists to elevate the product surface temperature only to inactivate any pathogen contamination associated with re-exposure of products to the post-processing environment. This can be achieved by applying heat alone or in combination with chemical decontaminants. Saturated, condensing steam is extremely efficient in its heat transfer characteristics compared to hot water. The Stork saturated steam-based post-process pasteurization system allows rapid elevation of product surface temperatures within its final package to sufficiently high temperatures to inactivate surface contamination, without significant loss of product quality characteristics such as purge, color and texture due to latent heat penetration into the product.

The Stork post-process pasteurization system was evaluated for its effectiveness to inactivate *L. monocytogenes* on the surfaces of hard salami, turkey breast, roast beef, cured hams and frankfurters. Products were surface inoculated with *L. monocytogenes*, vacuum packaged and steam pasteurized at 96.1°C (205°F) for 0, 2, 3, or 4 min. Surface pasteurization of hard salami at 203 °F resulted in 4.15 and 4.26 log CFU/cm^2 reductions of *L. monocytogenes* at 2 and 4 min residence times, respectively. Pasteurization of cured hams at 205 °F resulted in 2.94, 3.73 and 4.52 log CFU/ cm^2 reductions in *L. monocytogenes* at 2, 3, and 4 min residence times, respectively. Similar processing conditions resulted in 2.67, 3.57, and 4.48 log CFU/cm^2 reductions for roast beef and 1.99, 2.4, 1.83 log CFU/cm^2 reductions for turkey breast (this was a unique product that actually contained an internal wrap).

Reductions were 0.71 and 1.79 log CFU/ cm^2 when the frankfurters were pasteurized to end-point temperatures of 150 and 160°F at a chamber temperature of 205 °F in a single layer configuration (4 in a package). The temperatures were attained at the points where product surfaces heated the slowest (i.e. where the franks touched). No appreciable changes in product color and texture (hardness, springiness, cohesiveness and chewiness) were observed at these processing and target temperatures. Greater reductions (2.49, 3.54, 3.69, 3.9 log CFU/cm^2) in *L. monocytogenes* were observed with frankfurters that were individually packaged and heat treated to target temperatures of 150, 160, 170 and 180°F. Synergistic anti-*Listeria*l activity was observed with organic acid wash treatments in combination with heat for frankfurters.

Numerous products from several processors have been evaluated using the Stork system and results for *L. monocytogenes* reductions and resulting product quality have been very good. Purge rates, a negative factor associated with thermal treatments of such products, have been minimal and mostly acceptable. Recently, KSU and Stork have been working with BOC Gases to cryogenically chill products in a very rapid manner as they exit the steam system. This work has resulted in even greater quality maintenance of products and appears to offer a cost-effective means of chilling pasteurized products. Additionally, the packaging materials for our studies have been supplied by Cryovac and are specifically designed to withstand the aforementioned processing temperatures. The performance of these packages has been very good.

Chemical Treatments

Use of acidified sodium chlorite as a wash treatment (30 s) for franks resulted in up to 2.25 log CFU/ cm^2 reductions in *L. monocytogenes*. Similarly, a 4.04 log CFU/cm^2 reduction was observed using a Cetyl Pyridinium Chloride (CPC; 1%) dip treatment. To date, KSU has not performed formal sensory or shelf life evaluations on products treated with these chemicals. Casual observation of color has not demonstrated negative effects of their application.

Use of bacteriostatic agents has traditionally been used to extend the shelf life of RTE meat and poultry products and to control growth of potential pathogens during refrigerated storage. Recently, USDA-FSIS approved the use of sodium citrate, sodium lactate and sodium diacetate for meat and poultry products. In a study conducted at Kansas State University, buffered sodium citrate was able to prevent *L. monocytogenes* outgrowth over 4 weeks of storage at 39°F on vacuum packaged frankfurters.

These results indicate that post-process pasteurization using the Stork steam-based system, alone or in combination with bactericidal and/or bacteriostatic chemical agents, would effectively reduce or eliminate the risk associated with post-process *L. monocytogenes* contamination in packaged, RTE meat and poultry products that are not sliced. Sliced RTE products would require aseptic processing in true "cleanroom" conditions and/or the use of a post-packaging intervention treatment that completely penetrates the volume of product within the package (i.e. ionizing radiation or high pressure).

REFERENCES

Farber, J. M., and P. I. Peterkin. 2000. *Listeria monocytogenes*. In *The microbiological safety and quality of food* – Vol. I. Eds. B. M. Lund, T. C. Baird-Parker, and G. W. Gould. Aspen Publishers, Inc., Gaithersburg, MD.

Marsden, J. L., 1994. Industry perspectives on *Listeria monocytogenes* in foods: raw meat and poultry. Dairy, Food and Environ. Sanit. 14: 83-86.

Rocourt, J. 1990. Human listeriosis – 1989. WHO/HPP/FOS/91.3. World Health Organization, Geneva.

Rocourt, J., and R. Brosch. 1992. Human listeriosis – 1990. WHO/HPP/FOS. World Health Organization, Geneva.

Rocourt, J. and P. Cossart. 2000. *Listeria monocytogenes*. In *Food Microbiology: Fundamentals and Frontiers*. Eds. M. P. Doyle, L. R. Beuchat, and T. J. Montville. ASM Press. Washington, D.C.

Synnott, M. B., D. L. Morse, and S. M. Hall. 1994. Neonatal meningitis in England and Wales: a review of routine national data. Arch. Dis. Childhood. 71: 71-80.

Wang, C., and P. M. Muriana. 1994. Incidence of *Listeria monocytogenes* in packages of retail franks. J. Food Prot. 57: 382-386.