



Funded in part by
the Beef Checkoff.

2013 BEEF INDUSTRY
SAFETY SUMMIT
March 13 - 15, 2013 • Dallas, Texas

EXECUTIVE SUMMARY

INTRODUCTION

The 2013 Beef Industry Safety Summit, funded in part by the beef checkoff, marked the 11th year of what has continued to be a groundbreaking effort in providing the safest beef possible for consumers.

"As we look back at the first decade of summit meetings, we can be proud of our successes," said James "Bo" Reagan, Ph.D. and Senior Vice President of Research, Education and Innovation for the National Cattlemen's Beef Association (NCBA), a contractor to the Beef Checkoff Program, during his opening remarks. "But, at the same time, we know we have new challenges that we need to continue to identify and address. This is a never-ending journey."

Reagan gave credit to members of the Beef Industry Food Safety Council (BIFSCo), for their dedication to a difficult task. "We would not have had the success at this meeting over the years without your input and commitment to beef safety."

Weldon Wynn, the current chairman of the Cattlemen's Beef Board (CBB) and a cattleman from Star City, Ark. welcomed summit attendees.

"On behalf of the Cattlemen's Beef Board, I want to thank you for being here. The 700,000 people who raise beef in this country are committed to having and producing a safe product. As I look around at those of you that belong to BIFSCo, I see the expertise you bring to this meeting. With your cooperative efforts, I know the safety of our nation's beef supply is in good hands. We are a proud sponsor of this meeting."

Setting the Stage for a New Decade

The first summit focused entirely on *E. coli* O157:H7. A look back at the executive summaries from subsequent summits illustrates how the issue of beef safety has evolved. The 2013 Beef Industry Food Safety Summit was telling in the revelation that safety is not a finite issue with black and white answers. While research and science are the foundation of the advances made in improving the safety of U.S. beef, the 2013 summit, more than any other in the past, exemplified how societal concerns impact consumer and end-users' perceptions of beef safety and the beef industry.

BEEF INDUSTRY SUCCESS AND CHALLENGES

Chair: Bo Reagan, NCBA (a contractor to the beef checkoff)

Food Safety & The National Beef Quality Audit

Keith Belk, Colorado State University

The National Beef Quality Audits (NBQA) have been funded by the beef checkoff approximately every five years, beginning in 1991. The most recent audit was conducted in 2011 and concluded with industry strategy sessions in 2012. The objective of the project was to discern producer-related opportunities to improve the quality of beef at the consumption level.

"The audits have helped us identify quality challenges that need to be addressed in order to improve the entire beef supply," said Keith Belk, a member of the investigative team. "Those 'big ticket' items have changed over the years. Safety isn't necessarily considered a quality attribute in the strictest sense, but it came up regularly as a quality challenge in this audit."

Looking back at the top 10 quality concerns identified in previous audits, safety was not one of the areas listed. However, in this recent audit, for the first time, food safety and eating satisfaction became the two most predominant responses that affect the value of beef cattle (Table 1).

This audit included an economic analysis and determined downstream users' "willingness to pay" for specific attributes. Before someone was willing to purchase a product from the preceding

sector, they had to have, at minimum, guarantees of specific attributes. Ranking second to information about how the cattle were raised, was food safety.

"I think intuitively we all already knew this, but this is, to my knowledge, the first time it has been quantified," said Belk. "Respondents are not only focusing on the bacterial and biological hazards, but anything that might impact the safety of beef products."

The most recent audit also revealed an interesting "conundrum" as Belk termed it. Food safety was considered a strength by every sector of the industry, but issues impacting beef safety were also described as a threat. Those responses underscore the ever-changing landscape of beef safety and the need to constantly address emerging issues.

A survey of 3,700 beef cattle producers was also conducted as part of this comprehensive project. When producers were asked what their primary responsibility was, producing safe and wholesome beef tied for number one.

"Those responses say something very important about the production sector of the industry," said Belk. "Cattle raisers in this country are concerned about food safety, so if we can offer them effective tools to improve food safety, they are willing to implement them."

For more information, an executive summary of the 2011 National Beef Quality Audit can be accessed at <http://bqa.org/audit.aspx>.

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Keith Belk

Table 1. Industry Top Quality Concerns

2011 – Phase 1	2012 Cattlemen's College	Strategy Workshop
Food safety	Eating satisfaction	Food safety
Eating satisfaction	Foot safety	Eating satisfaction
How & where the cattle were raised	How & where the cattle were raised	How & where the cattle were raised
Lean, fat & bone	Lean, fat & bone	Cattle genetics
Weight & size	Cattle genetics	Lean, fat & bone
Cattle genetics	Visual characteristics	Weight & size
Visual characteristics	Weight & size	Cattle genetics

BEEF SUSTAINABILITY: MEETING TOMORROW'S DEMAND

Bo Reagan, NCBA (a contractor to the beef checkoff)

Kim Stackhouse-Lawson, NCBA (a contractor to the beef checkoff)

While the sustainability of the beef industry is not a safety issue in the strictest sense, it is an important component. Safety typically plays a role in the myriad definitions of sustainable beef production.

Bo Reagan and Kim Stackhouse-Lawson provided attendees a summary of checkoff-funded efforts to quantify the industry's achievements in providing a sustainable beef supply and identify opportunities for continuous improvement.

"We need to thank our producers as they took a big step two years ago and decided to put money into this effort—approximately \$1.1 million of checkoff money helped support this groundbreaking work," said Reagan.

The U.S. Beef Sustainability Project comprises three phases. The first phase, which is almost complete, includes a hotspot analysis consisting of a popular press literature review and a stakeholder survey to identify common misperceptions. The second phase includes a comprehensive ISO-compliant life cycle assessment. The third phase is the development of a modeling tool for beef producers along the supply chain to evaluate the sustainability of their operations.

Misperceptions regarding global beef industry sustainability are derived from a 2006 report from the Food and Agriculture Organization of the United Nations, titled *Livestock's Long Shadow*, which inaccurately blamed cattle for a number of environmental and social issues. "Beef production plays a role in feeding a world population that will reach 9 billion by 2050. Our industry needs to be part of the solution to this worldwide challenge," said Reagan.

The U.S. Beef Sustainability Project is the first and largest sustainability project of its kind, and is setting the standard for agricultural commodity sustainability research in the future. According to Reagan and Stackhouse, sustainability for the beef industry has been defined as "*Meeting the growing demand for beef by balancing environmental responsibility, economic opportunity and social diligence.*"

"As part of this process I've learned that many opportunities for becoming more sustainable may be too expensive to implement," said Reagan. "As we look at sustainability, it's critical that we look at ways to optimize production without undermining economic well-being."

For more information about the Beef Sustainability Project, visit <http://www.beefresearch.org>

INDUSTRY CHALLENGES AND LEARNINGS FROM THE PAST

Co-Chairs: Guy Loneragan, Texas Tech University

Hilary Thesmar, Food Marketing Institute (FMI)

Industry Vulnerabilities

Season Solorio, NCBA (a contractor to the beef checkoff)

Media coverage of the beef industry in 2012 was punctuated by three negative stories, including lean finely textured beef (LFTB), the United States' fourth case of BSE and transglutaminase, which was more commonly referred to by the media as "meat glue."

"It is critical to learn from those experiences and make sure we are better prepared in the future," said Solorio. To accomplish that goal, the team conducted a best practices assessment that included an audit of other industries, media coverage review and interviews with industry participants. "Our assessment helped us identify issues that are keeping industry participants up at night, and for which we need to be better prepared," said Solorio.

To continue to better prepare for challenges, Solorio said the team has committed to an annual vulnerabilities survey. Summit attendees were encouraged to take advantage of the resources the group offers, including the new web resource, www.factsaboutbeef.com.

Achievements and Future Challenges and Vulnerabilities: Perspective on Animal Welfare and Lessons Learned

Mike Siemens, Cargill

Siemens noted a quote from Dr. Temple Grandin to set the stage for his presentation. "I think using animals for food is an ethical thing to do, but we've got to do it right. We've got to give those animals a decent life and we've got to give them a painless death. We owe the animal respect."

He further cautioned those in production agriculture to understand the motives of activists. "It is always easier to convey a negative message versus a positive one," said Siemens.

Livestock welfare and food safety were two very separate issues until the Hallmark-Westland incident in 2008, which Siemens called a "game changer." Footage of a non-ambulatory cow being abused at a California slaughter facility was released by an activist group, and subsequently led to the largest ground beef recall on record.

Pointing to industry initiatives such as the Beef Quality Assurance (BQA) program, as well as regulatory requirements, such as the Humane Slaughter Act, Siemens outlined existing measures to assure proper animal handling procedures are in place. In addition, the existence of several industry-driven guidelines and welfare best practice documents underscore the industry's commitment to animal welfare.

Siemens recommended the supply chain take proactive steps to more effectively communicate its commitment to animal welfare to consumers.

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Temple Grandin

Action Items:

- Stakeholders must assist in the development of core messages about animal well-being for the media versus having someone else deliver less-than-accurate messages.
- The supply chain needs to learn how to interact with main stream audiences—match media technology to the audience, and be able to effectively tell the beef story.

The supply chain needs to be more transparent about the beef industry. Siemens indicated that enhanced programs and audit requirements for all meat production was likely. He underscored the importance of the beef industry identifying willful abuse and condemning those people or businesses that do not adhere to appropriate husbandry standards. “We have to defend what is scientifically proven, but at the same time understand societal concerns and their impact,” said Siemens.

Antibiotic Use in the Future

Mike Apley, Kansas State University

“As we look at a newborn calf and how we might interact with it from a pharmaceutical standpoint through its whole productive life, something we need to think about are ways we don’t have to interact with it,” said Apley. “We are at a time where we potentially have to reassess antibiotic usage to ensure that the tools we really need, continue to be available.”

Apley discussed concerns that have arisen since the release of Guidance 209 (The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals) by the Food and Drug Administration (FDA). In it, FDA asked for a voluntary reduction of antimicrobial use for those products that are important in human medicine, and if ineffective, said it will likely be enforced through regulatory action.

“Prevention and control of disease through antibiotic use are deemed by the American Veterinary Medical Association (AVMA) and by the current leadership in the FDA Center for Veterinary Medicine (CVM) as therapeutic uses; however new leadership may not see them in that light,” said Apley.

Apley outlined changes in antibiotic residue testing procedures at the harvest level that need to be better communicated to producers as the sensitivity of those tests has greatly increased. “Producers need to be diligent in understanding withdrawal times,” he added. “‘Zero tolerance’ is getting smaller due to advances in detection technology.”

Apley emphasized that stakeholders need to understand that antibiotic use in livestock production will continue to be a lightning rod issue. “As an industry, we need to look at our vulnerabilities and look at the tools we have to promote animal health and well-being. We need to make a strong stand now on the things that matter to animal health, before we are tried in the court of public opinion.”

Global Philosophies on Science

Paul Clayton, U.S. Meat Export Federation

According to Clayton, approximately 12 percent of U.S. beef production is exported, which adds approximately \$225 per head in value. Exports continue to be a growing market opportunity, but beef safety from an international viewpoint needs to be understood to ensure continued growth. “I see a uniform belief internationally in

the foundations of science, but I also see a variation in the application of science in policy and regulations among our trading partners,” said Clayton. He emphasized the importance of the United States’ position as a leader in food safety research, management and control as a point of differentiation and a competitive advantage in the international marketplace.

“Countries have the sovereign right to dictate their rules, so the regulatory environment among trading partners becomes something that is hard to predict,” said Clayton. “Add in the philosophy of precautionary principle, where the rules are sometimes made up as we go along, and it sometimes makes our job very difficult.”

International bans on growth promotant use are a good example of the application of the precautionary principle by trading partners when, in the absence of data, a concern about a production practice or phytosanitary issue is deemed sufficient to justify regulation.

“While growth promotants may be a beneficial technology for increasing efficiency in food production, they are difficult for international consumers and governments to understand and accept as safe,” said Clayton. “So we have a choice as an exporter—work within those constraints and develop a program that allows us access to that market, or fight what we know is bad science. If we choose to fight it, we potentially lose out on a valuable market opportunity.”

According to Clayton, pathogen and microbiological food safety issues rarely become a hurdle to exporting U.S. beef as the interventions and science employed by the U.S. beef industry and U.S. government have credibility internationally. Other issues, such as the approval and definition of food additives and ingredients generally recognized as safe in the United States, are sometimes lost in translation.

Looking ahead, Clayton believes the United States will remain a leading supplier of red meat to the world, but market access will still be a challenge in some countries due to the differences in foreign regulatory processes.

When these issues reach the news headlines, according to Clayton, they are often complicated by political issues and debates, with food safety a pawn in the discussion.

Update on Food Safety Best Practices for the Pre-Harvest Sector

Guy Loneragan, Texas Tech University

BIFSCo has developed Best Practices for every sector of the beef industry, focusing initially on the harvest and fabrication sectors, and subsequently expanding recommendations to non-intact beef, as well as the foodservice and retail sectors (www.bifsc.org). The Best Practices represent the best information and recommendations from leading researchers and the industry participants who utilize them.

“Our work began 10 years ago to deliver effective pre-harvest

While growth promotants may be a beneficial technology for increasing efficiency in food production, they are difficult for international consumers to understand and accept as safe.

Paul Clayton

interventions to cattle producers,” said Guy Loneragan. An action item from the 2012 Beef Industry Safety Summit was for BIFSCo to form a committee to update that original pre-harvest best practice document. According to Loneragan, who chaired the effort on the original document focused almost exclusively on opportunities to reduce *E. coli* O157:H7, but the revision has been expanded to also include non-O157 STEC and *Salmonella*.

To support the update process, the beef checkoff funded a white paper to better summarize more recent data that demonstrate compelling, experimental use of several production level (pre-harvest) interventions. Led by Dr. Todd Callaway, a researcher with the U.S. Department of Agriculture (USDA) Agricultural Research Service (ARS), the team developed two scientific manuscripts providing supporting evidence for the updated pre-harvest Best Practices.

According to Loneragan, the best practice recommendations for the pre-harvest sector are based on a two-tiered approach. The first tier is principled animal husbandry, which is a prerequisite to implementation of second tier approaches (similar to HACCP prerequisites).

- Clean feed
- Clean water
- Appropriately drained and maintained environment
- Relative freedom from pests, e.g., biting insects

While Loneragan said that none of these practices will necessarily have any meaningful impact on pathogen load in themselves, they are viewed as a foundation for the successful implementation of second tier technologies.

“Compelling published, experimental evidence exists for what we are terming second tier production intervention technologies,” said Loneragan. “Direct-fed microbials (probiotics) are widely used by the feedlot sector to maintain animal health, and have been shown to reduce *E. coli* O157:H7 shedding in cattle. We are also seeing positive effects on *Salmonella* prevalence and non-O157 STEC.” Other interventions, including two experimental vaccines developed to reduce *E. coli*

O157:H7 shedding in cattle, a bacteriophage pre-harvest hide wash, and products such as chlorate have all been shown to significantly reduce pathogen loads in multiple trials.

The regulatory approval process to allow these technologies to be available commercially has shown itself to be the biggest hurdle to advancing pre-harvest best practices. “For example, researchers have done an extensive amount of efficacy work with a probiotic product that currently doesn’t have a label claim for reducing *E. coli* O157:H7. Unfortunately, the manufacturer of that product probably won’t pursue such a label claim due to the difficulties encountered with licensing,” added Loneragan. He also noted the extensive effort by the beef industry and partner companies to gain approval for two vaccines shown to be effective against *E. coli* O157. One of these vaccine manufacturers has gained approval in Canada, but has walked away from the U.S. market due to an inability to work productively through the U.S. regulatory agencies. The other vaccine has been granted a conditional license but has not moved further. Sodium chlorate, also shown to be effective, has been awaiting approval as a food safety intervention for 10 years.

To overcome the hurdles and to advance pre-harvest best practices, the committee identified the following needs:

- Translate information to a BQA, producer-oriented document
- Determine if industry can adopt these technologies based on a quantitative risk assessment that evaluates the benefits and costs, since all interventions are less than 100 percent effective
- Provide additional data on pre-harvest controls for non-O157 STEC and *Salmonella*
- Identify a clear, achievable and affordable pathway to licensure or approval of label claims
- Determine ways to foster adoption of these technologies that optimize their impact on food safety, without undermining production

The updated Best Practices is available under the Technical Resources tab on www.bifsc.org.

BREAKOUT SESSIONS

Today’s Testing Dynamics for Non-O157 STEC

Co-chairs: Russ Flowers, Merieux NutriSciences (formerly Silliker) and Chad Martin, Tyson Fresh Meats

Non-O157 Regulatory Update

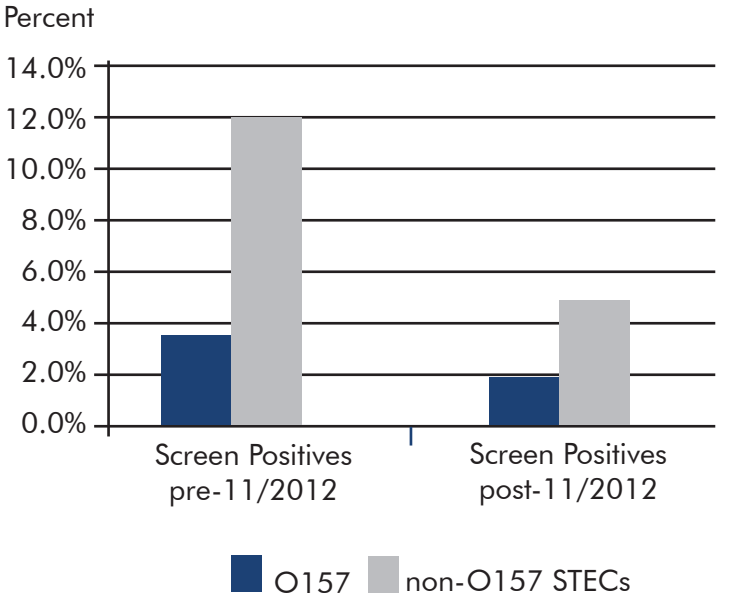
David P. Goldman, USDA Food Safety and Inspection Service

To provide background on current FSIS non-O157 policy, Goldman said FSIS declared six additional *E. coli* “O” groups (O26, O45, O103, O111, O121, O145) adulterants under the Federal Meat Inspection Act in September 2011 because, like *E. coli* O157:H7, they are considered “injurious to health under ordinary conditions.”

Since the expanded testing program began in June 2012, FSIS has tested 4,236 trim samples. However, not all of those were tested for non-O157 STEC. Of those samples, 23 were positive for O157, and 44 were positive for other STEC. Results from the MT60 testing program (domestic trim), where 2,053 samples were tested, showed 12 positive screens for O157 and 18 positives for other STEC. Overall, the rates are higher for STEC as a group than for *E. coli* O157:H7 alone. The overall screen positive for STEC in the MT60 testing program was 8.2 percent, and the overall number of presumptive positives was 2.4 percent.

FSIS observed that the seasonality effect experienced with O157 is also present among the non-O157 STEC (Figure 1).

Figure 1: Seasonality Effects
E. coli and non-O157 STECs



FSIS is now implementing Food Safety Assessment (FSA) in response to positive non-O157 and is looking at non-O157 controls during a routine FSA required as part of the Hazard Analysis Critical Control Point (HACCP) inspection program. Inspectors are also verifying whether establishments are performing the required reassessment of their HACCP plans in response to positive results for non-O157 STEC.

When the expanded testing program for non-O157 was announced, FSIS made some initial assumptions regarding the cost to the agency, as well as costs to the industry, to meet the enhanced requirements.

"FSIS has determined that potential public health benefits justify the costs," said Goldman, "But we have committed to reexamining the costs with the actual data that is now available before the program is expanded," he said.

Today's Testing Dynamics: Current Methods for Detection of STEC and Analytical Methods

Wendy McMahon, Silliker Food Science Center and Patrice Abault, BioAdvantage Consulting

Two presentations regarding current testing procedures for non-O157 STEC highlighted the need to improve the reliability of detection methods to meet the new regulatory requirements.

The speakers concluded their presentations with the following points:

- Reference and rapid detection methods are available and offer tools for STEC monitoring
- Limitations are still present and further developments are needed to strengthen robustness, reliability and ease of use
- Enrichment broth needs to prevent background flora development without affecting STEC growth
- More specific DNA targets may soon be available that will limit number of false positive results and improve specificity
- Plating may be improved by the use of two different agar

STEC: Perspective on Industry Data

Gary Acuff, Texas A&M University

Acuff presented an analysis of industry testing results in an effort to identify the best approach to effectively monitor for non-O157 STEC. Facilities providing data included harvest facilities ranging in size from large to very small according to established criteria. The data were blinded to prevent any biases. "Ultimately, we wanted to identify patterns in reduction. In other words, if we are reducing one serotype,

are we reducing another?" said Acuff. "Our experience has been that interventions that control E. coli O157:H7 are also effective against non-O157 STEC."

Most of the data included post-processing collection, versus a pre- and post-processing collection point. "In some cases, we are seeing less frequent detection of non-O157 STEC than O157, so that might be an indication of effective interventions. But, we do have very low detection rates as we are looking at thousands of samples, and only seeing 12 to 15 positives. It is very difficult to make conclusions with that kind of data."

The lack of a baseline with a comparison of pre- and post-processing also makes it difficult to make interpretations. The one common thread in the industry data, according to Acuff, is that "confirmation is difficult." Acuff provided industry participants a cautionary point: "The assumption is that a negative E. coli O157:H7 test result verifies the effectiveness of the food safety system; however, I think it is important for all of us to remember that in the realm of microbiological testing, a positive is always a positive, but a negative is never a negative." Acuff recommended that because of those challenges, the better approach may be to establish a performance objective. He cautioned if an outbreak or a recall occurs, the industry should ask if this information is enough to show that processes were effectively establishing controls.

Since E. coli O157 and non-O157 STEC are regulated as adulterants by FSIS, a zero tolerance for their presence in beef exists. "Since zero doesn't exist in microbiology, a performance objective that almost equates to zero may be more applicable," said Acuff.

To conclude, Acuff emphasized the need for additional research regarding non-O157 STEC and accurate detection methods. He told attendees to remember the reasons for validating their intervention methods:

- Meeting of regulatory requirements
- Process control
- Progress toward an end-point

"Bottom line, you need to make sure your process works," said Acuff.

"Many tools are available for verifying process control. You need to take advantage of them and spend energy challenging your system and understanding the unique microbial ecology of your facility. The ultimate goal is proving that your controls are effective."

For more information on validation of antimicrobial interventions, see *Food Protection Trends*. Vol. 33, No. 2 p 95-104.

Food Waste and Food Rescue

Co-Chairs and Presenters: Brad Morgan, Zoetis; Hilary Thesmar, FMI; and David Fikes, FMI

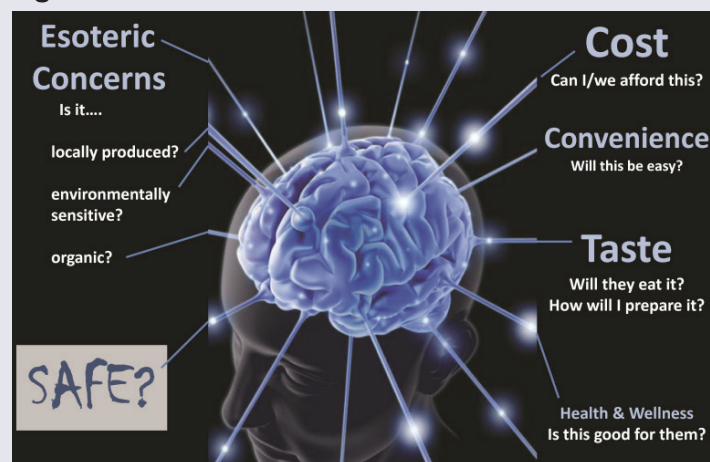
Take-home message: Food waste is a major worldwide problem with 1.3 billion tons or one-third of all the edible food produced worldwide wasted or lost each year. The UN Food and Agriculture Organization reports that 100 percent more food will be required in 2050 to feed the global population of nine billion with only 10 percent more farmland, 20 percent more production from increased cropping intensity, leaving 70 percent to come from new and existing agricultural technologies.

The Changing Consumer

Co-chairs: Russell Cross, Texas A&M and Hilary S. Thesmar, FMI
Presenters: David Fikes, FMI; John Lundeen, NCBA (A contractor to the beef checkoff); Kim Essex, Ketchum

Take-home message: With increased technology, rapid exchange of both accurate and inaccurate information, and a changing economy, today's consumer has new and more complex demands of the food chain (Figure 2).

Figure 2



To meet the needs of today's savvy new consumer, the industry must engage, do what's right, and tell people about it.

Building Consumer Trust – Lessons from Safety and Nutrition

Chair: Shalene McNeill, NCBA (A contractor to the beef checkoff)
Presenters: Mary Young, Edelman Public Relations; John Lundeen, NCBA (A contractor to the beef checkoff); Mandy Carr Johnson, NCBA (A contractor to the beef checkoff)

Take-home message: Triggered by the mortgage meltdown, ethics scandals, legislative earmarks and corporate “right sizing,” consumers are in a state of mistrust and want to hear that farming is evolving (Table 2).

The beef industry demonstrates the commitment made to

Table 2. What do you believe America’s farmers and ranchers should try to accomplish?

Continuously improve the methods they use to provide a healthy food	44%
Help consumers know more about where their food comes from	40%
Reassure consumers their food is safe and healthy	37%
Identify and share best practices	29%
Start a dialogue about how food is grown and raised	25%
Give consumers a chance to connect directly with the farmer and ranchers who grow America’s food	25%

progress by all sectors of the chain through “The Beef Industry’s Pledge to Consumers.” During the 10 years between 2002 and 2012, consumer confidence in the safety of fresh steaks and roasts rose from 74 percent to 88 percent. During the same period, confidence in the safety of fresh ground beef rose from 60 percent to 80 percent.

The Beef Industry’s Pledge to Consumers

As leaders in the beef industry, representing each link in the beef production chain, we reaffirm our commitment to further reduce the risks associated with foodborne pathogen by utilizing scientifically proven production practices and technologies. Our united goal is to produce, deliver and serve wholesome and safe beef for each and every family.

SALMONELLA — ADDITIONAL PERSPECTIVES

Co-Chairs: Brad Morgan, Zoetis and Guy Loneragan, Texas Tech University

FSIS Scientific Perspective on Salmonella in Beef

David P. Goldman, USDA Food Safety and Inspection Service

“Now that we have the non-O157 STEC policy in place, Salmonellosis will become the number-one objective in terms of policy initiatives,” said Goldman. “Updated FoodNet, released in mid-April, will be a report card for how well we have done in meeting goals to reduce foodborne illness.”

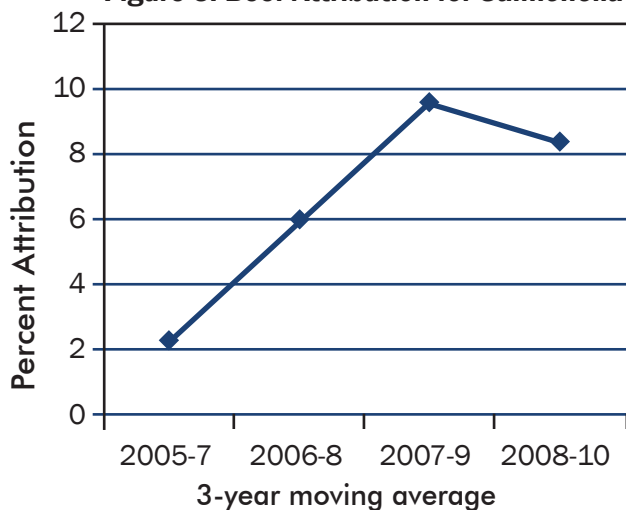
The incidence of *Salmonella* illnesses has remained relatively flat over time. The most recent data from 2011 did not represent a statistical increase over the 1996-1998 baseline, according to Goldman. Because *Salmonellosis* is often not severe enough for patients to seek hospital care, the observed case rate is extrapolated by the Centers for Disease Control (CDC) resulting in an estimate of about 1.2 million *Salmonella* illnesses per year.

According to Goldman, the three-year moving average for the percentage of outbreaks associated with beef is approximately 8.5 percent and was calculated using outbreak illness data where a single food ingredient was implicated (Figures 3 & 4). The numerator is the number of illnesses from beef-associated outbreaks and the denominator is the total number of illness from all outbreaks that had a food vehicle.

The agency is doing additional attribution work using a Danish model that will be used to quantify the contribution of animal-food sources to human *Salmonellosis*.

The preliminary results from the adapted U.S. model were described in a “methods” paper (Guo et al. Foodborne Path Dis. April, 2011). Though not a “results focused” paper, according to Goldman, the Phase I model estimates the relative contributions of FSIS-regulated products to human *Salmonellosis* at the following rates:

Figure 3. Beef Attribution for Salmonella



Source: FSIS analysis of CDC FDOSS outbreak data 2005-2010

- Chicken (48%)
- Ground beef (28%)
- Turkey (17%)
- Egg products (6%)
- Intact beef (1%)
- Pork (<1%)

In 2011, FSIS, CDC, and FDA formed the Interagency Food Safety Analytics Collaboration (IFSAC) with the initial objective of standardizing and advancing the source attribution of foodborne illnesses to specific foods and settings.

According to Goldman, IFSAC team members are working on a variety of projects to improve attribution methods and better estimate foodborne illness source attribution. The new estimates developed by IFSAC will help to enhance food safety initiatives and policies to further reduce the number of foodborne illnesses in the United States.

Goldman also discussed the FSIS *Salmonella* Verification Testing Program and what the data revealed about *Salmonella* subtypes and antimicrobial resistance. "The two serotypes we are most worried about are *Salmonella* Newport because of potential for multi-drug resistance (MDR) and *S. Montevideo*," said Goldman. "Montevideo is the most common *Salmonella* serotype found during FSIS testing for both ground beef and carcasses. Interestingly, *S. Dublin* ranks ninth on carcasses, but it's the second most common in ground beef."

Beef products have the greatest seasonal increase in contamination of all FSIS regulated products, according to Goldman. "On-farm and slaughter/processing interventions focused on reducing seasonal peak by adjusting the interventions to address seasonal fluctuations could be a low-cost option to prevent illnesses."

From 2007 to 2011, multi-drug resistant (MDR) *Salmonella* were reported in 17 out of 101 outbreaks; seven outbreaks were definitively linked to ground beef. In three outbreaks, illnesses were associated with consumption of both ground beef and intact beef products. Four of the investigations led to ground beef recalls.

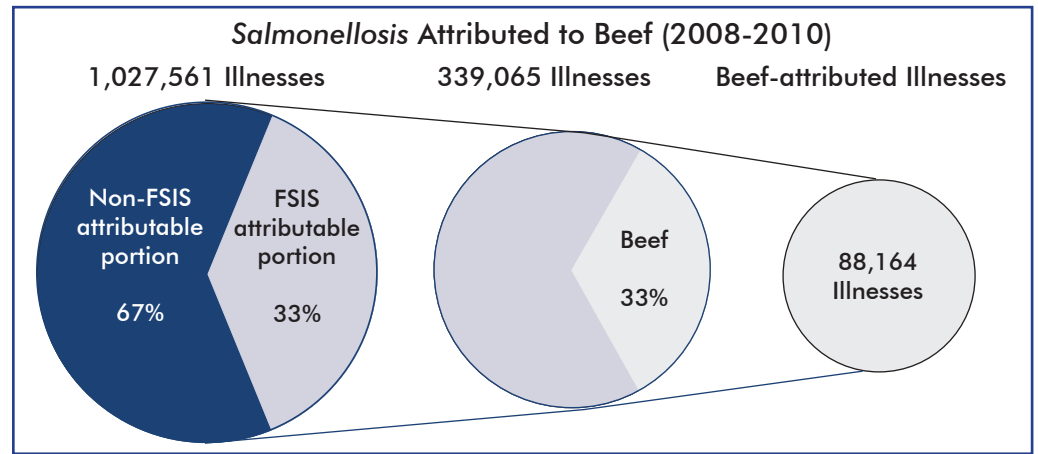
In October 2012, FSIS established the Strategic Performance Working Group charged with identifying interventions or actions to decrease FSIS-attributable *Salmonellosis* and reduce illnesses from *Salmonella*. "The issue of lymph node contributions to *Salmonellosis* has been identified by our group, just as it has by BIFSCo," said Goldman.

To conclude, Goldman discussed potential policy changes to *Salmonella* regulation in beef carcasses. "Using the new data, FSIS may consider changing the current number of allowable positives for ground beef."

Goldman concluded his presentation with an outline of FSIS research needs and priorities:

- Investigate and/or develop emerging pathogen screening methods
 - Rapid methods
 - Subtyping
 - Virulence characterization
 - Multi-analyte detection in a single sample
 - Real-time testing for high contamination levels
- Identify indicator/surrogate organisms for validation and monitoring
- Measure finished product effect of pre-harvest interventions

Figure 4. Sources to human *Salmonellosis*



***Salmonella*: Additional perspectives**

Guy Loneragan, Texas Tech University

Loneragan summarized results of 2012 surveillance data collected from harvest facilities in the BIFSCo microbiological sampling regions (Figure 5). The goal of this surveillance effort was to better describe the variation in prevalence that has been observed, particularly as it relates to region, season and animal type. Researchers collected samples from both feedlot cattle and cull cows (beef and dairy).

Researchers collected 5,456 subiliac lymph nodes and 5.3 percent were positive for *Salmonella*. Results from the sampling indicated a relatively stable and low prevalence of *Salmonella* positives among the cow population. The fed population demonstrated a marked seasonal effect and the prevalence was significantly higher than in the cull population. Region 3 (Southwest) demonstrated a significantly higher prevalence (Figure 6).

"We did make some assumptions in analyzing the regional differences, and used the plant location as a proxy for the source location of the cattle," said Loneragan. "While the fed population may have been finished in closer proximity to the harvest facilities where lymph node samples were collected, the cull population is potentially captured from a much larger geographic region, thus adding to the complexity of better understanding regional differences."

Figure 5. 2012 Surveillance

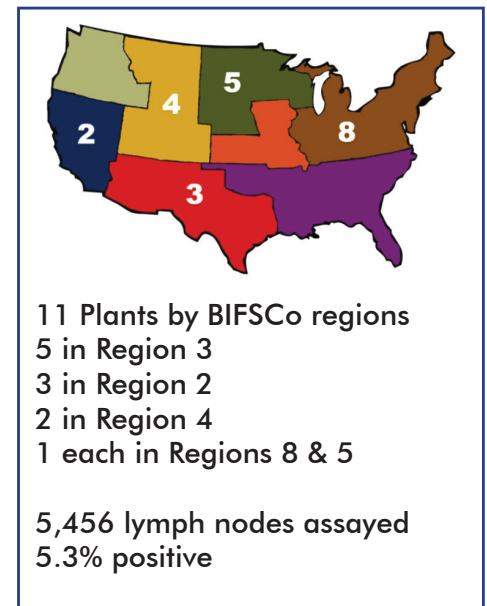
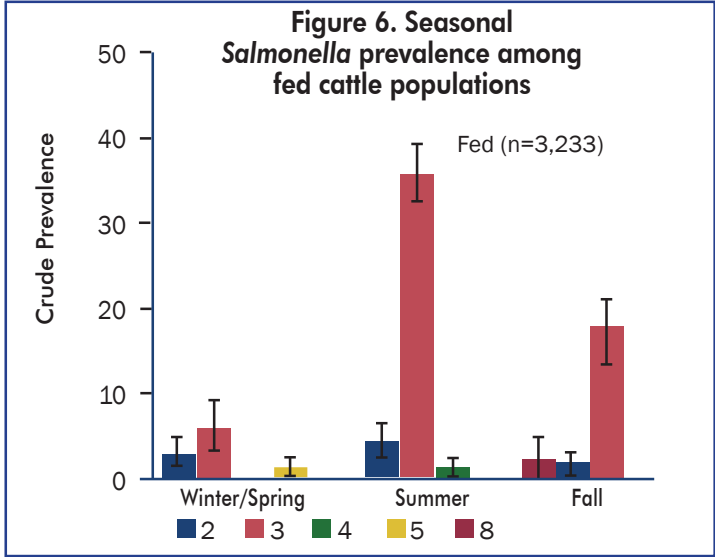


Table 3. Multiple Lymph Nodes per Carcass

Visit	Carcasses Sampled	Fecal Prevalence	Node Prevalence	Positive in 1 or more	Positive in all 6
3-Oct	15	80%	58.9%	100%	20%
17-Oct	30	100% (n=6)	56.1%	96.7%	23.3%
24-Oct	20	95%	15.8%	50%	5%
31-Oct	35	47.8% (23)	9.1%	37.1%	0%



In the fed population, the prevalence was more concentrated among a few serotypes. Conversely, in the cull population, a relatively low prevalence was spread among a large number of serotypes. Loneragan said the ultimate goal of the project is to determine carcass level prevalence; however, that is difficult due to the large number of lymph nodes that are present in cattle. To gain a better understanding of carcass-level prevalence, the researchers also conducted a multi-node sampling project where samples from six lymph nodes were collected from a fed beef plant in the southern region during the peak summer months (Table 3).

Data also demonstrate that differences exist between the lymph nodes in the probability of finding *Salmonella* positives.

In summary, Loneragan said the greatest prevalence was in fed cattle, in southern plants, during the summer and fall. Less than 1 percent of samples were positive from Region 4 compared to approximately 30 percent in Region 3. Previous research has shown significant operation differences in the number of *Salmonella* positives observed within the high prevalence region. “That difference might be worth exploring to try to uncover what might be some farm-level differences,” said Loneragan.

Salmonella in the Bovine Lymph Node: Research Update on the Transdermal Model of Infection and Potential Role of Flies

Tom Edrington, USDA-ARS

Edrington discussed work his research group has conducted to better understand acquisition uptake of *Salmonella* by lymph nodes, and to reliably produce positive samples for testing safety interventions in a laboratory setting.

“In our early work, we assumed that *Salmonella* resides in the gastrointestinal tract or maybe it was an oral challenge that was producing these nodes,” said Edrington. “We conducted a few studies where we were able to infect lymph nodes following an oral challenge, but the results were not consistent. So, while I’m not ruling out the oral route of challenge as important, it does not seem to be the primary route.”

Edrington and his team subsequently experimented with an intradermal challenge, using an allergy testing device that is used on humans to simulate biting flies on cattle.

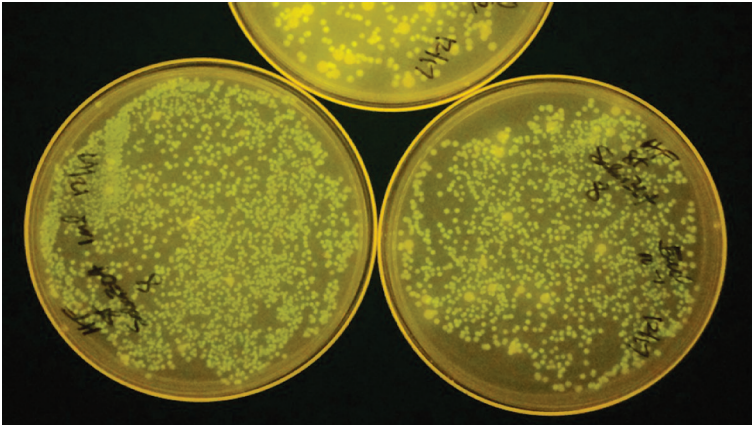
As part of the project, it was important to determine how long *Salmonella* stays in a lymph node, once acquired. Experimental data from the group demonstrate an animal likely needs a constant exposure to exhibit the prevalence levels that fellow researchers are seeing in their field collections. Edrington’s team found if any break in exposure occurred during challenge trials, then *Salmonella* shedding cleared within seven to 14 days.

Field data has also shown multiple serotypes in nodes, which didn’t surprise Edrington. In the lab transdermal exposures, the infection was very site-specific. Only lymph nodes in the vicinity of the exposure site were infected, however, with multiple inoculations, the regional uptake effect went away. Edrington hypothesized that the multiple inoculations were potentially more irritating to the cattle, causing them to lick the sites, leading to an oral challenge, as well as the intradermal challenge. This scenario would more closely approximate real-world infections from biting flies (Figure 7). Collaborators Pia Olafson and Kim Lohmeyer with the USDA ARS lab in Kerrville, Texas have contributed several findings to help better understand the role that flies may have in transmitting *Salmonella*.

Edrington and his team are working on the following research to continue to better understand what mechanisms lead to *Salmonella* contamination in beef cattle:

- Duration of infection
- Infectivity of different serotypes
- Role of flies
- Intervention strategies
- Regional differences
- Differences in dairy versus fed cattle

Figure 7. Cross section of a fly’s digestive tract
The green florescence indicates the presence of *Salmonella*.



Salmonella Virulence, Genomics, and Interactions with the Immune System

Dayna Harhay, USDA-ARS

"Every living thing has two ultimate goals—to survive and reproduce, and *Salmonella* is no exception," said Harhay. "If we think about that as we try to understand this pathogen, it may help us in developing effective controls."

Harhay discussed the evolution of *Salmonella* to *Salmonella enterica*, the subspecies that is adapted to warm-blooded hosts and causes illness in humans. To achieve survival, bacteria have evolved different host attachment mechanisms. They then invade their host and find ways to manipulate the host environment to survive. "As we work to develop beef safety interventions, our goal will be to find ways to disrupt that process," said Harhay.

Past research has demonstrated differences in virulence among serotypes. Harhay discussed results from a checkoff-funded study that examined the differences between four serotypes (*S. Newport*, *S. Typhimurium*, *S. Montevideo* and *S. Anatum*) commonly found in cattle. "Interestingly, *S. Montevideo* and *S. Anatum* are frequently found in ground beef and the lymph nodes, but *S. Newport* and *S. Typhimurium* are found much less frequently. When they are found, however, they cause illness outbreaks, so we were interested in the genetic differences between the serotypes."

According to Harhay, the results challenge the assertion that all *Salmonella* are equally virulent to humans. Harhay cautioned the group against a "zero tolerance" mentality as it might be impossible to achieve and may be more harmful than beneficial. The focus should be primarily on the virulent strains that cause the most severe illness.

Overview of U.S. Regulatory Processes for Commercial Approval of Pharmaceuticals and Biologicals

Pete Cornell, Zoetis

Regulations for both pharmaceuticals and biologicals developed within the framework of the treatment or prevention of clinical disease, including emerging diseases. Over time, regulations have extended to include agents that improve livestock performance, and most recently products intended to enhance human food safety.

According to Cornell, products used for the maintenance of human food safety through bacterial reduction in livestock are regulated in one of three ways:

1. A biological (typically a vaccine) can be approved for food safety based on requirements laid out by the USDA Center for Veterinary Biologics (CVB)
2. A pharmaceutical or a biological (e.g. a direct-fed microbial) can be licensed through the FDA Center for Veterinary Medicines (CVM)
3. A chemical or biological (e.g. bacteriophage) listed as Generally Recognized as Safe (GRAS) through the FDA Center for Food Safety and Applied Nutrition (CFSAN) can be used pre- or post-harvest

The approval process for pharmaceutical and biological products has a 100-year history of regulation. The Virus Serum Toxin Act of 1913 establishes the essential caveats that a product must meet:

- Pure: The product must be free from specified contaminating agents
- Safe: The product must be safe in the target species
- Potent: Each serial (batch) of product must be formulated and tested, to ensure effectiveness and reproducibility of activity as demonstrated in the registration data
- Efficacious: The product must be effective as claimed when used according to the label directions

Cornell outlined the extensive research needed to validate products and to secure potential licensure. "This is not a quick process," said Cornell. "As an example, we have been pursuing licensing on a product for the past eight years, and that was an existing compound. If it is a truly new chemical entity, then the process can take even longer."

Cornell outlined several challenges in gaining approval for food safety claims for pre-harvest interventions such as direct-fed microbials or vaccines designed to decrease *E. coli* shedding in cattle.

"These are novel applications, and thus the uncertainty may lead to lengthy review and approval times, which translate to high costs and long development times," said Cornell. "As pioneer products for a new claim, no clear minimum standards of efficacy exist on which reviewers can base their decisions or evaluate field data. You are effectively blazing a new path with this work."

The Challenge of Gaining Approval of Pre-harvest Technologies: Observations, Lessons Learned and Recommendations for the Future

Gary Weber, G.M. Weber and Associates LLC

In his presentation, Weber described an almost 12-year timeline that included an overwhelming number of obstacles to overcome in order to gain approval of an *E. coli* vaccine as a pre-harvest food safety intervention.

"When we began this process in 2000, initially in dialogues with the Animal Plant Health Inspection Service (APHIS) Center for Veterinary Biologics (CVB), the companies developing this technology were told that it was possible to have a food safety claim approved, and that they were willing to work with industry," said Weber.

In 2011, FSIS published a document entitled, Guidance for Pre-Harvest Management Controls and Intervention Options for Reducing *Escherichia coli* O157:H7 Shedding in Cattle, and the same year APHIS leadership raised concerns regarding the cost of pre-harvest vaccines as a factor in licensing.

"One agency seemed to be encouraging the use of pre-harvest interventions, and the other seemed to be blocking their development by creating hurdles to licensure," said Weber. "A public meeting hosted by USDA in October 2011, and a subsequent notice from APHIS-CVB (Notice #12-09) didn't seem to offer any more clear direction than we had with the notice released seven years prior."

Weber recommended other industry stakeholders move forward with the approval of pre-harvest interventions. "It is imperative that there is some level of significant agreement among industry participants, so that we can hold government agencies to specific, realistic and science-based decisions within the bounds of their legislative authority."

NON-INTACT BEEF — WHERE ARE WE NOW?

Co-Chairs: Mohammad Koohmaraie, IEH Laboratories and Cathy East, Safeway

Beef Safety: Mechanically Tenderized Products and Foodborne Pathogen Risk

Alejandro Echeverry, Texas Tech University

Echeverry reminded summit attendees of the regulatory definition of non-intact beef products.

“Any beef that that has been injected or enhanced with solutions, or mechanically tenderized by needling, cubing or pounding devices, or reconstructed into formed entrees is considered non-intact.” In addition, non-intact beef products include beef products that are chopped, ground, flaked, or minced, such as fresh veal sausage or fabricated beef steak.”

FSIS Definition of Non-Intact Beef

Non-intact beef products include beef that has been injected with solutions, mechanically tenderized by needling, cubing, Frenching, or pounding devices, or reconstructed into formed entrees (e.g., beef that has been scored to incorporate a marinade, beef that has a solution of proteolytic enzymes applied to or injected into the cut of meat, or a formed and shaped product such as beef gyros)... In addition, non-intact beef products include those beef products in which pathogens may be introduced below the surface by a comminution process such as chopping, grinding, flaking, or mincing (e.g., fresh veal sausage and fabricated beef steak).

The first outbreak involving non-intact beef products occurred in 2000, and in 2002 FSIS released a Comparative Risk Assessment for Intact (non-tenderized) and Non-Intact (tenderized) Beef (Figure 8). The risk assessment estimated the predicted probability of *E. coli* O157:H7 illness from intact steaks was one per 15.9 million servings and the illness estimate from non-intact steaks was one per 14.2 million servings. At the time, little research was available to accurately determine if non-intact beef products were at higher risk for pathogen contamination than intact products.

“As we examine the outbreaks involving non-intact beef products, we have to ask the question, ‘Would these outbreaks have happened if mechanical tenderization hadn’t occurred, or would illnesses have been minimized,” said Echeverry. “In other words, is there truly an increased risk from non-intact beef products?”

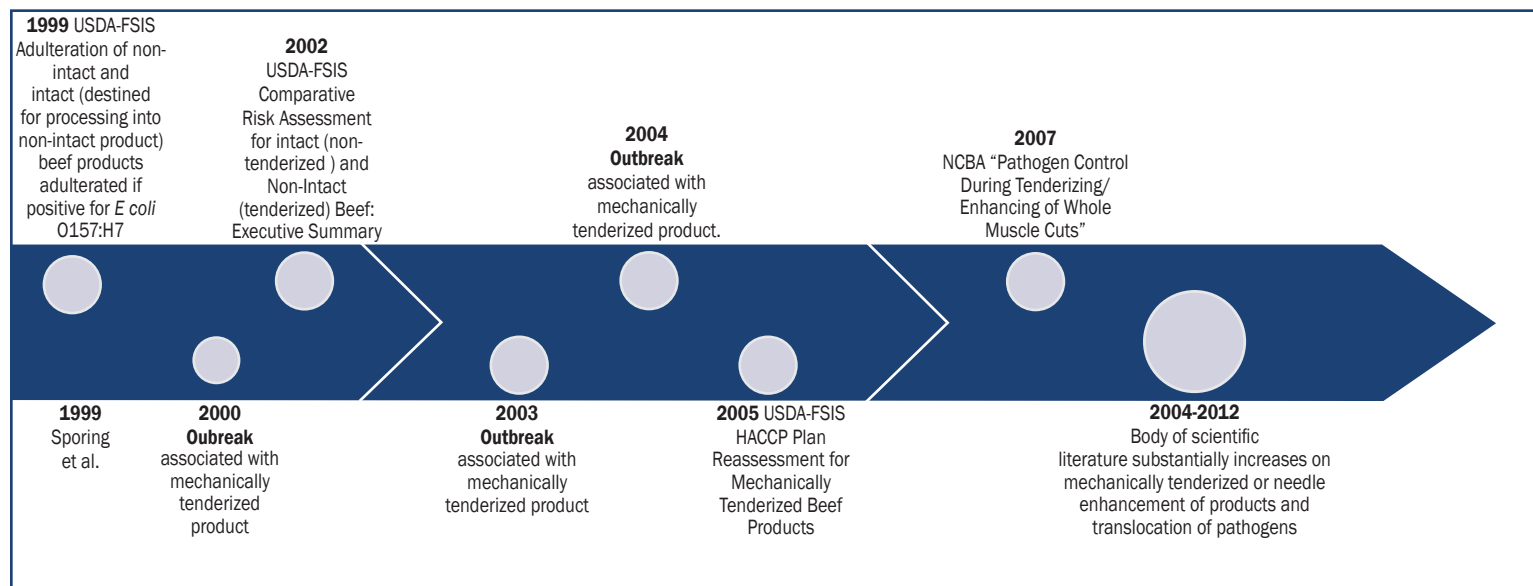
Since that time, research has identified several other issues that should be considered in assessing the risk of non-intact beef products versus whole muscle cuts.

- Other pathogens, including non-O157 STEC and *Salmonella*
- Use of interventions
- Impact of cooking
- Surface penetration (depth) of pathogen contamination after enhancement or tenderization
- High versus low level inoculation studies (‘real-world’ circumstances)

In summarizing current research, Echeverry said that the following assumptions can be made:

- Pathogens are transferred into the surface of needle tenderized steaks/subprimals
- Interventions reduce pathogen loads on the surface and subsequently reduce transfer into the surface
- Most pathogen transfer is to the upper or lower layers of the product with less being transferred to the middle
- It appears that cooking to 160° F kills *E. coli* O157:H7 on the surfaces and upper layers of beef

Figure 8. Timeline of relevant events impacting non-intact beef



Echeverry said future research should address the following:

- Better understanding of the behavior of other pathogens in non-intact beef products
- More research on various interventions, cooking methods and transfer rates
- Prevalence of pathogens in core of needle tenderized product in commercial settings
- Real-world “validation” or simulation of interventions in non-intact beef products
- Development of an updated risk assessment based on new research

Mechanically Tenderized Beef

Scott Goltry, American Meat Institute

To close out the session, Goltry provided attendees an update on regulatory issues impacting non-intact beef products.

“FSIS was petitioned to label mechanically tenderized beef by several consumer advocacy groups under the auspices of the

Safe Food Coalition and Conference of Food Protection,” said Goltry. “The petition requested that raw or partially cooked tenderized beef and products enhanced with solution or marinated be clearly labeled. The rule is still under review at the Office of Management and Budget. While we don’t know if the final rule will require this, the petition proposed that the labeling designation be incorporated into the product name and include validated cooking instructions.”

A Federal Register Notice (2010-012) dealing specifically with marinated and enhanced products also has been published and, in Goltry’s words, “is potentially duplicative to the proposed rule that is still at the Office of Management and Budget.”

Goltry reviewed eight recalls that occurred from 2000 to 2009 involving mechanically tenderized or marinated beef products and reviewed recent FSIS actions. “The bottom line is, we don’t know what the final rule will look like,” added Goltry.

PUTTING IT IN PERSPECTIVE

To close out the Summit, Russell Cross, Ph.D. and Head, Department of Animal Science at Texas A&M University, asked three industry participants to share their “key take-aways” from the 2013 Beef Industry Safety Summit.

“Since the first summit, we have made a significant amount of progress on food safety issues in the beef industry,” said Keith Belk of Colorado State University. “As a result, the beef industry is now used as an example of how to do things right. I think one thing that has become apparent is that we can’t put food safety in a compartment and ignore everything else that is going on around it. We are going to have to address beef safety in a more global fashion.”

“What wasn’t a ‘take-away?’” said Allison Nolz of Washington Beef. “As someone who works in a production facility, the real take-away message, and I can never hear it enough, is that we need to be able to defend our processes. Whatever the decisions we make, we need to be

able to defend our decisions with good science, and this meeting helps me do that.”

Ken Peterson, IEH Laboratories concurred. “This is the first Safety Summit I have attended, and it is extremely encouraging to see all of the research that has been funded by industry. That is absolutely to the credit of everyone in this room and the trade organizations. But, there are still a lot of questions and not enough answers.”

Peterson encouraged the group to continue to be proactive. “You have the facts, and you have the knowledge, so I encourage you to continue paving your path with information,” he added. “When you hear a critique of your industry or your product, if you haven’t laid the right foundation ahead of time, you lose weeks, months or years trying to get the right message out. You want to lay the groundwork in consumers’ minds, so when the bad times come, they have the context to reasonably consider an issue.”



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For more information on the Beef Industry Food Safety Council (BIFSCO) activities, visit www.bifSCO.org

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