

BEEF INDUSTRY SAFETY SUMMIT

Executive Summary



Dallas, Texas • March 4-6, 2014



The background of the page features a composite image. On the left, there is a vertical strip of a textured, light brown surface, possibly leather or parchment. The rest of the background is a solid light brown color with a faint, large-scale image of a cow's head in profile, facing left. Overlaid on this are several microscopic images of E. coli bacteria, which are rod-shaped with long, thin flagella. One large, detailed E. coli is in the upper right, and several smaller ones are scattered throughout the lower half of the page.

Since 2003, the Beef Industry Safety Summit has been the foremost annual event demonstrating the beef industry's commitment across all segments to producing the safest possible beef product for the domestic and global marketplace. The 2014 Summit was held in Dallas on March 4-6. The Summit is funded in part by the beef checkoff and the Beef Industry Food Safety Council (BIFSCo), a group instituted in 1997 to bring together representatives from all segments of the beef industry to develop industry-wide, science-based strategies to solve the problem of *E. coli* O157:H7 and other foodborne pathogens in beef.

A REFLECTION ON THE PAST, THOUGHTS ABOUT TODAY'S BEEF SAFETY ENVIRONMENT, AND A LOOK TO THE FUTURE

Moderator: Gary Smith, PhD, Emeritus, Colorado State University

The opening session of the Summit featured a panel of industry experts who have witnessed the evolution of both the industry's understanding of the foodborne pathogens that have threatened beef's safety as well as the industry's efforts across segments to mitigate those threats and meet regulatory requirements. The panel was moderated by Gary Smith, Ph.D., Professor Emeritus at Colorado State University. The panelists included Russell Cross, Ph.D., Texas A&M University; John Butler, CEO, Beef Marketing Group (BMG); Dell Allen, Ph.D., retired Cargill Meat Solutions vice president of technical services and food safety; and Dennis Hecker, senior vice president of quality assurance at Wendy's International.



Gary Smith asked each of the panelists to look back on their history with the industry and describe some of the key decisions and events that paved the way for progress in producing a safer product. He also asked that they give their perspective on the industry's current status and what might be important steps to shape the future of beef safety.



Russell Cross assumed leadership of the USDA Food Safety and Inspection Service in February 1992, at a time when only 300 of the 7,000 packing plants nationwide had voluntarily initiated Hazard Analysis and Critical Control Points (HACCP) plans. In response, the agency formed a HACCP operations task force and finalized the plan for "War on Pathogens," a risk-based approach to food safety. In March 1993, the agency (USDA-FSIS) instituted stricter enforcement of zero-fecal-tolerance for beef. In April, Congress approved \$3 million for more meat inspectors and \$8 million for the "War on Pathogens" and, by May, Congress had granted authority to FSIS to conduct food safety research. Ultimately, HACCP became a mandated requirement for meat plants and an International HACCP Alliance was formed.



John Butler of BMG provided a beef producer's perspective on beef safety. He explained how BMG has evolved in their thinking from being in the cattle business in 1997 when the company was formed to being in the beef business today. Initially BMG considered safety a packer issue but now sees it as a full-chain issue, including pre-harvest. In 2000, BMG developed a pre-harvest HACCP program called Progressive Beef, a quality management system designed specifically for feedyards, verified annually by USDA-certified 3rd party auditors. BMG has found that this systemized approach to business has generated a positive profit-and-loss statement.

Consumers expect food safety in today's environment. Reducing the pathogen load on feedyard cattle places the packer in a better position to mitigate the burden in the packing plant. Additional pre-harvest interventions that are effective and economically feasible are needed. Above all else, producers must see their responsibility as extending beyond their fence lines and view beef

safety as a full-chain concern. Nevertheless, impediments remain to implementing this kind of system across the cattle-feeding segment. It requires operational transparency and traceability, which is often considered an unnecessary constraint in the "cattle-feeding" business.



Dell Allen considered the implications of the 1993 FSIS announcement of a "Zero-Tolerance" policy on the presence of fecal, ingesta and milk on beef carcasses during the slaughter process a significant milestone in the steps the processing sector took to address pathogens. Later in the same year, on September 29, the administrator of FSIS announced that henceforth, *E. coli* O157:H7 would be an adulterant in raw ground beef.

The industry's initial approach to *E. coli* O157 positives resulted in a large amount of waste in beef that could have been heat-processed and used for food. In time, thanks in part to the work by the USDA Meat Animal Research Center, interventions such as steam vacuums, steam pasteurization cabinets, and wash cabinets were approved. Eventually, responsibility for beef safety transitioned from USDA to the packing plant. Researchers around the country, USDA and industry collaborated to develop, validate and implement the interventions that today help keep America's beef safe.



Dennis Hecker explained that Wendy's safety priorities have remained the same over time: protect public health and protect the brand. However, the strategies for addressing these priorities are very different now than in 1993. The science has led to a greater understanding of O157 and STECs, improved diagnostics, numerous interventions, and better sampling.

Today, ubiquitous information shared through social media means news goes public immediately. Misinformation travels at the speed of light. Overcoming the consumer belief that information on the internet must be true is the greatest industry obstacle. To protect their brand in today's information age, Wendy's has developed a social media plan which includes a department dedicated to monitoring social media platforms. Given this change in information sharing, the principles of BIFSCo increase in importance. Collaboration among industry segments and regulatory agencies is critical to provide safe beef.

In closing, Smith emphasized that BIFSCo and events like the Beef Industry Safety Summit must continue to ensure the industry's food safety efforts move forward. The industry has been fortunate to have solid scientific and technical support to meet the complex challenges faced over the last 20 years. Initially, the industry was motivated as a consequence of failure and those who have not invested in processes to improve systems will continue to be reactive in their approach. Moving forward, the industry must continue to share science and data and not allow safety to become a competitive advantage among companies. Being as strong as the weakest link in the production chain necessitates a continuous improvement mentality for all.

BREAKOUT SESSIONS

Beef Industry Challenges – International Perspectives

Cheyenne Dixon, USMEF

The U.S. exported 102,265 metric tons of beef products (including variety meats) at an estimated value of \$6.157 billion last year. Export markets are crucial for the red meat industry, as they provide outlets for a number of products that have minimal value domestically. However, a variety of economic and technical barriers still prevent the United States from gaining full access or sending as much volume as desired to certain export markets. Numerous technical barriers to trade are in place today due to concerns such as residues, animal disease, animal welfare, food safety technologies and the use of growth promotants. BSE-related restrictions remain in place in more than 20 countries. Additional issues include synthetic hormones, beta agonists, dioxin, and other residues. Increasingly, import markets are requiring animal welfare standards for exporting countries. The U.S. government and industry trade associations continue to reference domestic and international standards to negotiate further access for beef in these nations.

Meat processors in the United States must ensure their products meet regulatory performance and zero-tolerance standards. Customer-specific, finished-product, microbiological requirements continue to tighten. Just as the United States tests certain



imported meat products for specific pathogens, U.S. exports face microbiological testing at points-of-entry into numerous markets. However, many of these export markets have non-science-based import testing requirements, such as holding fully cooked and raw meat products to the same standard or not distinguishing between intact and non-intact products. Many interventions currently used in the United States aid in reducing potential contamination, including the use of thermal and acid processing aids. The list of approved processing aids is included in FSIS Directive 7120.1. However, certain export markets do not approve all the processing aids listed in the Directive for use on red meat products entering their markets. This poses certain food safety and border-compliance issues for processors and exporters, both domestically and internationally.

Post-harvest Safety/HACCP/Validation

Randy Phebus, PhD, Kansas State University • John Luchansky, PhD, USDA-ARS • Kerri Harris, PhD, Texas A&M University

Shiga-toxigenic *E. coli* (STEC) in the Beef Chain: Assessing and Mitigating the Risk by Translational Science, Education and Outreach

Co-project directors:

Randall Phebus and John Luchansky

The five objectives of CAP are:

1. STEC detection – reagents, sampling, assays, technology, partnerships
2. STEC biology – microbiology, ecology, epidemiology, modifiable risk, best targets
3. Interventions for STEC risk reduction – value, feasibility, cost-benefit, impacts
4. STEC risk analysis – risk assessment - Quantitative Microbial Risk Assessment (QMRA)
5. Beef chain STEC-8 translational education, outreach, and evaluation

Randy Phebus and John Luchansky updated attendees on the USDA, NIFA and, O103, O121, O45, O145, O157:H7/NM and O104:H4) in beef across the integrated beef system. A CAP priority is to develop a comprehensive, quantitative, microbial risk-assessment for STEC in beef that identifies current data gaps and uncertainties attributable to STEC. The team members include 13 universities and 50 collaborators, USDA-ARS (ERRC and MARC) and the Los Alamos National Lab.

The project extends across all industry segments and includes three core pillars:

- Pre-harvest research: live cattle and beef producers
- Post-harvest research: slaughter, fabrication, meat processing & processors
- Consumer research

Much of the presentation to Summit participants was focused on post-harvest CAP activities. Dr. Phebus discussed issues associated with veal production. Publication of studies validating intervention strategies for STEC control in veal is sparse. Veal assessment is included in CAP because so little data is available and governmental testing indicates a greater risk of STEC associated with veal products, particularly bob veal. Currently, two bob veal carcass validations are completed and one is planned for 2014-2015.

Dr. Luchansky presented data on a number of validation studies currently in process or recently completed for detection and control of STECs on beef hides and carcasses. Cultural and molecular detection methods have been established. The fed cattle-to-carcass STEC prevalence field study has been completed, and the STEC-8 modeling and non-intact validations are nearing completion. Several activities in 2014-2015 address objective 3 including the completion of STEC serotype comparisons and modeling, impact of STEC contamination point on downstream interventions, validation of sequenced interventions, electrostatic spray applications along processing chain, fed carcass chemical intervention validations, subprimal intervention development and validation, risk determination and interventions associated with various non-intact beef products, and beef trim decontamination technologies.

International HACCP Alliance Q & A

One of the hallmark Summit sessions was the open Q & A conducted by Kerri Harris, president and CEO of the International HACCP Alliance. Attendees were able to ask questions specifically related to their operations’ HACCP plans, Food Safety Assessments (FSA), and process validation trials. The free flow of information during this session allowed participants to gain insight from other attendees and HACCP experts which can be used to improve safety systems in their operations.

Microbial Methodology

Marie Bugarel, PhD, Texas Tech University
Kendra Nightingale, PhD, Texas Tech University

Marie Bugarel and Kendra Nightingale covered the fundamentals of molecular biology and cell physiology as they apply to the development, implementation and interpretation of molecular detection and subtyping approaches to detect and characterize foodborne pathogens. Molecular approaches to food safety include nucleic-acid-based methods to detect foodborne pathogens and subtyping approaches to discriminate isolates belonging to a given pathogen beyond the species or subspecies level. Molecular detection assays are routinely employed by regulatory, commercial-testing and research laboratories as a rapid, sensitive and specific, approach to screen food and environmental samples for the presence of foodborne pathogens as well as to confirm the presence of foodborne pathogens in a sample.

PRE-HARVEST BEEF SAFETY

Moderator: Guy Loneragan, PhD, Texas Tech University • David Renter, PhD, Kansas State University • Angie Siemens, PhD, Cargill • Bill Flynn, DVM, MS, FDA, Center for Veterinary Medicine

Shiga Toxin-producing E. coli CAP Grant: Pre-harvest Progress and Plans

David Renter is the lead on the CAP grant’s objective 2, which is to “characterize the biology, ecology, and epidemiology of STEC.” The grant’s original purpose was to address all aspects of O157, but it was expanded to include the non-O157 STECs declared adulterants in 2011. Dr. Renter presented an update on the pre-harvest aspects of CAP including what has been learned, where are the data gaps, and next steps.

Table 1. Preliminary fed cattle fecal prevalence

Serotype	Culture	Direct PCR
O26	22.3%	20.3%
O103	24.6%	11.8%
O111	0.8%	0.8%
O157		49.9%
O121		10.7%
O45		10.4%
O145		2.8%

Some significant findings include:

- Serotype O104 appears to be relatively uncommon (~20%) in cattle feces but the strains do not have virulence genes as seen in the atypical STEC in the German outbreak (Nagaraja et al)
- Table 1 details the preliminary fed cattle fecal prevalence though many serogroup-positive samples did not harbor Shiga toxin genes (Cernicchiaro et al)
- E. coli O26 prevalence in feedlot cattle feces was 23.9% (260 of 1089) but most O26 were atypical enteropathogenic E. coli, not STEC (Paddock et al)

Molecular subtyping approaches to characterize foodborne pathogens include DNA band-based methods that generate fragment pattern data or “DNA fingerprint” types as well as DNA sequence-based approaches, which rely on generation of DNA sequence data for one or more loci in order to differentiate isolates belonging to a given pathogen. Molecular subtyping approaches have been used for surveillance purposes and microbial source-tracking, and to probe the molecular ecology, evolution and population structure of foodborne pathogens, along with other research applications such as defining the underlying genetic mechanisms associated with niche adaptation or strain-specific virulence differences.

Although DNA band-based subtyping approaches (e.g., pulsed field gel electrophoresis and ribotyping) have been most routinely employed to characterize foodborne pathogens, a wealth of DNA sequencing data is now available for foodborne pathogens. In addition, the recent emergence of next generation sequencing technologies promises increased available DNA sequence data for foodborne pathogens, where multiple genome sequences for a given pathogen can be compared to develop improved molecular detection assays and novel DNA sequence-based subtyping methods.

- O157 vaccine and DFM had no significant effect on non-O157 STEC shedding (Cernicchiaro et al)
- O157, O26 and O103 were the most prevalent STEC in a longitudinal sample of cattle feces (Cernicchiaro et al)
- In fecal samples, the presence of STEC serotypes was significantly associated with other serotypes (Cernicchiaro et al) which could lead to practical broad-based interventions

The 2013-2014 feedlot study examined the prevalence of seven STEC serogroups (O26, O45, O103, O111, O121, O145, O157) and associated virulence genes in fed cattle feces. Table 2 compares the summer 2013 and winter 2014 preliminary results.

Table 2. Cumulative prevalence by O serogroup

Gene	Summer 2013	Winter 2014
	n (%)*	n (%)*
O26	131 (22.7)	2 (0.6)
O45	91 (15.8)	7 (2.1)
O103	347 (60.2)	154 (45.8)
O111	1 (0.2)	0 (0.0)
O121	13 (2.3)	4 (1.2)
O145	17 (3.0)	0 (0.0)
O157*	247 (42.9)	0 (0.0)
Total	576† (100)	336‡ (100)

In 2014, sampling will expand to include other U.S. production systems, risk factors, seasonal and yearly effects.

† Denominator based on 24 pens
‡ Denominator based on 14 pens
n represents the samples that are PCR positive for the O gene of interest
* For O157: CT-SMAC plates, positive to agglutination and Indole and confirmed by PCR

Salmonella Public Health Challenges Pre-harvest Beef Safety

According to Angie Siemens, *Salmonella* is a critical challenge in the beef industry, and ultimately, *Salmonella* is a pre-harvest issue. According to CDC, 1,220,767 *Salmonella* illnesses sourced from all foods occur in the United States annually, with 33.1% (404,074) attributed to FSIS product. Foods in order of highest-to-least number of contributions are broiler carcasses, pork carcasses, deli meats, ground beef, turkey carcasses, ground turkey, beef carcasses and ground chicken. The FSIS goal for 2020 is to reduce FSIS-attributable *Salmonella* illnesses by 25% compared with the average annual number of *Salmonella* illnesses in the United States from 2007 to 2009 (Figure 1).

In the past, both *E. coli* and *Salmonella* have been found in feces and considered contaminants if passed to carcasses during processing. In response, the industry developed and implemented a number of science-based interventions to reduce carcass contamination in the plant.

The difficulty with *Salmonella* compared to O157:H7 is that the source point for H7 has been identified, but *Salmonella* doesn't operate the same way. A *Salmonella* surveillance study of the subiliac lymph nodes of cattle from October 2009 to November 2011 showed a spike in prevalence August through September. The study also indicated significant differences in prevalence across plants, a higher prevalence in fed cattle than cull cattle, and significant differences among feedlots. Because some cattle are carriers of *Salmonella* in the lymphatic system, carcasses are not sterile at the harvest plant. Plants do not have interventions to reduce or eliminate *Salmonella* in the lymphatic system. Pre-harvest interventions must be identified, approved through the appropriate regulatory agency, and implemented for *Salmonella* to be reduced in the future.

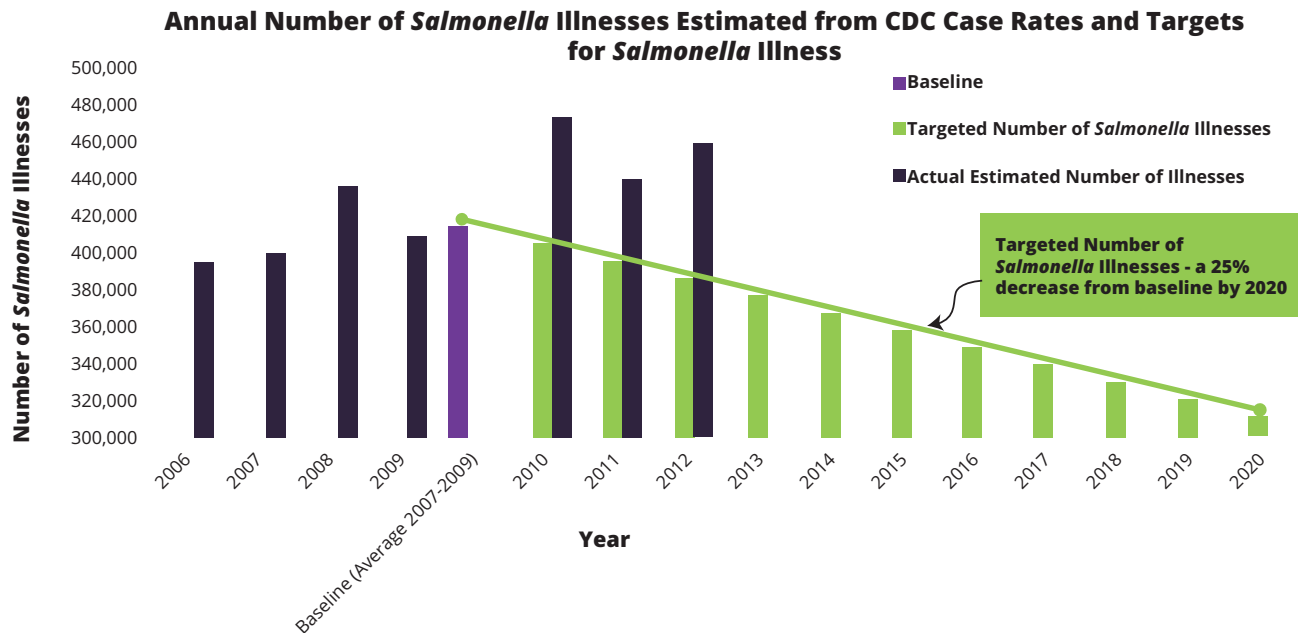


Figure 1. Annual Number of *Salmonella* Illnesses Estimated from CDC Case Rates and Targets for *Salmonella* Illness

Table 3. Science-Based Processes – Interventions

	Intervention	Description
Beef Harvest/Fabrication	Hide-On Carcass Wash	Wash prior to removing the hides High or low pressure/with or without Striker/ with or without antimicrobial
	Pre-Evisceration Carcass Wash	Antimicrobial Organic Acid or Hot Water
	Post-Evisceration Carcass Wash	Antimicrobial Application
	Final Carcass Wash	Bromine or PAA Solution
	Thermal Pasteurization System	*CCP Steam Pasteurization OR 195° - 198° F Water
	Pre-Chill Carcass Spray	Antimicrobial Application
	Carcass Chilling	Intermittent Antimicrobial Cold Water Spray to Speed Chilling Process
	Pre-Fab Carcass Spray	Antimicrobial Application
	Sub-Primal Spray	Antimicrobial Application
Grind	Pre-Grind Trim Treatment	Antimicrobial Application
Further Processing	Non-Intact Beef Primals	Antimicrobial Application
	High Pressure Processing	Finished product treatment

Pre-harvest Interventions: Regulatory Considerations

Bill Flynn updated Summit participants on animal feed, food additives, Generally Recognized as Safe (GRAS), animal drugs, and new animal drug applications (NADA) from FDA's perspective.

A new animal drug cannot be sold in interstate commerce unless it meets specific regulatory criteria. When a NADA is approved, it means the product is safe and effective for its intended use and the production of the drug preserves its identity, strength, quality and purity. Historically, in order to meet the safety standards for NADA approval, the animal drug must be reasonably certain to cause no harm in people and meets an appropriate balance of risk/benefit to animals.

The range of human food safety standards to be met by a new animal drug includes toxicology studies on the drug; the impact of the use of antimicrobials on the microbes in the animal and, subsequently, on the food; the impact of the residues in the food on

the intestinal flora of humans; and the development and validation of methods to measure drug residues in edible tissues.

In regards to animal safety, the cumulative effect of the drug must not adversely affect the treated animals, and the toxic effects of the drug must be identified. Also, a margin of safety for the labeled dosage regimen must be identified. Along with human and animal safety standards, a new drug must also meet specific environmental criteria. Before approval, a new drug must be the subject of a number of studies, most likely multi-location, to build substantial evidence of the drug's effectiveness for each intended use and to ensure the production of the drug does not negatively impact its identity, strength, quality and purity.

In closing, Dr. Flynn acknowledged the challenges posed by new technologies navigating existing regulatory pathways. He commented on the potential many pre-harvest pathogen-reduction products have to limit pathogen exposure, and although more work is needed, he looks forward to continued collaboration with the industry to address the challenges.

According to the Federal Food, Drug and Cosmetic Act (FDCA):

- Animal feed is defined as "articles intended for use for food for animals other than man and which is intended for use as a substantial source of nutrients in the diet of the animal, and is not limited to a mixture intended to be the sole ration of the animal..."
- A food additive is "any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting characteristics of any food..." unless it is generally recognized as safe (GRAS), such as forages, grains, and most minerals and vitamins. A food additive is considered unsafe unless its use conforms to an existing food additive regulation. A food ingredient that is neither GRAS nor an approved food additive can cause a "food" to be adulterated and illegal to market in the United States.
- A new animal drug is defined as "articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals and articles intended to affect the structure or any function of the body of man or any animals."

LIFETIME ANIMAL WELLNESS

Moderator: Russell Cross, PhD, Texas A&M University • Bruce Feinberg, McDonald's • Calvin Booker, DVM, MVetSC, Feedlot Health Management Services

Global Animal Health and Welfare

Bruce Feinberg began his presentation by explaining that McDonald's serves 70 million customers in 35,000 restaurants in 120 different countries every day. Their customers expect a safe, affordable, value-added meal, and managing that commitment to consumers requires a very large, complex, global organization. Because of their size and the amount of food purchased, McDonald's commands a great deal of attention in the global marketplace.

McDonald's does not raise animals nor do they run slaughter operations, but they are actively involved in animal health and welfare because research shows customers hold them to a high standard and expect them to do the right thing. The mission statement of their global animal health and welfare team is to make "meaningful and enduring improvements to the health and welfare of those animals in our supply chain throughout their lives." Historically, their focus has been on the welfare of animals at slaughter facilities, but they are now expanding the focus to include the animal's entire life span.

McDonald's commitment to animal welfare began in the early 1990s when they formed a relationship with Dr. Temple Grandin and AMI and adopted an objective measurement system for slaughter facilities. Over the years, they've initiated a variety of welfare initiatives. Most recently, they formed the Global Animal

Health and Welfare Team which now has 40 members with sub-teams working on various projects. The goal is auditing and continuous improvement for all species.

Today's customer expects McDonald's to do more than just run good restaurants. They expect McDonald's to do the right thing. For McDonald's, it's always about the customer and the customer mindset has changed since the 1950s. Feinberg focused on three areas:

- Most consumers are disconnected from their country's agricultural roots. Less than 2% of the U.S. population is involved in agriculture, although agricultural output has increased. Improved production is good news for a growing global population. The consumer disconnect from agriculture frames the dilemma McDonald's faces every day. For many, their perception is based on a proxy of reality. For example, the consumer's lack of knowledge regarding agriculture combined with their love and care for their pets changes their perspective. Americans spent \$50 billion on pets last year.
- Consumer perceptions are often based on information on the internet or told by their neighbor, not from what they learn from experts. In the 1950s and 1960s, McDonald's was new and convenient but most food was prepared at home. The food industry was trusted and appreciated. The microwave was new technology. Today's consumer expects access to fresh food all year long as well as global and ethnic options. The food industry is under a great deal of scrutiny and food technology is vilified. To try and

meet these consumer perceptions, McDonald's menu options have proliferated, which has posed financial challenges.

- Consumer expectations of industry leaders are formed in a “post-trust era.” They expect transparency in the food manufacturing process today while, in the past, there was inherent trust in food science. This image has radically changed and consumers not only don't trust brands like McDonald's, they also don't trust government, media, corporations, non-profits, and perhaps even, on occasion, family and friends.

Research shows the top priorities for McDonald's customers are the humane treatment of animals and minimizing antibiotic use. In another study, McDonald's customers said animal health and ethical animal production are highly correlated with food safety, quality and healthfulness. This finding brought home the vital importance of animal health and welfare to the integrity of the McDonald's brand which is based on safe, quality food.

Lifetime Wellness in Cattle Production

Calvin Booker reiterated concerns mentioned by other presenters regarding the current consumer mindset. Beef consumers and the general public have limited knowledge of food and animal production systems. They are apprehensive about “factory farming,” animal welfare and well-being, antimicrobial use and antimicrobial resistance, and growth implants. Given this consumer environment, the proposed solutions include more regulation of large farms, mandatory verification of animal welfare, enhanced regulation of antimicrobial use and a ban on growth implants. Dr. Booker suggests alternative approaches to these consumer concerns which include education and transparency about modern production systems, conversations about the importance of sustainability, application of the “One Health” concept and promotion of human and animal well-being. Regardless of the specific issue or concern, connecting with the public, addressing their concerns, owning mistakes, and earning the public's trust are all part of maintaining our social license to operate as an industry.

With respect to animal welfare and animal well-being, assuring “lifetime wellness” throughout the beef production system is an important concern for the general public. Lifetime wellness can be described in many ways, but Feedlot Health Management Services (FHMS) has developed the following definition as a

Lifetime Wellness is defined by Feedlot Health Management Services as:

sustainable animal health and production programs from birth to harvest through active monitoring, real-time individual animal data collection, and ongoing research and development to ensure healthy, productive animals and a safe food supply.

guide for animal health management and production in the beef cattle industry: “sustainable animal health and production programs from birth to harvest through active monitoring, real-time individual animal data collection, and ongoing research and development to ensure healthy, productive animals and a safe food supply.” This definition includes the three Es of sustainability: ethical, environmental, and economical.

With this definition at hand, FHMS has set forth to develop measures/targets to reduce morbidity and mortality, improve growth, feed efficiency, and carcass traits, and promote “normal”/ acceptable behavioral response of cattle to the environments in which they are raised. In addition, FHMS has developed data collection and monitoring systems to allow for the conduct of “real-time” monitoring and surveillance, as well as the conduct of research and development programs in commercial production units. This allows for veterinary and production oversight of commercial operations on a daily basis, 365 days of the year, over a wide geographical distribution. These tools and systems also provide the ability to bridge the gap between the various sectors of the beef cattle industry to provide a broader application of the lifetime wellness concept. FHMS is driven to “do better things, not just do things better.”

In summary, assuring lifetime wellness throughout the beef production system can be an important public concern and could be addressed as part of maintaining the beef industry's social license to operate. While some people may view this as a daunting or unnecessary requirement, many of the tools, systems, approaches, and applications to ensure lifetime wellness are already being implemented by veterinary and production experts in the cattle operations of progressive, industry-leading, beef cattle producers.

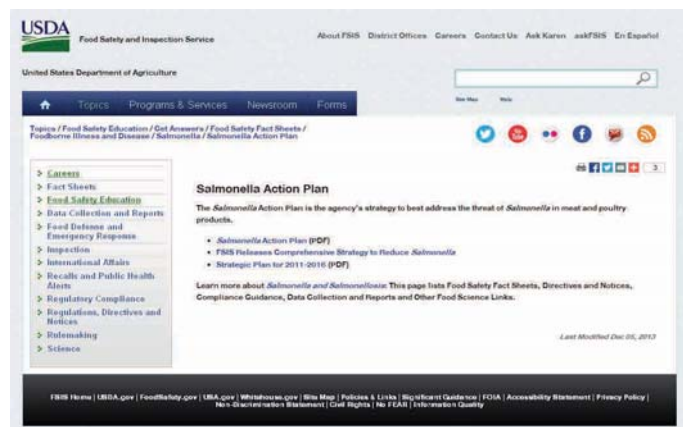


REGULATORY UPDATE

Moderator: J.O. “Bo” Reagan, PhD, 2013 BIFSCo Chair • Al Almanza, USDA, Food Safety Inspection Service Bill Flynn, DVM, MS, FDA, Center for Veterinary Medicine • David Goldman, MD, MPH USDA, Food Safety Inspection Service • Tom Chiller, MD, MPH, CDC, National Center for Emerging and Infectious Zoonotic Diseases (NCEZID)

FSIS Update

According to Al Almanza, *Salmonella* is a top priority for FSIS this year; it causes more than one million illnesses each year and is responsible for 35% of hospitalizations and about 28% of deaths from foodborne illness. The *Salmonella* Action Plan (link is <http://www.fsis.usda.gov/wps/portal/food-safety-topics/food-safety-education/get-answers/food-safety-fact-sheets/foodborne-illness-and-disease/Salmonella/sap>), released in December 2013, focuses primarily on poultry but will have an impact on beef and pork. The raw beef samples collected for STEC testing will be analyzed for *Salmonella*. FSIS plans to work with industry to determine the impact of *Salmonella* in the lymph nodes and to identify possible solutions. In addition, they are increasing efforts to educate the public about *Salmonella*, why it is more challenging than other pathogens, and why certain cooking and handling practices are required.



In order to achieve greater compliance to system validation among all establishments, FSIS issued the fourth draft of their guidance document. Almanza plans to bring together more industry representatives, now and in the future, when addressing regulatory issues to ensure optimal implementation procedures. He also advised that the rule on mechanically tenderized products is still in process. The veal carcass baseline survey is scheduled to begin during the third quarter of the government's fiscal year. Actions will be determined after assessing the data and the prevalence of STEC-positive samples. Currently, the Poultry Slaughter Rule is in departmental review and Almanza stated it should proceed to OMB soon and be finalized.

Updates from FDA/CVM

The National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS) was established in 1996 as a collaboration among state and local public health departments, CDC, the U.S. Food and Drug Administration (FDA), and USDA. This national public health surveillance system tracks changes in the antimicrobial susceptibility of certain enteric (intestinal) bacteria found in ill people (CDC), retail meats (FDA), and food animals (USDA) in the United States. The program continues to evolve. Fourteen states collect retail meat samples and send them to FDA for analysis regarding antibiotic resistance. USDA has recently improved methods for sampling animals. The goal is to identify measures that are responsive to public health concerns without compromising animal health.

For access to FDA Guidance Documents, go to:

[Guidance Document #209](#)

[Guidance Document #213](#)

The NARMS program helps protect public health by providing information about emerging bacterial resistance, the ways in which resistance is spread, and how resistant infections differ from susceptible infections. It's known that resistance occurs naturally in the environment, but it's important to distinguish naturally occurring resistance versus acquired resistance. Gaps in our understanding of resistance exist and the science is evolving, but the complexities should not keep us from identifying steps to help mitigate risk.

Since 2003, a process has been in place to evaluate new animal drugs for their microbiological effect on bacteria of human health concern. Products pre-dating this process may have resistance issues. Recent efforts have focused on ensuring judicious use of all existing antibiotics including those pre-dating 2003.

Guidance 209, "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" was finalized in April 2012 with the goal of preserving the availability of effective drugs for both humans and animals. While assuring the judicious use of medically important drugs, antimicrobials must continue to be available to combat disease in animals including treatment, control and prevention. The key principles of Guidance 209 are to limit the use of antimicrobials to therapeutic purposes (no growth promotion) and to increase veterinary involvement.

The drugs affected by Guidance 209 include medically important antimicrobials administered in feed and/or water, which are approved for production uses (growth promotion or feed efficiency) and available over the counter. Guidance 213, which adds detail to Guidance 209, states that seven classes of drugs are affected: aminoglycosides, lincosamides, macrolides, penicillins, streptogramins, sulfonamides, and tetracyclines. The overall timeline is that all drugs affected will be shifted over to the use outlined in the guidance documents by December 2016. Once the status of these antimicrobials have been changed, and their labels updated, they cannot legally be used for growth promotion and will come under veterinary oversight and be available only as a prescription or Veterinary Feed Directive (VFD). The primary objective is to include the veterinarian in the decision-making process. He will not be required to administer products. Drug sponsors are required to communicate their intentions regarding Guidance 213 in March 2014 and the agency will publish an update describing the response.

In closing, Flynn explained the next steps include monitoring the implementation of the changes in the regulation, updating the public on completed changes to affected products, and evaluating the rate of adoption of the recommended changes at the end of three years. The NARMS program will monitor trends in antimicrobial resistance among foodborne bacteria from humans, retail meats and animals, in order to affirm the success of the program.

FSIS Science Update

David Goldman provided updates on multiple topics from the FSIS perspective including *Salmonella* in beef, FSIS participation in NARMS, and further characterizations of STECs.

Figure 2 illustrates the framework for monitoring progress toward the 2020 Healthy People Goal related to *Salmonella*. The FSIS attribution is calculated as a percentage of salmonellosis cases derived from single-ingredient sources. Of the one million cases between 2009-2011, 31% (310,000 illnesses) are attributed to single-ingredient sources, of which 13% (40,300 illnesses) are attributed to beef. Last year's report of the years 2008-2010 showed the FSIS attribution was 36% with beef responsible for 26%.

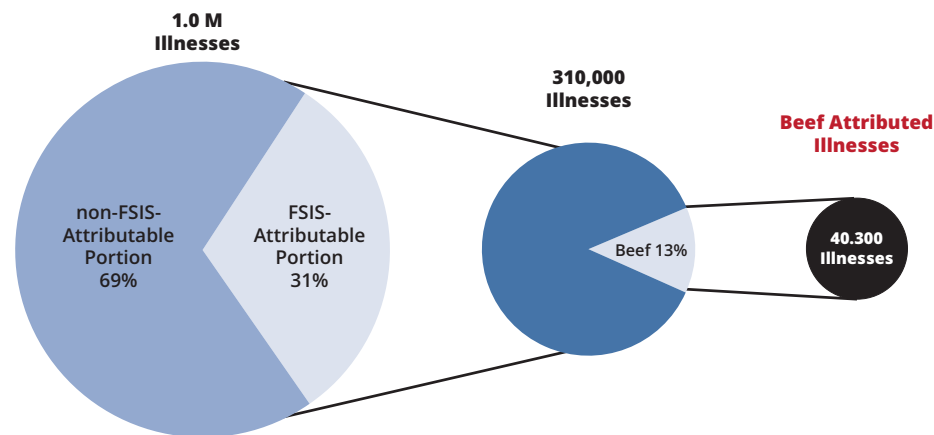


Figure 2. Percentage of salmonellosis cases derived from beef.

The *Salmonella* verification program in beef tracks the volume-weighted percent positive samples on beef carcasses and ground beef. The percent positive in ground beef has remained unchanged since 2005 while the percent positive on carcasses has improved. This suggests the carcass may not be the primary source of *Salmonella* in ground beef and other factors may be at play, including cross-contamination and the possibility of lymph nodes as a contributor.

Figure 3 shows the alignment of the percent *Salmonella*-positive in ground beef as tested and tracked by FSIS and AMS. The AMS data

show a significantly lower percent positive than the FSIS data. The analysis is ongoing and they plan to examine other factors that may have contributed to the disparities in the data.

As a participant in the NARMS program, FSIS contributes isolates from various sources. The bulk of the samples come from the *Salmonella* HACCP Verification Testing Programs for the four major species: turkeys, chickens, swine and beef. A recent contribution by FSIS is the ability to serotype the *Salmonella* isolates in FSIS labs. Previously, the data were sent to the ARS NARMS database but now a large majority of the data resides with FSIS. An early criticism of the program was that the animal arm consisted of meat samples, which was believed to be duplicative of the retail sampling, and more importantly, concern was

expressed that the animal arm was not well represented by meat samples. After discussions with FDA, FSIS changed to a cecal sample testing program which is being administered within the agency. Figure 4 (see next page) illustrates the results of the testing from October 2013 through December 2013. Testing is ongoing to determine if these results are representative of what actually happens on the farm.

FSIS is collaborating with ARS on a study to fulfill three objectives: identify STECs in beef including serogroups not screened for during routine testing, identify the co-colonization of FSIS-adulterant STECs and/or potentially pathogenic STECs in

beef, and identify the virulence factors of both. To date, the study has shown that non-adulterant *stx*- and *eae*-positive STECs are present in raw beef, and the presence of an adulterant STEC cannot be positively correlated to the presence of other pathogenic STECs. The agency still maintains the position that interventions designed for O157 will work on the other STECs. Possible outcomes from this study may include the conclusion that additional research on this topic is warranted, publication in a peer-reviewed journal, changes to the agency approach to analyzing adulterant STECs in beef, and the refinement of the FSIS-adulterant STEC definition.

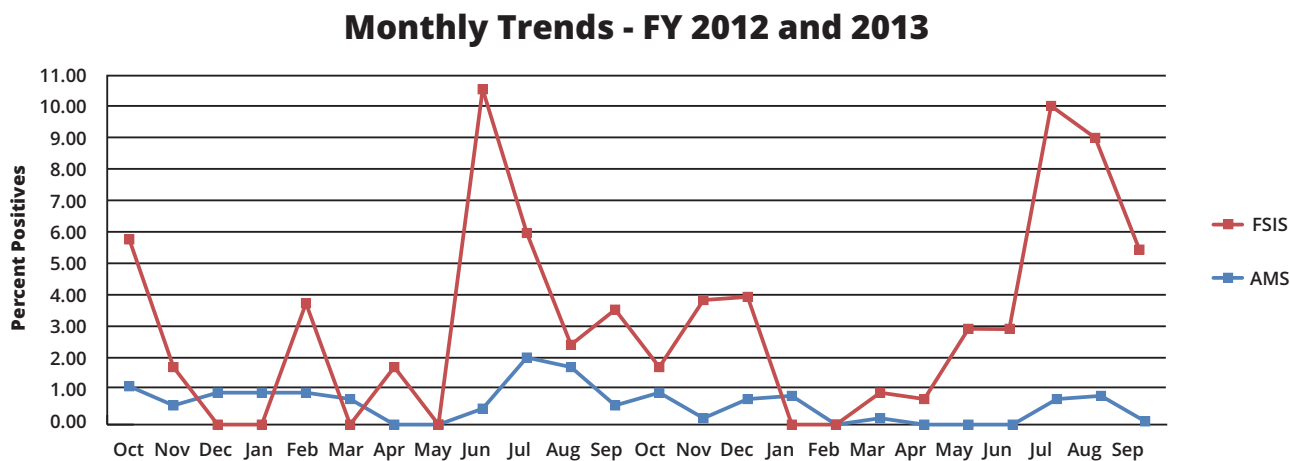


Figure 3. Percent *Salmonella*-positive in ground beef as tested and tracked by FSIS and AMS

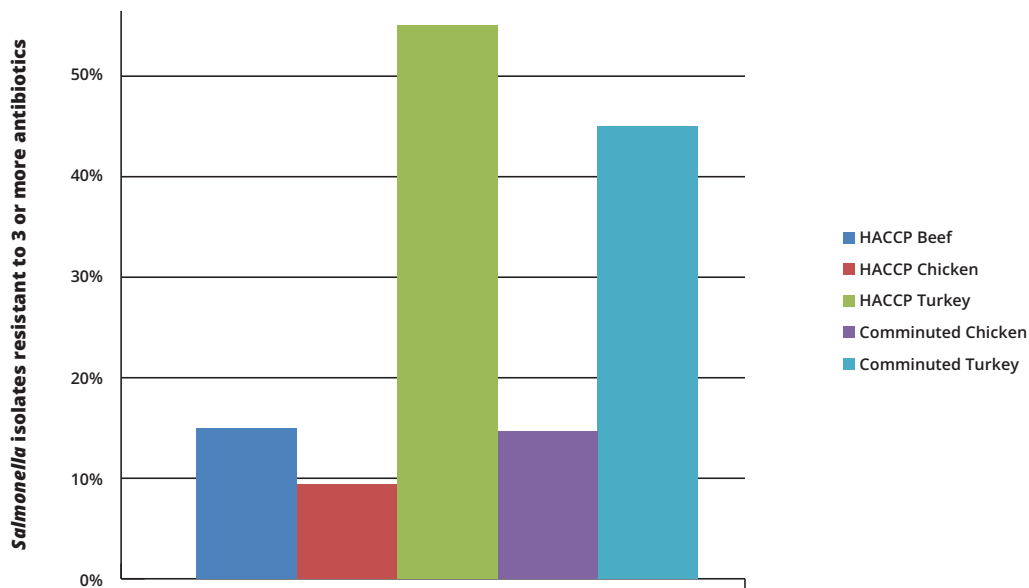
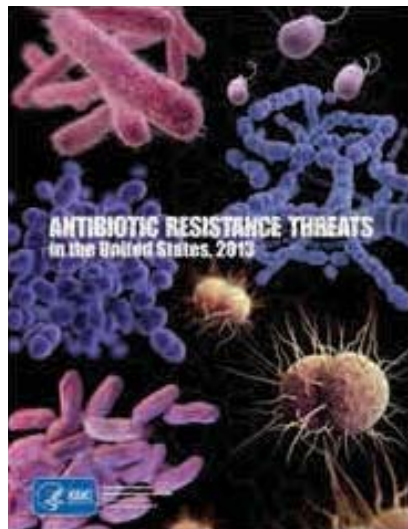


Figure 4. Percent of multidrug-resistant *Salmonella* isolates in various products (October – December 2013)

CDC Report: Antibiotic Resistance Threats in the United States, 2013

According to the CDC 2013 report, antibiotic resistance is one of the most serious health threats facing the world. It undermines the ability to fight infectious diseases and manage infections developed in patients who are being treated for other conditions. Studies estimate resistance costs the United States \$20 billion in direct health care expenses and up to \$35 billion in lost productivity.

When treatment is needed for infections, resistance may cause early treatment failures resulting in longer illnesses, more hospitalizations, more invasive infections and even more deaths. An additional concern is that when the genes causing an organism to become resistant are located on a mobile genetic element, the resistance is easily transferable to other related pathogens. Tom Chiller reported another major CDC concern is the decrease in the number of new antibiotics being approved at a time of increased resistant illnesses. The number of new antibiotics approved between 1980 and 1984 was 18, while only two new antibiotics were approved between 2010 and 2012.



The 2013 CDC report on antibiotic-resistance threats is a landmark report providing information on the current threats having the most impact on human health, a ranking of resistance threats, and four core actions critical to halting resistance. The full report can be found at <http://www.cdc.gov/drugresistance/threat-report-2013/>. The report shows resistance is promoted by antibiotic use in any setting (health care, community and agriculture), provides estimates of resistant enteric infections in *Salmonella*, *Campylobacter*, and *Shigella*, explains CDC efforts to prevent resistance in food, and educates the public on resistance and how to prevent resistant infections.

The CDC report listed four core actions to prevent the spread of resistance:

- Preventing infections, preventing the spread of disease
- Tracking
- Improving antibiotic prescribing and use, aka “stewardship”
- Developing new drugs

CDC will continue to track foodborne illness, monitor trends in infections, investigate outbreaks, determine illness attribution, educate consumers, and support state and local health departments.

The Beef Industry Safety Summit continues to provide the venue for industry experts to gather in a non-competitive environment to advance their common goal of ensuring the safest possible beef supply for the domestic and global marketplace.

Mark your calendars for next year's 13th annual event!
Beef Industry Safety Summit
March 3-5, 2015
Dallas, Texas

Further details about next year's Summit will be posted to www.bifsc.org as they become available.



Funded in part by
the Beef Checkoff.

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

© 2014 Cattlemen's Beef Board & National Cattlemen's Beef Association